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CEEASY: A Guiding Tool Throughout the Medical Devices CE Marking Process

Case Study: MiWEndo

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"Nothing in life is to be feared, it is only to be understood. Now is the time to understand more, so that we may fear less." – Marie Curie

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Abstract

The medical device sector has been growing for the last years and it is expected to keep growing. As CE marking is necessary to sell products in Europe, everyday more entrepreneurs need to learn how the CE marking process works. Finding information is easy, what is difficult is to identify the information that applies to a specific product, which ends up in manufacturers referring to consultant companies (which are really expensive).

CEEASY has been created from the premise that the CE marking process can be done without a consultant but is cumbersome. CEEASY is a free online tool for novice people in regulation. Different resources (surveys, classifications, guides, templates and samples) have been designed to help users get more device-specific information in each step of the process. With the help of CEEASY entrepreneurs not only will save money but time.

The second part of the project is a use case. Here we use all the resources that can be found in CEEASY's website in a real case, the project MiWEndo developed by BCN MedTech research group. MiWEndo aims to bring to the market a new medical device to improve colonoscopy using microwave imaging. A complete overview of the regulatory path for MiWEndo has been developed. All the steps of the CE marking process that could be realized (according to the actual state of their project) have been realized, and for the future steps recommendations on how to resolve them are provided.

Keywords

CE marking · Medical Devices · European legislation · Manufacturer · Guiding tool

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1. INTRODUCTION

The number of entrepreneurs that create start-ups around their newest ideas, technologies and products is increasing every year. The medical devices sector does not differ from the general trend, and it is predicted to be growing for several years. This market is expected to reach an estimated $409.5 billion by 2023 with a Compound Annual Growth Rate (CAGR) of 4.5%.[1]

In order to have a successful business the most important part is the revenue, which necessarily translates to selling the product. Therefore, being able to sell the product around the world is one of the most important key processes. To sell a product in the European Economic Area (EEA), having the European CE mark is mandatory. With this information, is easy to think that if the medical sector is growing, the number of certificates issues will increase too.

That last premise is false. From 2011 to 2016, the global medical device sector has increased[2], but on the other hand, the number of valid CE certificates issued has decreased. In 2014, 22487 certificates were issued, while in 2016 and 2017 approximately 3000 certificates less were issued. The number of withdrawn certificates in 2016 was almost six times higher than in 2010.[3] Another alarming fact is that in 2016, 68% of the certificates were issued to companies located outside of Europe.[4]

We can conclude that, although the global market increases, the European certification decreases. One of the reasons could possibly be that the way to CE marking is too complicated for manufacturers. The main problem is that learning how to do all the paperwork requires a lot of time because the documentation available is only addressed to experts and becomes too cumbersome for entrepreneurs. Learning the CE marking process alone requires a lot of time and learning it with the help of a regulatory consulting company is quite expensive; for entrepreneurs, time and money are the two most valuable resources.

CEEASY was born out of the premise that learning the EU regulation is not difficult but time consuming. CEEASY gives free and fair European regulatory advice on **medical devices** for any kind of user (experienced or amateur). In order to test the usefulness of this new guiding tool, all of its resources will be used to assess a UPF research team with the regulatory aspects they will soon undergo.

2. CEEASY

The CE marking is a certification mark that indicates that the manufacturer or importer of a product claims compliance with the relevant EU legislation applicable to a product, regardless of the place of manufacture and it is necessary for products that are manufactured, sold or imported within the European Economic Area (EEA).[5]

Therefore the CE marking applies to four main actors[6] (also known as 'economic operators')[1] which are the following:

- **Manufacturer:** any natural or legal person (established inside or outside the EEA) that manufactures a product or has a product designed, **and** places it on the market under his own name or trademark. Responsible for the conformity of the product, draw up technical documentation and declaration of conformity, affixing CE marking and follow traceability requirements.
- **Authorized Representative:** legal entity established in the EEA that performs the CE marking process in the name of a manufacturer established outside the EEA. The authorized representative is appointed by the manufacturer. Responsible for preparing the declaration of conformity and affixing the CE mark.
- **Importer:** natural or legal person established in the Union who places a product from a third country on the EU market. Obligations built on the obligations of the manufacturer.
- **Distributor:** natural or a legal person in the supply chain, other than the manufacturer or importer, who makes a product available on the market.

[1] See section 3 of '*The Blue Guide' on the implementation of EU product rules 2016* for more information. *The Blue* Guide corresponds to the Official Journal of the European Union, volume 59 of 26 July 2016.

CEEASY is a public online free site to help entrepreneurs obtain the CE mark themselves for **medical devices that fall under Council Directive 93/42/EEC** of 14 June 1993 concerning medical devices.

CEEASY's website: www.miralles3996.wixsite.com/ceeasy

Figure 1. CEEASY's logo

The website was created using the Wix platform as it has a 'drag and drop' structure that enables the creation of a more creative website, it is free, user-friendly at most importantly it enables to upload files up to 15MB. **CEEASY's** logo was designed with the help of Logojoy, the logo is based on the premise that using CEEASY leads to a faster understanding of the CE marking process. CEEASY's slogan is: ***"See, it's easy!"*** which comes from the fact that most people believe that CE marking is difficult.

CEEASY's target users are entrepreneurs with knowledge and expertise in medical devices, but novice in its regulation; which means that all the offered resources aim to make this process understandable and easy-going. Those resources are:

- Concise information on the CE Marking process.
- Glossary.
- Detailed pipeline of the whole CE marking process for medical devices. This pipeline is thought to be used by manufacturer and it **just** takes into account the regulatory aspects of the process (not the design phase, validation tests or clinical trials).
- In each step of the process, resources such as flow charts, tables, guides and templates are provided to help the user obtain specific information and get a clear picture of what to do (and most importantly: **how** to do it).

For information on the whole overview of the process, go to section 3, where the Case of study is explained.

The steps covered by CEEASY are based on the widely known division of the CE marking process into 6 steps, although some other mid-steps have been added.[7], [8]

The website is pipeline-based, which means that is thought to be read following an order. Starting from the ‘CEEASY’ page, which is the ‘about’ main page, explaining what is, why is it useful and how will help the user. The second page consists of a concise description of what CE Marking is. And the third page is the whole CE marking process (as explained from sections 2.2. to 2.10). As seen in Figure 2 a bar at the top of the website shows the user’s progress: in green the steps accomplished, in blue the current step and in grey the future steps.

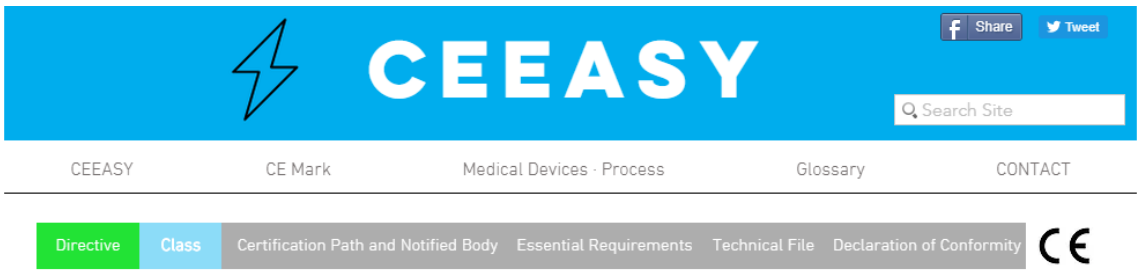

Figure 2. CEEASY's heading for the pages related to the process. The bar shows a timeline of the steps from the start until the CE mark is obtained.

CEEASY is a user-friendly website: ’download’ symbols (Figure 3) are used to make resources are easy to find, ‘Did You Know…’ boxes (Figure 4) are used to provide facts and curiosities and ‘Attention’ boxes (Figure 5) to write statements that should not be dismissed. Finally, all the ‘actions’ required by the user, are shown in a purple box.

Figure 3. Different download buttons. In order: other website, download document, download guide, download template and download image or figure.

Figure 4. Example of a 'Did You Know' box

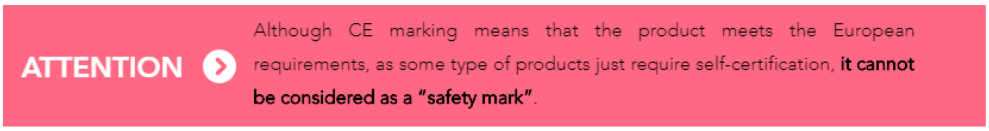

Figure 5. Example of an 'Attention' box

2.1. Step 1 - Directives and Regulations

Which directive applies to a medical product? A **directive** is a legislative act that sets out a goal that all EU countries must achieve, although it is up to the individual countries to devise their own laws on how to reach these goals.[2] On the other hand, a **regulation** is a binding legislative act and must therefore be applied in its entirety across the EU.[9] The three main directives covering medical products are[10]:

- **Council Directive 93/42/EEC of 14 June 1993 concerning medical devices**.[11] It is abbreviated as MDD, which stands for Medical Device Directive. Examples of medical devices that fall under MDD: stethoscope, non-invasive electrodes, electrocardiograph, prosthesis or a stent.

[2] For exemple, in Spain all directives are transposed to 'Real Decretos'.

- **Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices**.[12] It is abbreviated as AIMDD, which stands for Active Implantable Medical Devices Directive. Examples of products that fall under this directive: implantable cardiac pacemakers, bladder stimulators or cochlear implants.
- **Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices**.[13] It is abbreviated as IVDD, which stands for *in vitro* Devices Directive. Example of products that fall under this directive are: pregnancy tests, blood sugar monitoring systems for diabetics or HIV tests.

Other directives that the user should take into account are shown in Annex 1.

Although directives try to define its scope as accurate as possible, there are different **borderline** products (products that could fit in different definitions and therefore is hard to say which directive must apply). In order to solve so, the European Commission wrote a "Manual on Borderline and Classification in the Community regulatory framework for medical Devices"[14]; it talks, for example, of software, which are harder to classify due the increasing technologies.

In order to know which of these three (or others) directives govern a particular device, a conceptual map has been designed (attached in Annex 2). This conceptual map not only leads to the main directive that needs to be followed, but to other directives that must be also taken into account according to the device features (such as potential hazards or presence of dangerous substances). The conceptual map has also been implemented as a survey, a 'Google Form' (created with 'Google App Script'). The survey is called: '**Decision on which directives apply to a medical product"** and it is available in the website. [3]

[3] Click here to see the online survey on applicable directives.

If the device falls under the Medical Devices Directive (93/42/EEC), the user proceeds to the following step.

2.2. Step 2 – Device Classification

Once knowing which directives apply to a particular product, the next step is to determine if the directive requires a product classification. Devices under AIMDD do not require any kind of classification.[12] Devices under IVDD are classified according to lists A or B in Annex II to IVDD.[13] Medical Devices under MDD are classified into 4 groups ranging from low risk to high risk.[11] The classification is done through 18 rules set out in Annex IX to MDD. The 4 groups are:

- **Class I** devices are considered to be **low risk** devices. Though it is true that those may have a measuring function and/or need to be sterile, which are then considered to be **Class Im** or **Class Is**, respectively, and are considered to be of **low-medium risk**.
- **Class IIa** devices are considered to be of **medium-low risk**.
- **Class IIb** devices are considered to be of **medium-high risk**.
- **Class III** devices are considered to be of **high risk**.

There are some existing flow charts[4] to classify a medical device according these 18 rules, yet it is not user-friendly as the result is obtained by mid-results (which means that you need to go throughout the whole flow chart to make sure the classification is done correctly). For this reason, CEEASY provides a new survey to obtain **the classification and by which rule it is classified**. As the previous one, the survey available in the website as a 'Google Form', created with 'Google App Script', and it is called: '**Classification of Medical Devices in terms of Directive 93/42/EEC'**.[5] The survey is scripted in a complete different order than the exposed in the eighteen rules in order to make it as short as possible (remember that the goal is to do all the steps in the fastest way possible). The survey starts with the special rules (as those may discard any other options) and

[4] Find existing information, flow charts and examples on medical device classification in "Medical Devices: Guidance Document – Classification of medical devices" written by the European Commission DG Health and Consumer.
[5] Click here to see the survey on classification.

is then followed by a combination of active devices and non-invasive/invasive/transient surgically invasive/short term surgically invasive and long term surgically invasive. This new architecture assures the shortest paths to the final classification. The survey is also provided as a flow chart (attached in Annex 3).

The Medical Devices classification into four (or six) categories: Class I, (Is, Im), IIa, IIb and III, is the most known classification. There are other classifications known as **codes**[15], which are helpful when applying for the CE Mark: it is useful because this code gives much more information on the device. While Classes classify the device according to risk, codes classify them according to what they are and their intended use. The list of all the MD codes is in Annex 4.

2.3. Step 3 (Part 1) – Conformity Assessment Process: Modules

The conformity assessment aims to demonstrate whether specified requirements relating to a product have been fulfilled. This process covers both the design and the production phase and can be done in different ways, called modules. **Modules** lay down the responsibilities of the manufacturer (and its authorized representative) and the degree of involvement of the in-house accredited or notified conformity assessment body. Modules are defined in a general way, they are transposed to conformity assessments for each single directive (as the requirements differ from one directive to another). In MDD, the conformity assessments are defined in Annexes from II to VII. Table S1 (supplementary material) shows the correlation between the general modules and the Annexes of MDD. [16]

This is the trickiest step as different procedures lead to the same end. Table 1 shows the different paths that manufacturers can choose to obtain the CE marking. It also states, the most popular and the second most popular choice for each class according to the results of the ‘Distribution between different

conformity assessment modules under MDD" done by Team NB Medical Devices Surveys from 2014 to 2017. [17-20]

Type of device	Procedure	
Class I (Non-sterile, Non-measuring)	Annex VII	In-house accreditation, no need of third party (Notified Body).
Class I (sterile and/or measuring)	Annex VII + Annex IV	
	Annex VII + Annex V	Recommended for sterile devices Most popular
	Annex VII + Annex VI	
Class IIa	Annex II (excluding point 4)	Most popular Recommended for sterile devices
	Annex VII + Annex IV	
	Annex VII + Annex V	Second most popular
	Annex VII + Annex VI	
Class IIb	Annex II (excluding point 4)	Most popular Recommended for sterile devices
	Annex III + Annex IV	
	Annex III + Annex V	Second most popular
	Annex III + Annex VI	
Clas III	Annex II	Most popular
	Annex III + Annex IV	
	Annex III + Annex V	Second most popular

Table 1. Certification paths for each class of medical device according to MDD.

It can be seen that Class I non-sterile and non-measuring devices have the easiest path to CE Marking that is to follow Annex VII. They do not require a third party and only need to prepare the technical documentation (go to section 2.7).

For all other cases, a third party (Notified Body) is required. Therefore, it is recommended to choose the regulation route taking into account the Notified Body.

2.4. Step 3 (Part 2) – Conformity Assessment: Notified Body

The Blue Guide[6] defines **Notified Bodies** as (paraphrasing) conformity assessment bodies which have been officially designated by their national authority to carry out the procedures for conformity assessment within the meaning of applicable Union harmonisation legislation when a third party is required.

The **New Approach Notified and Designated Organisations** (NANDO) database [21] keeps record of all the designated NB per Member State: an up-to-date list with identification number of each NB and the tasks for which it has been notified.

Manufacturers can choose which Notified Body may verify the compliance assessment of its product. Any accredited NB established in any EU Member State (independently of the manufacturer's country) can be chosen, although it is highly recommended to choose taking into consideration the technical competence of the body, the product-type and the given service. Therefore, **the manufacturer should take into account if the body can inspect that kind of product-type as well as the experience of the body in that product-type**.[22]

With all that, in order to help the manufacturer make such decision (of both Notified Body and Conformity Assessment path), we compiled the technical competence for each product-type of all Notified Bodies (accredited for directive 93/42/EEC) in Table A13-2 (Annex 13)[6]. As seen, there are 59 Notified Bodies accredited for this directive, but each NB covers different product-types (defined by codes, remember that codes' definitions are in Annex 4) by different

[6] The table is available in Excel format in CEEASY's website.

certification paths. Table A13-2 also takes into account different limitations for each single case. All information has been extracted from the NANDO database at the European Commission's website on legislation 93/42/EEC.[21]

In order to choose a NB, sometimes it may be useful that the NB is also accredited for Active Implantable Medical Devices and/or In vitro diagnostic medical devices (as your device may be a borderline product). Therefore, Table A13-1 shows whether the NB complies with AIMDD and/or IVDD. It also states if it complies with other directives related to medical devices as directives concerning: machinery, electromagnetic compatibility, personal protective equipment and measuring instruments. With all that, a rating among all the Notified Bodies has been performed to help the user choose. The definition of such rating is explained at the beginning of Annex 13.

Finally, before choosing a NB it must be said that manufacturers should not be just taking into account the current device but all product-types they aim to manufacture (as changing the Notified Body –as the CE mark label would be different– expenses in manufacturing would arise, new documents are needed and fees have to be paid).

2.5. Step 4 (Part 1) – Essential Requirements

Essential requirements (ER) define the results to be attained or the hazards to be dealt with, but do not specify the technical solutions for doing so.[7] These requirements are designed to ensure a high level of protection and arise from certain hazards associated with the product, its performance, a protection objective or a combination of these. This step consists on making sure that the device complies with the essential requirements set out in Annex I of MDD[11].

Usability[8], understood as the characteristics of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction, has been gaining importance in the last years. Taking usability into account as well as the

[7] Definition according to The 'Blue Guide'.[6]
[8] Definition according to Clause 3.17 of EN 62366:2008+A1:2015.

essential requirements improves the user's performance in using the device as it reduces the training effort needed, the user's stress and, consequently, reduces use error. In other words, it means to design a device with a friendly interface, so that being misused by the user is unlikely. For medical devices, usability requirements are set out in the standard: EN 62366.[9] [23]

As essential requirements are applied as a function of the hazard inherent to a given product, the manufacturer needs to carry out a **risk analysis**[24] In this way, the manufacturer is able to identify all possible risks, determine the applicable essential requirement and apply it, which must result in: eliminating or reducing the risk (safe design and construction), take adequate protection measures (for risks than cannot be eliminated) and inform users of the residual risks. [25]

To do so, CEEASY offers an easy guide to know how to perform a risk analysis (Annex 5) and also a template (Annex 6).

2.6. Step 4 (Part 2) – Harmonized Standards

While essential requirements just state the results that have to be achieved, not how; **harmonized standards** give detailed manufacturing specifications. The degree of detailed wording in standards is intended to create legally binding obligations, but they do leave room to technical interpretation. In order to facilitate the standardisation of the requests, the European Commission assigned different European organizations (CEN[10], CENELEC[11], ETSI[12]) to develop standards in accordance with the essential requirements of the directives. Standards are a way to comply with Essential Requirements (ER) but are of voluntary use. [26]

CEEASY offers information on where to find these standards. An analysis of the most used standards was aimed to be performed, but as standards cost between 100€ and 1.500€, the analysis could not be performed due a lack of accessibility.

[9] EN ISO 62366:2015 – Medical Devices – Application of usability engineering to medical devices.
[10] CEN: European Committee for Standarization www.cen.eu
[11] CELENEC: European Committee for Electrotechnical Standarization www.cenelec.eu
[12] ETSI: European Telecommunications Standards Institute www.etsi.org

The best place to search the list of all harmonized standards is the New Approach Standardisation in the Internal Market website[27] as it has the option to search by directives. A website to have a first contact with harmonized standards concerning medical devices is the European Commission's website. Once the user has identified the specific standard, he or she might refer to: CEN, CELENEC and ETSI. In order to find information about a specific standard the most recommendable site is the CEN standard search page. CEN's website is focused on all the sales points (which are national organizations) where you can buy the standard. On the other hand, ETSI enables the user to download some of their standards for free.

2.7. Step 5 – Technical Documentation

Once the final design is done, the next step is to gather all the product-related information in a **Technical File** also called technical documentation. A technical file is the proof that product complies with the essential safety and health requirements set down by the relevant directives.[6] Talking about medical devices, it demonstrates compliance with essential requirements (Annex I of MDD).

Technical Files (TF) are required for all classes of medical devices (I, Im, Is, IIa, IIb, and III). Files for Class I will not be reviewed by a NB while the rest do. It is recommended to have it reviewed by an external consultant. For Class III devices, the technical file is called Design Dossier.

The technical file needs to be written by the manufacturer (or the Authorized Representative). Writing a Technical File is complex, for this reason Annex 7 presents a guide and Annex 8 a template to help the user write their own TF.[28]

The proposed guide, although useful, is quite general as the details included in the documentation depend on the nature of the product. Therefore, we recommend to read the conformity assessment of choice.[13] If the product is

[13] Conformity Assessments are defined in Annexes II to VII in MDD.

considered as ‘special’, being a custom-made device or a device for clinical investigations, read Annex VIII of the same directive.

At this point all the documentation has to be handed to the Notified Body (if a third party is required) which will perform all the necessary tests and audits and will finally issue the CE certificate.

2.8. Step 6 – Declaration of Conformity and Affixing CE Mark

Once the CE marking is obtained, or self-certified for Class I devices, the manufacturer needs to write statement affirming that:

- the device meets all the essential requirements set out in Directive 93/42/EEC,
- the device has undergone the appropriate conformity assessment procedures, and
- the device is designed in accordance with the technical documentation.

This document is called Declaration of Conformity (DoC) and has to be available to authorities at the EU point of entry that is the EU distributor. A copy must be kept for at least 10 years after the product is placed on the market. [6]

It is a one-page document that includes[11]: the name of the manufacturer and authorized representative, product or family product (and all its variants, catalog numbers), directives involved, class of device, standards used, where test results can be found, conformity assessment procedure, Notified Body name and number, certificate number, who is the responsible in the company and place and date of issue. In Annex 9 there is a template with all the above stated information in a one-page format.

As for what affixing the CE marking refers, the manufacturer needs to add the CE conformity marking which consists of the initials ‘CE’ as shown in Figure 6.

If a Notified Body is involved in the conformity assessment, the four digit identification number of the Notified Body should be placed below or beside (in the right side) of the CE conformity mark.

The vertical dimension may not be less than 5mm, and proportions must be respected.

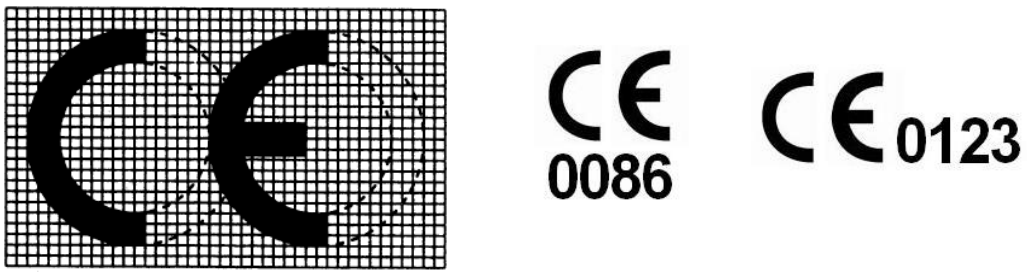

Figure 6. CE conformity marking label. First image shows not only the symbol but its proportions and without a NB number (due self-certification). The other two symbols mean that the CE certificate has been issued by a NB (corresponding to the number).

Once the product has obtained the CE compliance with Directive 93/42/EEC, a maintenance has to be done to remain complying with the directive and the essential requirements.

2.9. CE Marking Maintenance

CE Certificates for medical devices last for 5 years. The Certificate has to be renewed before the due date, if not, the manufacturer will have to stop selling the product until the new certificate is issued. During these five years, all changes related to information on the technical file must be notified.

The most important part is **vigilance**. Any incident regarding any device (of any class) must be reported to the national or European authorities. Those include any malfunction or deterioration in the performance of the device, or any technical or medical reason leading to a systematic recall of the product. And any appropriate measures shall be adopted. In close relation, **traceability** is important too; if a recall needs to be done it is necessary to know who owns (other companies, hospitals or patients) all the products of the same lot or model. [6]

2.10. Medical Devices Directive's Future

In April 2017 a new regulation on medical devices (**EU-MDR)** was created **(Regulation (EU) 2017/745)**[14] and this legislation repeals both the MDD (93/42/EEC) and AIMDD (90/385/EEC). Currently both legislations are in force: the new one entered into force on 25 May 2017 and the latest will be no longer in force since 25 May 2020. During this period, all three legislations can be applied.

The main changes are among others: increased number of classification rules (from 18 to 22), more insight in the criteria for designating Notified Bodies, more importance on post-market surveillance (vigilance and traceability by introducing an "implant card", for instance) and reinforcement on clinical evidence. [29]

In the same way, the IVD directive (98/79/EC) was repealed by the new EU-IVDR regulation (Regulation (EU) 2017/746)[15] which entered into force in May 2017. Until 26 May 2022 both regulations are valid, then the former will no longer be in force.

Major changes include: an expansion of the scope of the directive, a newer classification to four Classes of risk (from lowest to highest risk, classes from A to D) and documentation must be kept for 10 years (five more than currently) after the last placing on the market. The new risk-rule classification system will lead to a reduction of self-declared devices, meaning that the 80% of IVDs will require the participation of a Notified Body to obtain the CE mark.[30]

[14] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[15] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnòstic Medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

3. CASE OF STUDY: MiWEndo

The *Simulation, Imaging and Modelling for Biomedical Systems (SIMBIOSYS)* and *Sensing in Physiology and Biomedicine (PhySense)* research groups are currently working on a project called **MiWEndo**. Both groups are part of the BCN MedTech unit of the Information and Communication Technologies Department at Universitat Pompeu Fabra (UPF).

MiWEndo team is mainly formed by qualified researchers with no experience in regulatory affairs. Learning about CE marking alone and from scratch takes a lot of time, and learning it with the help of a regulatory consultant is expensive; when it comes to research time and money are the most valuable and scare resources. With the help of CEEASY, we aim to prove that learning how the CE marking process works is not only free but faster.

Although it may be assumed that the CE marking process starts once the product is finally developed and tested, it actually should be taken into account since day one. As the team is currently in the design phase, a first approach to the CE marking process has been performed.

3.1. Device Description

Before undergoing the CE marking process, a **clear and brief** description of the device is needed to correctly do each of the six main steps[16]. The description should include: what it is, what it is made of, how it works, its intended use, user and conditions.

- **What is it:** MiWEndo stands for Microwave Endoscopic Imaging, it is a real-time microwave imaging device for endoscopic explorations and interventions. The device consists of a head of microwave sensors (antennas) that couples to the distal end of a standard colonoscope and an external unit that processes and displays the data acquired by the head.

[16] See sections from 2.1 to 2.8.

- **What it is made of**: The head is composed by a cylindrical antenna array with multiplexing and feeding network. The head is encapsulated to set a physical barrier between the patient and the circuitry. The external unit contains the transceiver (which generates and receives the microwaves), the head controller, the signal processor and the visualisation screen.

- **How it works**: The antennas transmit and receive microwave signals that interact with the colon tissue. The received signals are transmitted to the external unit and are processed. MiWEndo retrieves the dielectric properties of colon tissues that allow to classify them and determine if they are malignant or not.

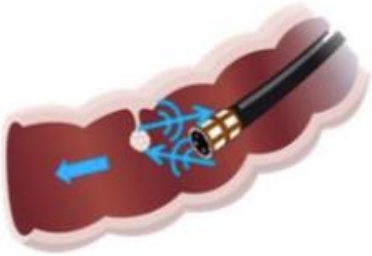

Figure 7. Graphical drawing on how MiWEndo works.

- **Intended use, user and conditions**: To use in a colonoscopy procedure by a doctor expert in digestive endoscopy. It is used in order to have more information (not just the optical image) on the types of tissues in the colon. As it is able to increase the field of view, the polyp miss rate may be reduced. The tissue classification capability will help doctors in the decision-making that may contribute to the reduction of repeated colonoscopies. [31]

With all this information, the first step is to determine which directives apply to the device.

3.2. Applicable Directives

To start with, the CEEASY's survey on **"Decision on which directives apply to a medical product"**[17] has been performed. The device perfectly falls under the 'Medical Device' definition, as it does not contain any pharmaceutical,

[17] Click here to start the survey.

immunological or metabolic components, and it has diagnostic purposes. And as according to Directive 2006/42/EC on machinery[18], MiWEndo is not considered as machinery.

Software is also included in the Medical Devices directive as it performs an action on data. When contrasting the information with the Borderline Medical Device Manual[14], the conclusion is the same. Therefore, the whole device is governed by **Directive 93/42/EEC concerning Medical Devices**[19].

As the device works with microwaves, the directive according to Electromagnetic Compatibility[20] has to be taken also into account specially *Article 7*. The device must meet the Essential Requirements set out in this directive, although the main directive that governs the device is the MDD.

3.3. Device Classification

Before classifying our medical device, as it is connected to another medical device (endoscope), we need to know the classification of this other device.

According to the CEEASY's survey on "Classification of Medical Devices in terms of Directive 93/42/EEC"[21] and the Medical Devices Guidance Document[32] the endoscope itself is a Class I device, but if the endoscope has optic fibres connected to lasers is then considered a Class IIa device.

With this, we can undergo the classification for our product: either connected to a Class I or a Class IIa device, MiWEndo is a Class IIa medical device. The rule that takes into account both scenarios is rule 10. Therefore: **MiWEndo is a transient active invasive medical for diagnosis of Class IIa by rule 10.**

The first point of rule 10 states "Active devices intended for diagnosis are in Class IIa: if they are intended to supply energy which will be absorbed by the human

[18] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC.
[19] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
[20] Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic Compatibility.
[21] Click here to start the survey.

body, except for devices used to illuminate the patient's body, in the visible spectrum."

The second type of classification needed is by **codes**, according to Annex 3, the device of study is an **Imaging device utilising non-ionizing radiation**, which corresponds to **MD 1202.** The device also consists of Software, which falls under code **MD 1111** (Software).

3.4. Conformity Assessment

According to Table 2, medical devices in Class IIa can be certified by four different conformity assessment routes:

Class IIa	Annex II (excluding point 4)	Most popular Recommended for sterile devices
	Annex VII + Annex IV	
	Annex VII + Annex V	Second most popular
	Annex VII + Annex VI	

Table 2. Conformity assessment processes for Class IIa Medical devices. Framgent of Table 1.

Out of this four options, the most popular option is: **Annex II (excluding point 4),** which we strongly recommend. Therefore, the conformity assessment route is an **EC Declaration of Conformity based on a full quality assurance (excluding point 4).**

3.5. Notified Body

The Notified Body should be competent for Class IIa medical devices, devices that fall under MD 1202 and MD 1111 (as software is also involved, although is part of the device, it is better to work with a NB that works with software certification), and finally, the conformity assessment (Annex II, excluding point 4).

From the 59 NBs accredited for Medical Devices Directive, through a selection process (detailed in Annex 10), a total of 11 ‘best possible choices’ has been defined:

0044	0050	0086	0120	0123	0197	0344	0402	0459	1434	1783

The way to choose between them is to talk to the NBs about quotes and the time it would take; and then take the most appropriate decision. Talking to other manufacturers and getting their feedback is valuable too.

3.6. Essential Requirements

Essential requirements (ER) are set out in Annex I of MDD and in Annex I of the Directive 2014/30/EU relating electromagnetic compatibility. MiWEndo project is currently in the design phase of the device, an analysis of the ER that apply to this concrete device has been done. The device must therefore be designed in such a way that all the statements in Annex 11 are fulfilled.

In order to fulfil all the requirements above (that apply to the final design of MiWEndo), all the necessary measures will be adopted. A way is to apply the harmonized standards concerning medical devices. Below there is a list of some of the standards that could be of use, although the whole list is in the *European Commission*’s website.[33]

European Standardization Organization: CEN

- EN ISO[22] 10993:2017 – Biological evaluation of medical devices. Parts 1, 3, 4, 5, 7, 9, 11, 13, 15 and 18.
- EN ISO 11607:2017 – Packaging for terminally sterilized medical devices.
- Related to sterilisation:
    - EN 556:2015 – Sterilization for medical devices – Requirements for medical devices to be designated ‘STERILE’. Parts 1 and 2

[22] ISO stands for International Organization for Standardization

    - EN 11135:2014 – Sterilization of health-care products. – Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices.
    - EN ISO 11737-2:2009 – Sterilization of medical devices – Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
- EN ISO 14155:2011 – Clinical Investigation of medical devices for human subjects – Good clinical practice
- EN 14971:2012 – Medical Devices – Application of risk management to medical devices
- EN ISO 15223:2016 – Symbols used with medical device labels, labelling and information to be supplied. Part 1

European Standardization Organization: CENELEC

- EN 60601:2014 – Medical Electrical Equipment. Parts 1 and 2. Especially EN 60601-1-2:2015 – General requirements for basic safety and essential performance. Requirements and tests.
- EN 62304:2006 – Medical Device Software – Software life-cycle processes.

Last but not least, the usability requirements standard: EN ISO 62366-1:2015 – Medical Devices – Application of usability engineering to medical devices.

With this, an **Essential Requirements Checklist** has to be performed. An example of a checklist can be found in *Medical Device Academy*'s website.

A **risk analysis** should also be performed. Both things complement each other, and having all the ER in mind is really helpful when doing the risk analysis. [23]

Apart from the essential requirements, the conformity assessment of choice was the one described in Annex II, which is the **full quality assurance system**. Which

[23] Remember that a guide and template to perform the risk analysis are provided in Annexes 5 and 6 respectively.

means that a Quality Manual System (QMS) needs to be done. **An easy way to comply with all the aspects is to comply with UNE-EN ISO 13485:2016.** [34] This ISO defines all the requirements of a **quality management system (QMS)** when an entity needs to demonstrate its capacity to provide medical devices according to the essential requirements. The ISO is issued for 'family of devices'. For example if the same group develops a new device really similar to MiWEndo (such as an endoscope to detect different tissues in the oesophagus) the same QMS would be valid as the design and manufacturing process would be really similar.

Information on the QMS can be found in the BSI Notified Body's website [35] or in Emergo's website (a regulatory consulting company). In CEEASY's website there is a QMS example of a product called B·Tell (a Class Is / Im device).

3.7. Technical File

Before being able to write the technical file, all the information needs to be gathered (or created). As seen in the Annex 7 (TF Guide), the most important parts of a technical file are:

- **Description of the device**: design, characteristic, intended purpose, medical condition, accessories, classification and criteria and conformity assessment route. – We already have all this information.
- **The Essential Requirements checklist**. – Annex 11 sets out all the applicable essential requirements.
- **Risk assessment**. The use of EN ISO 14971:2012 is strongly encouraged. – Use the guide and template in Annexes 5 and 6.
- **Results from Design Validation tests** (also known as **Bench Testing**): results from test reports such as device's performance and safety, mechanical, physical and/or chemical studies; biocompatibility; packaging; shelf-life and sterilization (if applies). – Harmonized Standards set out how

to perform this tests; in Section 3.6 there is a list of useful standards for MiWEndo. If others are needed, refer to CEN or CELENEC websites.

- **Manufacturing**: Provide a manufacturing flow chart and description. Demonstrate check points and monitoring steps. Take special consideration on critical subcontractors. – At this stage, providing any kind of advice is really difficult, as the current device's design is not the final one.
- **Clinical Evaluation**: Summary of the Clinical Evaluation Report (CER). – More information in section 3.8.
- **Labelling and Instructions for Use:** Include a draft of the labels and instructions for use. – Not relevant at this stage.
- **Declaration of Conformity.** Include a draft. – This is the easiest document to prepare and there is also a template in Annex 9.

3.8. Clinical Evaluation

The Clinical Evaluation needs to be performed according to Annex X in the MDD. It aims to confirm the conformity with the requirements under the normal conditions of the device, and the evaluation of side-effects and of the acceptability of the benefit/risk ratio. The data can be obtained from:

- Existing scientific literature relating to the safety, performance, design characteristics and intended purpose where:
    - There is demonstration of equivalence of the devices (between the one from the literature and MiWEndo, in this case), and
    - Data demonstrates compliance with the relevant ER.
- Results of all clinical investigations made.
- Combination of both.

When performing a clinical investigation, ethical considerations have to be taken into account. Complying with *ISO 14155:2011 – Clinical investigation of medical devices for human subjects – Good clinical practice* is useful.[36] Once the protocol

is designed, it is highly recommended to ask for the Notified Body's assessment (just to be sure the obtained results will be useful for certification).

The clinical evaluation described above corresponds to the one set out in MDD, but as legislation is soon repealed by Directive EU-MDR 2017/745, it is highly recommended (not to say mandatory) to follow the procedure set out in this new directive. The new clinical evaluation is based on MEDDEV 2.7/1 Revision 4[24].

In the case of MiWEndo, the clinical trial would be performed in Spain; in such case, it is mandatory to get in contact with the *Agencia Española de Medicamentos y Productos Sanitarios* (AEMPS)[25] and the *Comités de Ética de Investigación con medicamentos* (CEIm). There are a lot of different CEIms in Spain, the whole list of CEIms can be found in the AEMPS' website.[37] Of all the CEIms in Catalunya, I would like to mention two of them as the former works together with UPF and the latter as it is already collaborating in MiWEndo project.

- CEIm Parc de Salut Mar
- CEIm Hospital Clínic de Barcelona

In order to perform a clinical trial, the investigator needs to contact with one CEIm. Taking the CEIm at Hospital Clínic as an example, the project should be presented in e-mail format to ceic@clinic.cat. This Committee is in charge giving advice to researchers on ethics, methods, statistics, monitoring and coordination of the trial. The Clinical Trial Unit (CTU) of Fundació Clinic, would be actually be in charge of performing the trial.

The clinical investigation needs to be accepted by both the CEIm and the AEMPS, therefore when estimating the total cost of the clinical trial, taxes of both procedures are taken into account.

[24] Guidelines on Medical Devices written by the European Commission concerning Clinical Evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC.
[25] Go to the AEMPS website for Medical Devices Clinical Investigations, here.

	Project	Euros
CTU (Fundació Clínic)[38]	Protocol Design	2.000 €
	Wording of the information sheet for the patient and informed consent	120 €
	Documents for the clinical trial solicitude at AEMPS	900 €
	Documents for the clinical trial solicitude at CEICs	300 €
	Solicitude for insurance policy	120 €
	Register of the Clinical Trial (www.clinicaltrials.gov)	240 €
	Project Management 1-5 centers	1.200 €/month
	Final Report of the Study	9.000 €
CEIm Hospital Clínic[39]	Medical device with the approval of another CEIm	150€
	Medical Devices Clinical Trial	1.500 €
AEMPS[40]	Authorization of a medical device clinical trial	816,08 €
	Minimum quote for a one month-long trial:	**16.346,08 €**

Table 3. List of minimum procedures to perform related to a clinical trial. CTU fees correspond to 2012. CEIm: Comité de Ética de la Investigación con medicamentos. AEMPS: Agencia Española de Medicamentós y Productos Sanitarios

An insurance policy is required for any given clinical trial, an estimation of the cost could not be performed.

3.9. MiWEndo's Regulatory Affairs Pipeline

The MiWEndo Team is currently in the preclinical validation phase of the project.

At the moment, they know under which directive the device falls, the classification and the conformity assessment of choice. The next steps are the following: choose a Notified Body and perform a **risk analysis** according to the essential requirements set out in Annex II of the MDD, as explained in section 3.6. Once they know how to comply with all the ER, the **final design of the device** needs to be done. Meanwhile, they should start thinking about the **manufacturing process**, identifying which manufacturers will be subcontracted; determine if the device or part of the device will be reusable and in this case define the sterilization procedure; etc… When they have all this information, the QMS can be performed.

Then it is time to validate the design of the device (testing) and the clinical trial. To do so, they will have to contact a CEIm (as explained in section 3.8), design a protocol and get it accepted by the AEMPS. This procedure, defined as 'AEMPS Acceptance of Clinical Trial' in Annex 12 can take up to 100 working days.[41] After acceptance, the clinical trial will be performed. When the Clinical Evaluation Report is written the TF can be written too. With all this, the team will be able to submit the Technical File to the Notified Body, which may spend about 5 months[26] (in the Gantt chart this step is defined as 'NB Auditing and Testing') performing audits and tests, which translates to the time from submission to approval. At that point, the CE certificate will be issued.

Once the CE marking is obtained, some vigilance acts must be conducted. If any substantial change is made in the device or manufacturing process, the certificate is valid for 5 years. Before its expiration date, the manufacturer will have to renew the certificate.

Taking into account all this information, a detailed pipeline of the steps they will need to follow in the near future is shown in Annex 12 (Gantt chart of the Upcoming Regulatory Events). As MiWEndo team expects to finish the preclinical validation at the end of 2019, the Gantt chart shows that the CE certificate would be issued by May 2021 (at least). Therefore, the current MDD legislation will no longer be in force. The CE marking procedure will have to be done according to the new MDR legislation (Regulation (EU) 2017/745).

[26] According to Emergo's Comparison of time, cost and complexity of getting regulatory approval for Medical devices. Click here access the website. Last visited (June 2, 2018)

4. FUTURE WORK

As explained in section 2.10., the medical device directive is going to be repealed by a new one. At the moment, neither consulting companies in Europe such as Qserve have a clear idea on how this new legislation is going to be applied. During the last year, Qserve been doing webminars on the Fundamental changes from MDD to EU-MDR. [42]

For what CEEASY refers, the future work consists in updating all the information, surveys and resources according to the new EU-MDR. In this way, CEEASY might be used by everyone, not just amateurs, manufacturers used to the MDD will have to learn the fundamental changes. Another thing that needs to be improved is to give more specific case-by-case information.

In terms of the case of study, according to the proposed pipeline (Annex 12) MiWEndo team will be affected by this new regulation. The steps and estimated duration of the proposed pipeline will not change due the new regulation, providing a useful estimation. On the other hand, the information in close relation to the current directive will have to be updated with the new regulation (such as the classification).

5. CONCLUSION

CE marking process is generally seen as a black box by entrepreneurs. There is a huge amount of information available but is not presented in an understandable way for the entrepreneur. For this reason they refer to a consultancy to assist them in the regulatory process. CEEASY makes this step easier as exposes an organized and summarized version of the most important things from the manufacturer's point of view about the procedure.

All currently available online information of free access is too general. So when the user reads it has the wrong impression that the process is fast and easy, but when considering a particular case, many questions arise. In general, there is a lack of specific information. CEEASY tried to fix this with the use of surveys and templates. The first three steps achieved so (identifying directives, classifying devices and choosing both the conformity assessment and a Notified Body), but when it comes to the essential requirements and the technical file, giving specific information becomes hardly impossible. Manufacturers end up using the services of EU regulatory consultant companies.

Even if CEEASY could provide the most specific case-by-case information, the main concern is: would a Notified Body issue a certificate if any consultant company has not helped in the procedure? There is no way to know this at the moment. In my opinion, CE marking nowadays is a business between Notified Bodies, authorized representatives and consulting companies. For example, Notified Bodies could provide much more information than they do, but they do not because in this way manufacturers will hire a consulting company or will have their certificate withdrawn and then repeat the process again (so either the NB wins more money, or an authorized representative does).

With all this, we can conclude that using CEEASY does not mean that the whole process can be done just with it, at least not in the present day; but its use will sure help entrepreneurs to know the CE marking process and more specific information than most of the existing websites.

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7. SUPPLEMENTARY MATERIAL

Module	Name	Covers		In-house accreditation***	EU-type examination	In Directive 93/42/EEC corresponds to	Name of the procedure
		Design	Production				
A	Internal Production Control	✓	✓	✓		Annex VII	EC Declaration of Conformity
B*	EU-type Examination	✓			✓	Annex III	EC Type-Examination
D**	Conformity to EU-type based on quality assurance of the production process		✓		✓	Annex V	EC Declaration of Conformity (Production quality assurance)
E**	Conformity to EU-type based on product quality assurance		✓		✓	Annex VI	EC Declaration of Conformity (Product quality assurance)
F**	Conformity to EU-type based on product verification		✓		✓	Annex IV	EC Verification
H	Conformity based on full quality assurance	✓	✓			Annex II	EC Declaration of Conformity (Full quality assurance system)

*Module B always needs to go followed by modules D, E or F.
**This modules need to follow module B, so that both design and production are covered.
*** In-house accreditation means that no third party is required (no need of NB).

Table S 1. Relation between the general modules and the conformity assessment procedures defined in Council Directive 93/42/EEC concerning medical devices.

8. GLOSSARY

AEMPS: Agencia Epañola del Medicamento y Productos Sanitarios

AIMDD: Active Implantable Medical Devices Directive, which corresponds to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

Authorised Representative: Legal entity established in the European Economic Area that performs the CE marking process in the name of a manufacturer established outside the EEA.

CE: European Conformity

CEIm: Comité de Ética de la Investigación con medicamentos

CEN: European Committee for Standardization

Clinical Trial: any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.

Conformity Assessment Body: Body that performs one or several elements of conformity assessment, including one or several of the following activities: calibration, testing, certification and inspection.

Declaration of Conformity (Doc): Written statement by the manufacturer to demonstrate the fulfilment of the EU requirements relating to a product bearing the CE.

Design Dossier: see Technical File

Directive: Legislative act that sets out a goal that all EU countries must achieve, although it is up to the individual countries to devise their own laws on how to reach this goals.

Distributor: Natural or legal person in the supply chain, other than the manufacturer or importer, who makes a product available on the market.

DVT: Design Validation Tests

EEA: European Economic Area. Also known as **European Market**:

ESO: European Standardization Organization

EU-MDR: Medical Device Regulation. Which is: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Harm Physical injury or damage to the health of people, or damage to property, or the environment

Hazard: Potential sources of harm.

Importer: Natural or legal person established in the Union who places a product from a third country on the EU market.

ISO: International Organization for Standardization. Organization that develops and publishes International Standards.

IVDD: *In vitro* Devices Directive, which corresponds to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

QMS: Quality Management System can be expressed as the organizational structure, procedures, processes and resources needed to implement quality management.

Manufacturer: Any natural or legal person (established inside or outside the EEA) that manufactures a product or has a product designed, and places it on the market under his own name or trademark.

Medical Device: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conceptions,

and which does not achieve its principal intended action in or on the human body by pharmaceutical, immunological or metabolic means, but which may be assisted in its function by such means.

MEDDEV: Abbreviation for Medical Devices.

MDD: Medical Devices Directive, which corresponds to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Notified Body: Organization that has been accredited by a Member State to assess whether a product meets certain standards.

Product lifetime: considered as the time from manufacture until the device ceases to fulfil its intended use.

Regulation: binding legislative act and must therefore be applied in its entirety across the EU.

Risk: Combination of the probability of occurrence of harm and the severity of that harm

Shelf life: time the device can be kept in the packaging prior to use.

Technical File: documentation intended to provide information on the design, manufacture and operation of the product. Called Design Dossier for Class III devices.

Usability: Characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction.

8. ANNEXES

Annex 1: CE Marking Scope and Other Directives.

CE MARKING SCOPE

The types of products affected by European Directives are:

- **active implantable medical devices**,
- appliances burning gaseous fuels,
- cableway installations designed to carry persons,
- construction products according to Regulation (EU) No. 305/2011 under specific rules,
- eco-design of energy related products,
- electromagnetic compatibility,
- equipment and protective systems intended for use in potentially explosive atmospheres,
- explosives for civil uses,
- hot-water boilers,
- ***in vitro*** **diagnostic medical devices**,
- lifts,
- low voltage,
- machinery,
- measuring instruments,
- **medical devices**,
- noise emission in the environment,
- non-automatic weighing instruments,
- personal protective equipment,
- pressure equipment,
- pyrotechnics,
- radio and telecommunications terminal equipment,
- recreational craft,
- restriction of the use of certain hazardous substances in electrical and electronic equipment RoHS 2,
- safety of toys,
- simple pressure vessels.

OTHER DIRECTIVES

A medical device could in fact fall under any other of this directives. In order to make sure read carefully the scope of each of the directives.

- **Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use**. Medicinal products such as: paracetamol, ibuprofen or aspirin. This directive needs to be taken into account as some medical devices may incorporate medicinal products; therefore, it is important to know how to distinguish between a medicinal product and a medical device.

- **Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC**. This directive is important and devices incorporating human blood or blood products are not considered to be medical devices and therefore are governed by this directive.

- **Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells**. Products that contain human tissues and cells are not considered medical devices and therefore are governed by this directive.

- **Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products**. This one is necessary in case of misunderstanding between medical device and cosmetic product.

- **Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC**. As the name says, it governs clinical trials on medicinal products for human use.

There are other directives that, although will not govern a product, may be complementary to a previously mentioned directive. A list of some of these directives or regulations are:

- **Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery**, and amending Directive 95/16/EC. This directive is necessary for medical products considered also as machinery where relevant hazards may exist.

- **Directive 2014/30/EU** of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to **electromagnetic compatibility**.

- **Regulation (EC) No 1272/2008** of the European Parliament and the Council of 16 December 2008 on **classification, labelling and packaging of substances and mixtures,** amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

- **Directive 2014/35/EU** of the European Parliament and of the Council 26 February 2014 on the harmonization of the laws of the Member States relating to the **making available on the market of electrical equipment designed for use within certain voltage limits**.

- **Directive 2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on **machinery** and amending Directive 95/16/EC.

- **Directive 2014/53/EU** of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of **radio equipment** and repealing Directive 1999/5/EC.

- **Directive 2001/95/EC** of the European Parliament and of the Council of 3 December 2001 on **general product safety**.

- **Directive 2014/668/EU** of the European Parliament and of the Council of 15 May 2014 on the **harmonization of the laws of the Member States relating to the making available on the market of pressure equipment**.

Annex 2: Decision on which directives apply to a medicinal product

This conceptual helps the user decide if a concrete device is in fact a:

- Medical Device
- Active Implantable Medical Device
- *In vitro* Diagnostic Medical Device
- Medicinal Product

It also gives the user information on all the directives or regulations that should be taken into account for a concrete device. It also helps the user understand how software and accessories are regulated with the current in force directives.

This conceptual map works in a easy way: start from question one and keep going. Once the user gets to a result (Figure A2-1), which is shown in blue, you will need to go to the Answers' page and look for the obtained answer (Figure A2-2).

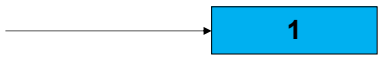


Figure A2-1. Example of a final result.

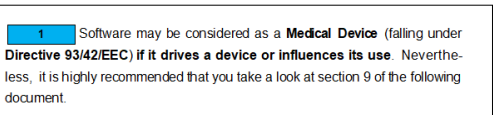


Figure A2-2. Example of a explanation of a result (in page: Answers)

ADVICE:

Please, make sure your answers are as accurate as possible; to do so, check the attached glossary for this specific task.

GLOSSARY

Active Implantable Medical Device: any medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure. *(Defined according to Directive 90/385/EEC)*

Advanced Therapy Medicinal Product: means any of the following medicinal products for human use: *(Defined according to Regulation (EC) No 1394/2007)*

- A **gene therapy medicinal product**: biological medicinal product which has the following characteristics: a) contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence, b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence. Vaccines against infectious diseases are not included. *(Defined according to Annex I part IV to Directive 2001/83/EC)*
- A **somatic cell therapy medicinal product**: biological medicinal product which has the following characteristics: a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor; b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing, or diagnosing a disease though the pharmacological immunological or metabolic action of its cells or tissues. *(Defined according to Annex I part IV to Directive 2001/83/EC)*
- A **tissue engineered product**: which is a product that contains or consists of engineered cells or tissues and is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue. It may contain cells or tissues of human or animal origin, or both. The cells or tissues may be viable or non-viable. It may also contain additional substances (cellular products, bio-molecules, bio-materials, chemical substances, scaffolds or matrices). *(Defined according to Regulation (EC) No 1394/2007)*

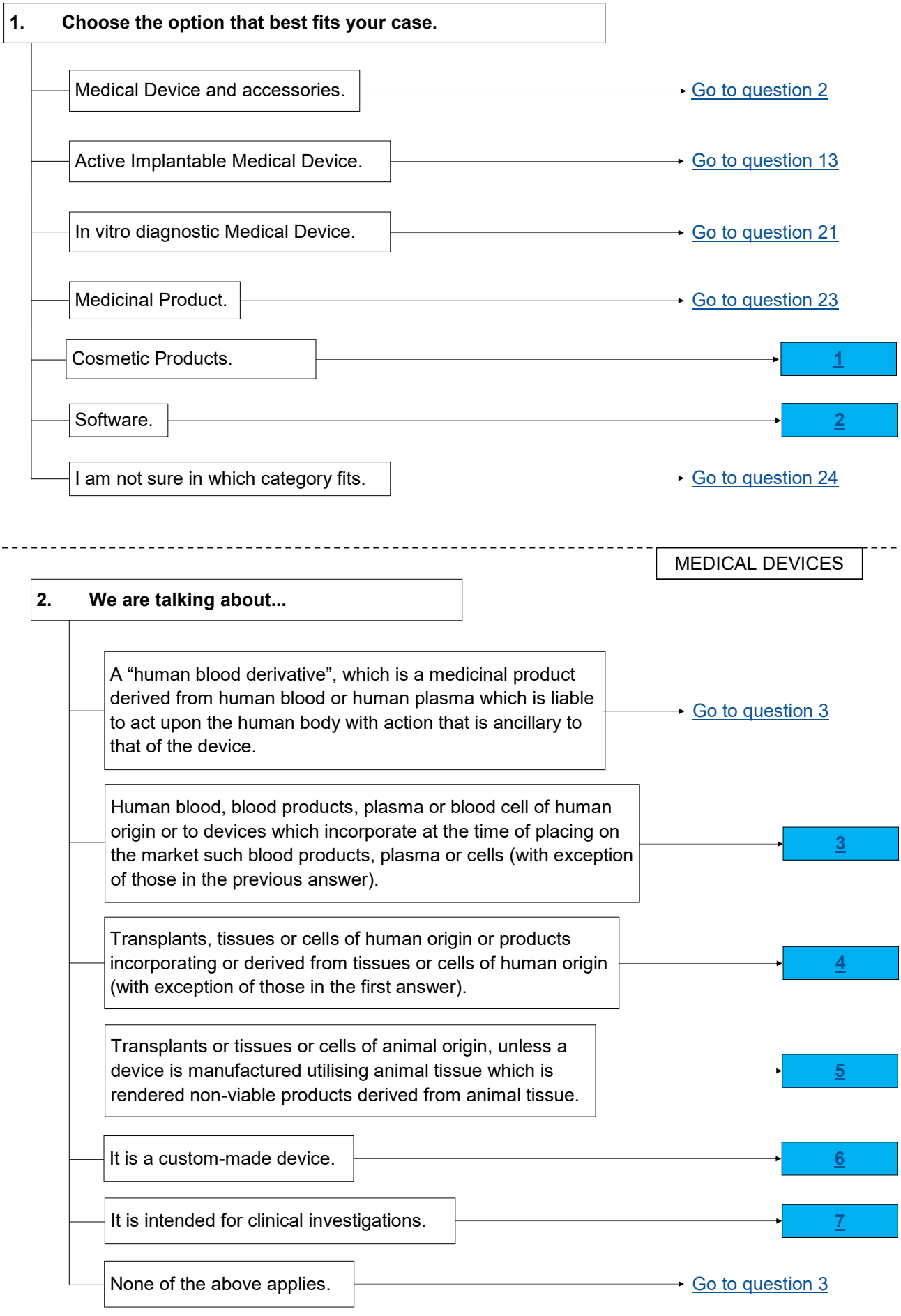
***In vitro* Diagnostics Medical Device**: any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state, or a congenital abnormality or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures. Specimen receptacles are considered to be *in vitro* diagnostic medical devices. Products for general laboratory use are not *in vitro* diagnostic medical devices unless specifically intended by the manufacturer. *(Defined according to Directive 98/79/EC)*

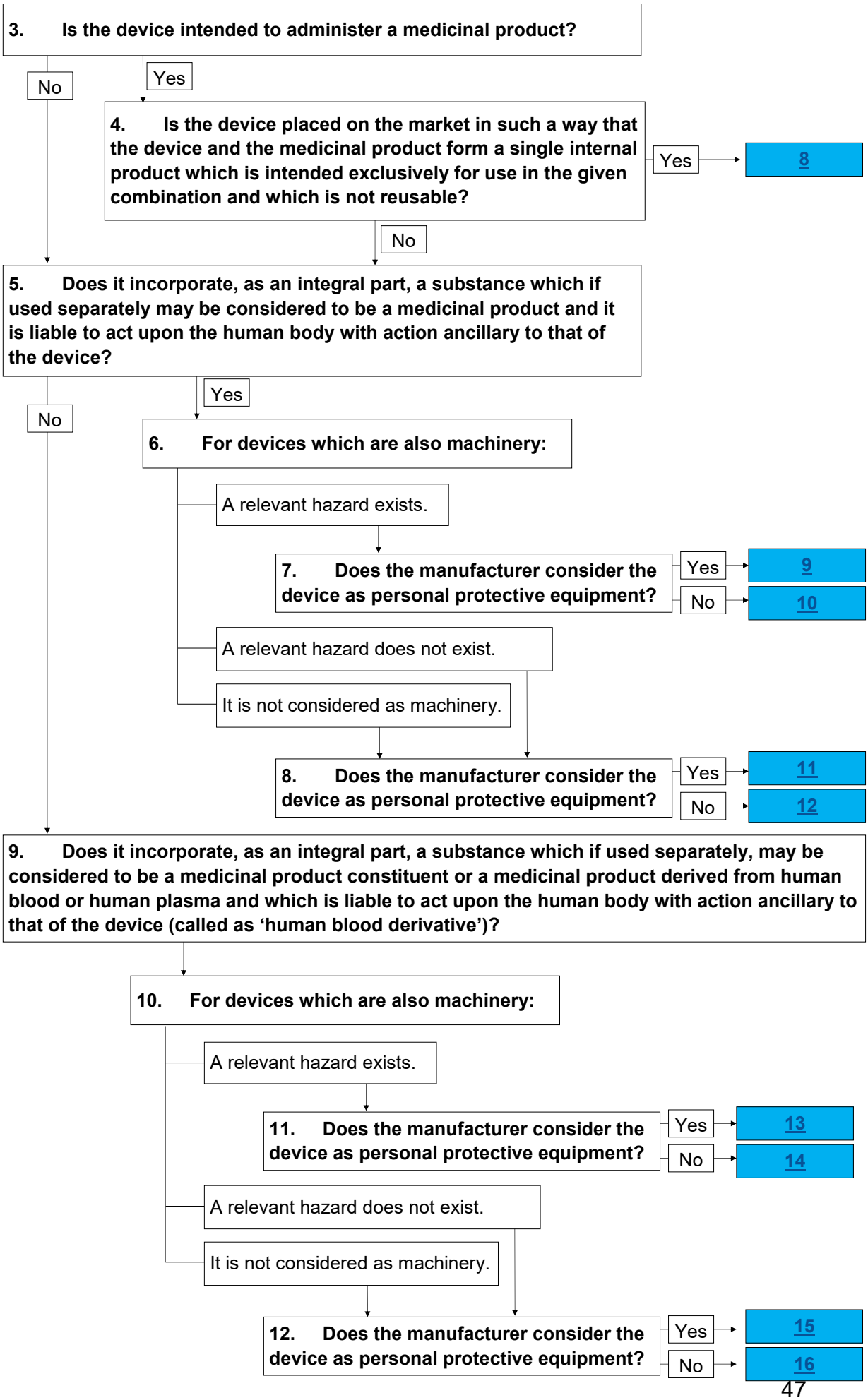
Medical Device: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

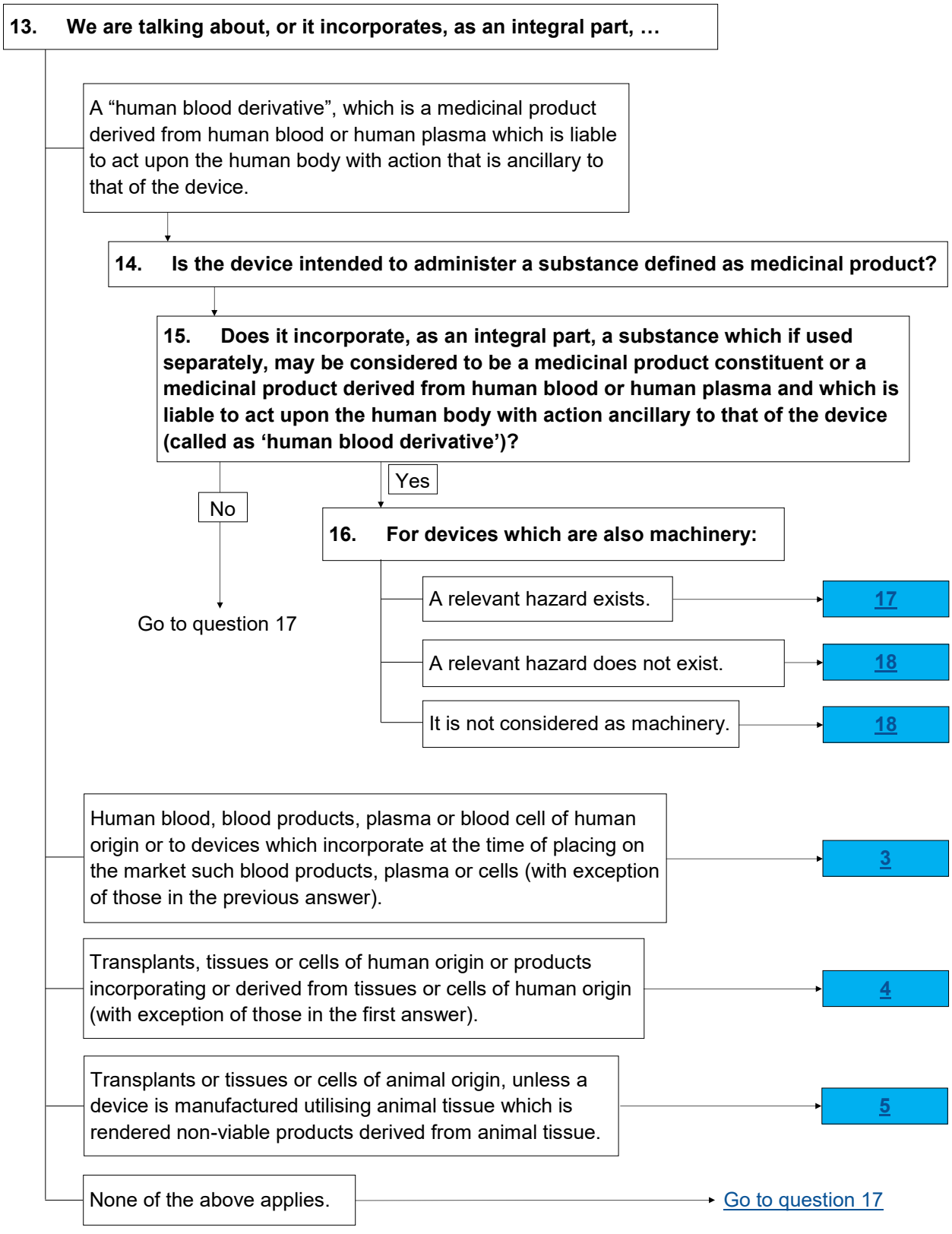
- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conceptions,

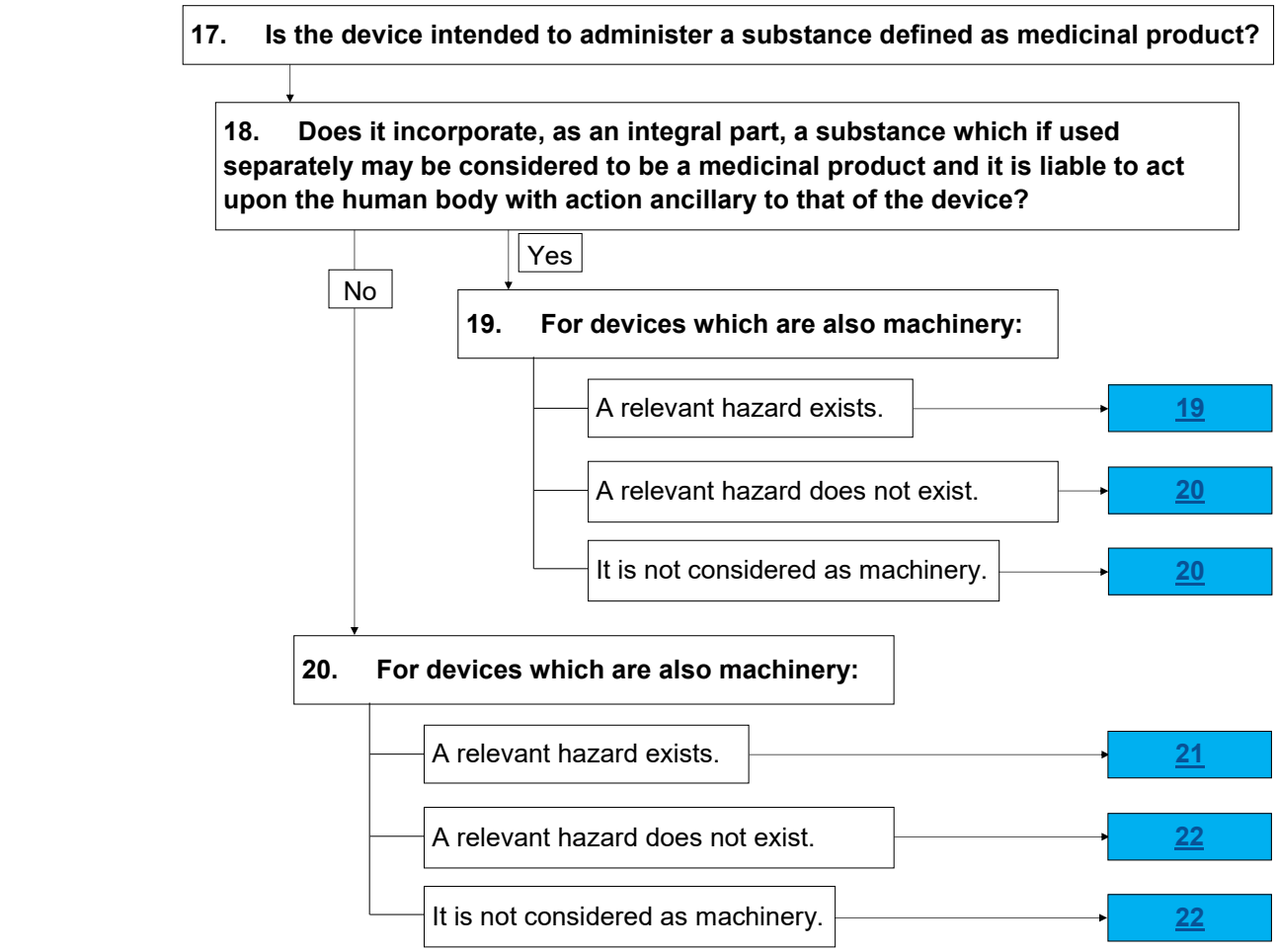
and which does not achieve its principal intended action in or on the human body by pharmaceutical, immunological or metabolic means, but which may be assisted in its function by such means. *(Defined according to Directive 93/42/ EEC)*

Medicinal Product: any substance o combination of substances presented as having properties for treating or preventing disease in human beings; or, any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. *(Defined according to Directive 2001/83/EC)*

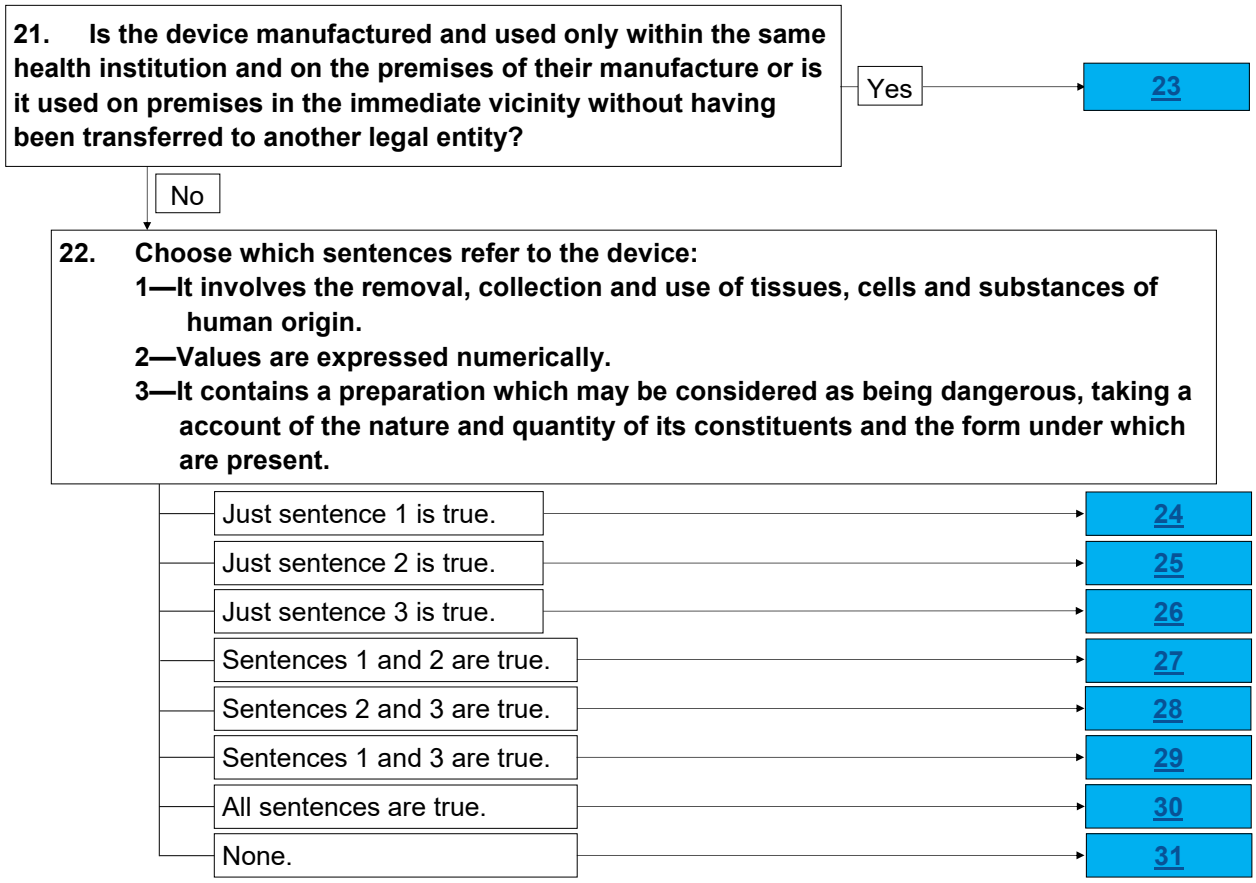

1. Choose the option that best fits your case.
Medical Device and accessories.
Go to question 2
Active Implantable Medical Device.
Go to question 13
In vitro diagnostic Medical Device.
Go to question 21
Medicinal Product.
Go to question 23
Cosmetic Products.
1
Software.
2
I am not sure in which category fits.
Go to question 24
MEDICAL DEVICES
2. We are talking about...
A “human blood derivative”, which is a medicinal product derived from human blood or human plasma which is liable to act upon the human body with action that is ancillary to that of the device.
Go to question 3
Human blood, blood products, plasma or blood cell of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells (with exception of those in the previous answer).
3
Transplants, tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin (with exception of those in the first answer).
4
Transplants or tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable products derived from animal tissue.
5
It is a custom-made device.
6
It is intended for clinical investigations.
7
None of the above applies.
Go to question 3


3. Is the device intended to administer a medicinal product?
No
Yes
4. Is the device placed on the market in such a way that the device and the medicinal product form a single internal product which is intended exclusively for use in the given combination and which is not reusable?
Yes
8
No
5. Does it incorporate, as an integral part, a substance which if used separately may be considered to be a medicinal product and it is liable to act upon the human body with action ancillary to that of the device?
Yes
No
6. For devices which are also machinery:
A relevant hazard exists.
7. Does the manufacturer consider the device as personal protective equipment?
Yes
9
No
10
A relevant hazard does not exist.
It is not considered as machinery.
8. Does the manufacturer consider the device as personal protective equipment?
Yes
11
No
12
9. Does it incorporate, as an integral part, a substance which if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma and which is liable to act upon the human body with action ancillary to that of the device (called as 'human blood derivative')?
10. For devices which are also machinery:
A relevant hazard exists.
11. Does the manufacturer consider the device as personal protective equipment?
Yes
13
No
14
A relevant hazard does not exist.
It is not considered as machinery.
12. Does the manufacturer consider the device as personal protective equipment?
Yes
15
No
16


13. We are talking about, or it incorporates, as an integral part, …
A “human blood derivative”, which is a medicinal product derived from human blood or human plasma which is liable to act upon the human body with action that is ancillary to that of the device.
14. Is the device intended to administer a substance defined as medicinal product?
15. Does it incorporate, as an integral part, a substance which if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma and which is liable to act upon the human body with action ancillary to that of the device (called as ‘human blood derivative’)?
No
Go to question 17
Yes
16. For devices which are also machinery:
A relevant hazard exists.
17
A relevant hazard does not exist.
18
It is not considered as machinery.
18
Human blood, blood products, plasma or blood cell of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells (with exception of those in the previous answer).
3
Transplants, tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin (with exception of those in the first answer).
4
Transplants or tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable products derived from animal tissue.
5
None of the above applies.
Go to question 17



IN VITRO DIAGNOSTIC MEDICAL DEVICES



MEDICINAL PRODUCT

23. Is a medicinal product prepared in accordance with...

- A medical prescription for an individual patient (commonly known as the magistral formula). → 32
- The prescriptions of a pharmacopoeia and it is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula). → 33
- None of the above.

24. The Medicinal Product is:

- Intended for research and development trials. → 34
- An intermediate product intended for further processing by an authorized manufacturer. → 35
- Any kind of radionuclides in the form of sealed sources. → 36
- Made up or consisting of whole blood, plasma or blood cells of human origin, except for plasma which is prepared by a method involving an industrial method. → 37
- Any advanced therapy medicinal product. → 38
- None of the above. → 39

BORDERLINE PRODUCTS

25. Choose the case that best fits your doubt.

- Medical Device VS *In vitro* Diagnostic Medical Device. → 40
- Medical Device VS Active Implantable Medical Device. → 41
- Medical Device VS Medicinal Product. → 42
- It is an accessory → 43

ANSWERS

1 Cosmetic Products fall under **Directive 76/768/EEC.**

2 Software may be considered as a **Medical Device** (falling under **Directive 93/42/EEC**) **if it drives a device or influences its use**. Nevertheless, it is highly recommended that you take a look at section 9 of the following document.

3 In this case, **Directive 2002/98/EC** setting standards of quality and safety for the collection, testing and processing, storage and distribution of human blood and blood components shall govern.

4 In this case, **Directive 2004/23/EC** on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human cells and tissues shall apply.

5 In this case, **Commission Regulation (EU) No 722/2012** concerning particular requirements with respect to active implantable medical devices and medical devices manufactured utilizing tissues of animal origin shall govern.

6 Although this device should fall under Directive 93/42/EEC concerning Medical Devices, as it is a custom-made device, it does not require CE mark, and therefore does not fall under this directive.

7 This device, as it is a medical device should fall under Directive 93/42/EEC concerning Medical Devices, but as it is intended for clinical investigations, it is governed by **Directive 2001/20/EC** on the approximation of the laws, regulations and administrative provisions of the Member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

8 This single product shall be governed by **Directive 2001/83/EC** on Medicinal Products for Human Use. The essential requirements of **Annex I to Directive 93/42/EEC** on Medical Devices shall apply, as far as safety and performance-related device features are concerned.

9 As it incorporates as an integral part, a substance which if used separately may be considered to be a medicinal product and it is liable to act upon the human body with action ancillary to that of the device: **the device shall be evaluated and authorized in accordance of directive 90/385/EEC**. As it is also defined as machinery, where a relevant hazard exists: **the essential health and safety requirements set out in Annex I to directive 2006/42/EC** shall be met too to the extent to which those essential health and safety requirements are more specific than those set in Annex I to Directive 90/385/EEC.As the device is intended by the manufacturer to be used in accordance with both the provision on personal protective equipment in Council Directive 89/868/EEC and Medical Devices Directive 93/42/EEC, **the relevant basic health and safety requirements of Directive 89/868/EEC** shall also be fulfilled.

10 As it incorporates as an integral part, a substance which if used separately may be considered to be a medicinal product and it is liable to act upon the human body with action ancillary to that of the device: **the device shall be evaluated and authorized in accordance of directive 90/385/EEC**. As it is also defined as machinery, where a relevant hazard exists: **the essential health and safety requirements set out in Annex I to directive 2006/42/EC** shall be met too to the extent to which those essential health and safety requirements are more specific than those set in Annex I to Directive 90/385/EEC.

11 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As it incorporates as an integral part, a substance which if used separately may be considered to be a medicinal product and it is liable to act upon the human body with action ancillary to that of the device: **the device shall be evaluated and authorized in accordance of directive 90/385/EEC**. As the device is intended by the manufacturer to be used in accordance with both the provision on personal protective equipment in Council Directive 89/868/EEC and Medical Devices Directive 93/42/EEC, **the relevant basic health and safety requirements of Directive 89/868/EEC** shall also be fulfilled.

12 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As it incorporates as an integral part, a substance which if used separately may be considered to be a medicinal product and it is liable to act upon the human body with action ancillary to that of the device: **the device shall be evaluated and authorized in accordance of directive 90/385/EEC**.

13 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As it is also defined as machinery, where a relevant hazard exists: **the essential health and safety requirements set out in Annex I to directive 2006/42/EC** shall be met too to the extent to which those essential health and safety requirements are more specific than those set in Annex I to Directive 90/385/EEC. As the device is intended by the manufacturer to be used in accordance with both the provision on personal protective equipment in Council Directive 89/868/EEC and Medical Devices Directive 93/42/EEC, **the relevant basic health and safety requirements of Directive 89/868/EEC** shall also be fulfilled.

14 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As it is also defined as machinery, where a relevant hazard exists: **the essential health and safety requirements set out in Annex I to directive 2006/42/EC** shall be met too to the extent to which those essential health and safety requirements are more specific than those set in Annex I to Directive 90/385/EEC.

15 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As the device is intended by the manufacturer to be used in accordance with both the provision on personal protective equipment in Council Directive 89/868/EEC and Medical Devices Directive 93/42/EEC, **the relevant basic health and safety requirements of Directive 89/868/EEC** shall also be fulfilled.

16 The device **falls under Directive 93/42/EEC** concerning Medical Devices.

17 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As it is also defined as machinery, where a relevant hazard exists: **the essential health and safety requirements set out in Annex I to directive 2006/42/EC** shall be met too to the extent to which those essential health and safety requirements are more specific than those set in Annex I to Directive 90/385/EEC. As it incorporates as an integral part a substance which, if used separately, may be considered to be a medicinal product constituent or human blood derivative: Upon completing the manufacture of each batch of devices the manufacturer shall **inform the notified body of the release of the batch of devices** and send it to the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State Lab in accordance with **Directive 2001/83/EC**.

18 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As it incorporates as an integral part a substance which, if used separately, may be considered to be a medicinal product constituent or human blood derivative: Upon completing the manufacture of each batch of devices the manufacturer shall **inform the notified body of the release of the batch of devices** and send it to the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State Lab in accordance with **Directive 2001/83/EC**.

19 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As it is also defined as machinery, where a relevant hazard exists: **the essential health and safety requirements set out in Annex I to directive 2006/42/EC** shall be met too to the extent to which those essential health and safety requirements are more specific than those set in Annex I to Directive 90/385/EEC. As it incorporates as an integral part, a substance which if used separately may be considered to be a medicinal product and it is liable to act upon the human body with action ancillary to that of the device: **the device shall be evaluated and authorized in accordance of directive 90/385/EEC**.

20 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As it incorporates as an integral part, a substance which if used separately may be considered to be a medicinal product and it is liable to act upon the human body with action ancillary to that of the device: **the device shall be evaluated and authorized in accordance of directive 90/385/EEC**.

21 The device **falls under Directive 93/42/EEC** concerning Medical Devices. As it is also defined as machinery, where a relevant hazard exists: **the essential health and safety requirements set out in Annex I to directive 2006/42/EC** shall be met too to the extent to which those essential health and safety requirements are more specific than those set in Annex I to Directive 90/385/EEC.

22 The device **falls under Directive 93/42/EEC** concerning Medical Devices.

23 This kind of devices, as are only used within the same health institution, are not affected by the right of a Member State to subject such activities to appropriate protection requirements.

24 This device **shall fall under Directive 98/79/EC** concerning *in vitro* diagnostic medical devices. It shall also be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine **and by any Member States regulations on this matter**.

25 This device **shall fall under Directive 98/79/EC** concerning *in vitro* diagnostic medical devices. Values must be given in legal units conforming to the provisions of Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement.

26 This device **shall fall under Directive 98/79/EC** concerning *in vitro* diagnostic medical devices. In relation with devices containing dangerous preparations, relevant **danger symbols and labelling requirements or Directive 67/548/EEC** (repealed by Regulation (EC) No 1272/2008) shall apply.

27 This device **shall fall under Directive 98/79/EC** concerning *in vitro* diagnostic medical devices. It shall also be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine **and by any Member States regulations on this matter**. Values must be given in legal units conforming to the provisions of Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement.

28 This device **shall fall under Directive 98/79/EC** concerning *in vitro* diagnostic medical devices. Values must be given in legal units conforming to the provisions of Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement. In relation with devices containing dangerous preparations, relevant **danger symbols and labelling requirements or Directive 67/548/EEC** (repealed by Regulation (EC) No 1272/2008) shall apply.

29 This device **shall fall under Directive 98/79/EC** concerning *in vitro* diagnostic medical devices. It shall also be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine **and by any Member States regulations on this matter**. In relation with devices containing dangerous preparations, relevant **danger symbols and labelling requirements or Directive 67/548/EEC** (repealed by Regulation (EC) No 1272/2008) shall apply.

30 This device **shall fall under Directive 98/79/EC** concerning *in vitro* diagnostic medical devices. It shall also be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine **and by any Member States regulations on this matter**. Values must be given in legal units conforming to the provisions of Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement. In relation with devices containing dangerous preparations, relevant **danger symbols and labelling requirements or Directive 67/548/EEC** (repealed by Regulation (EC) No 1272/2008) shall apply.

31 This device **shall fall under Directive 98/79/EC** concerning *in vitro* diagnostic medical devices.

32 Given the personalized nature and the method of preparation, this kind of medicinal products are excluded from Directive 2001/83/EC on medicinal products for human use. Nevertheless, take a look at **Regulation (EC) No 726/2004** for the authorization and supervision of medicinal products for human and veterinary use.

33 This kind of medicinal products are not covered by Directive 2001/83/EC on medicinal products for human use. Therefore, take a look at **Regulation (EC) No 726/2004** for the authorization and supervision of medicinal products for human and veterinary use.

34 This device shall fall under **Directive 2001/20/EC** on the approximation of the laws, regulations and administrative provisions of the Member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

35 This kind of medicinal products are not covered by Directive 2001/83/EC on medicinal products for human use. Therefore, take a look at **Regulation (EC) No 726/2004** for the authorization and supervision of medicinal products for human and veterinary use.

36 This kind of medicinal products are not covered by Directive 2001/83/EC on medicinal products for human use. Therefore, take a look at **Directive 2013/59/EURATOM** laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

37 In this case, **Directive 2002/98/EC** setting standards of quality and safety for the collection, testing and processing, storage and distribution of human blood and blood components shall govern.

38 This kind of medicinal product shall be governed by **Regulation (EC) No 1394/2007** on any advanced therapy medicinal product.

39 In this case, **Directive 2001/83/EC** on medicinal products for human use shall apply.

40 As your device is a borderline device: check sections 1 and 2 of the following document.

41 As your device is a borderline device: check section 3 of the following document.

42 As your device is a borderline device: check section 4 of the following document.

43 As your device is a borderline device: check section 7 of the following document.

Annex 3: Medical Devices Classification in terms of Directive 93/42/EEC

This conceptual map leads to the classification of a medical device according to the Classification Rules set out in Annex IX of **Council Directive 93/42/EEC of 14 June 1993 concerning medical devices**.

In order to obtain a good classification, different implementing rules must be followed: rules concerning the Directive (which are explained in Annex IX Point 2 of MDD) and rules concerning the conceptual map format. The latest are:

- Results shown in green (Figure A3-1) mean that the classification is done and there is no need to proceed with the test.

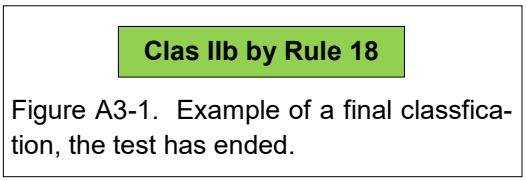


Figure A3-1. Example of a final classfication, the test has ended.

- Results shown in blue mean that although the given rule applies to the device (and a classification can be done), it does not mean that other rules apply (Figure A3-2). Therefore, when a blue class is obtained: the user must continue the test until no other question follows (Figure A3-3). Then, the user will need to decide, among all the mid-classifications, which is the final one by:
    - Choosing the classification of highest value (I < IIa < IIb < III) and its corresponding rule.
    - When several rules apply, leading to the same class, the strictest rule governed by the intended purpose of the device, shall be chosen.

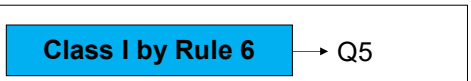


Figure A3-2. Example of a mid-classfication, but the test has **not** ended.

Figure A3-3. Example of a mid-classfication, but the test has ended.

ADVICE: *Please, make sure your answers are as accurate as possible; to do so, check the attached glossary for this specific task.*

GLOSSARY

According to duration: *(Defined according to Directive 93/42/EEC)*

- **Transient**: Normally intended for continuous use for less than 60 minutes.
- **Short term**: Normally intended for continuous use for not more than 30 days.
- **Long term**: Normally intended for continuous use for more than 30 days.

Accessory: article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device. *(Defined according to Directive 93/42/EEC)*

Active Device for Diagnosis: Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities. *(Defined according to Directive 93/42/EEC)*

Active Medical Device: Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand alone software is considered to be an active medical device. *(Defined according to Directive 93/42/EEC)*

Active therapeutical Device: Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap. *(Defined according to Directive 93/42/EEC)*

Body orifice: any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma. *(Defined according to Directive 93/42/EEC)*

Central Circulatory System: the following vessels: arteriae pulmonales, aorta ascendens, arcus aorta, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior. *(Defined according to Directive 93/42/EEC)*

Central nervous system: brain, meninges and spinal cord. *(Defined according to Directive 93/42/EEC)*

Intact skin: non-damaged skin. *(Defined according to Directive 93/42/EEC)*

Invasive Device: A device which, in whole or in part, penetrates the body, either through a body orifice or through the surface of the body. *(Defined according to Directive 93/42/EEC)*

***In vitro* Diagnostics Medical Device**: any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state, or a congenital abnormality or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures. Specimen receptacles are considered to be *in vitro* diagnostic medical devices. Products for general laboratory use are not *in vitro* diagnostic medical devices unless specifically intended by the manufacturer. *(Defined according to Directive 98/79/EC)*

Medical Device: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

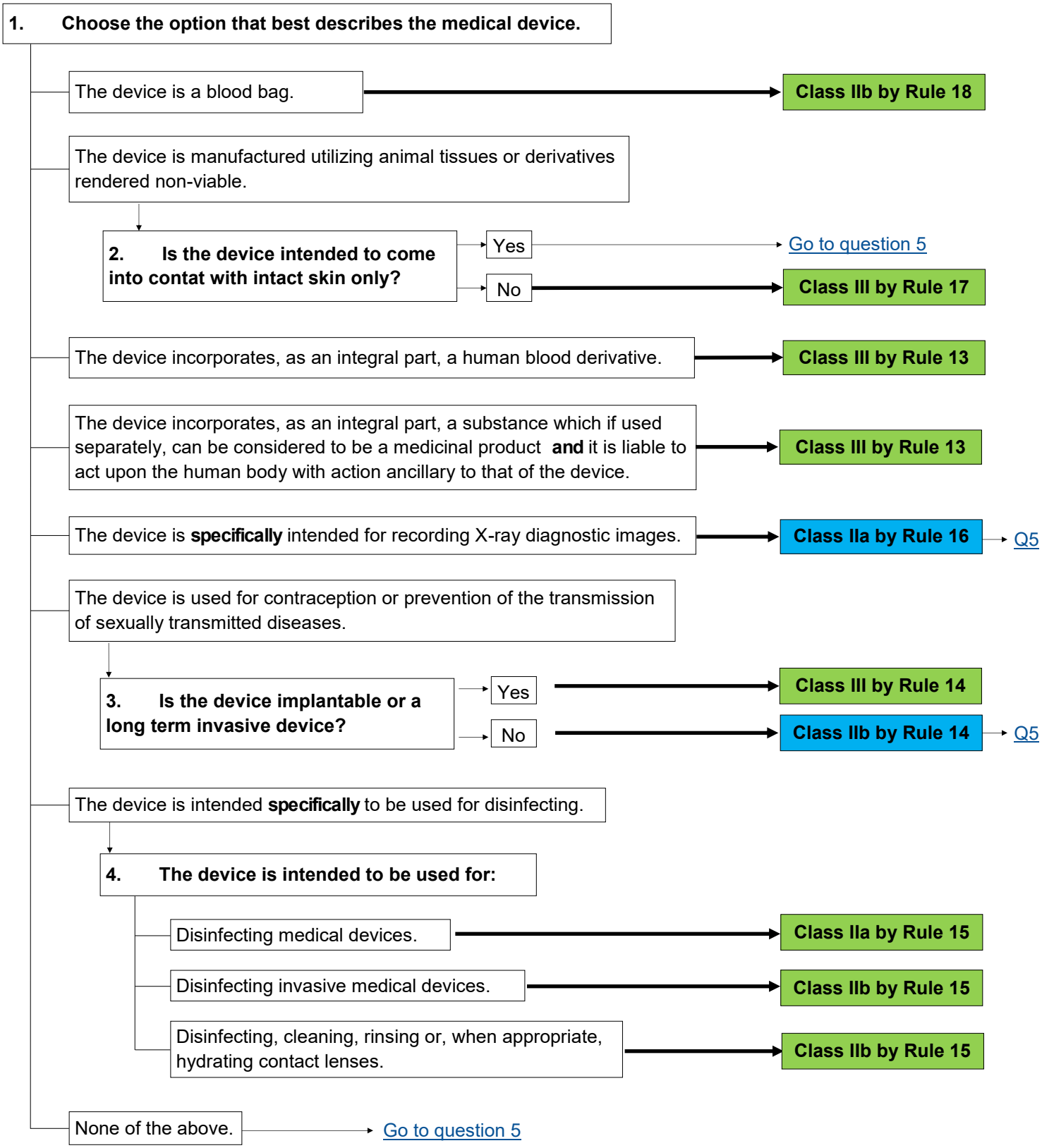
- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conceptions,

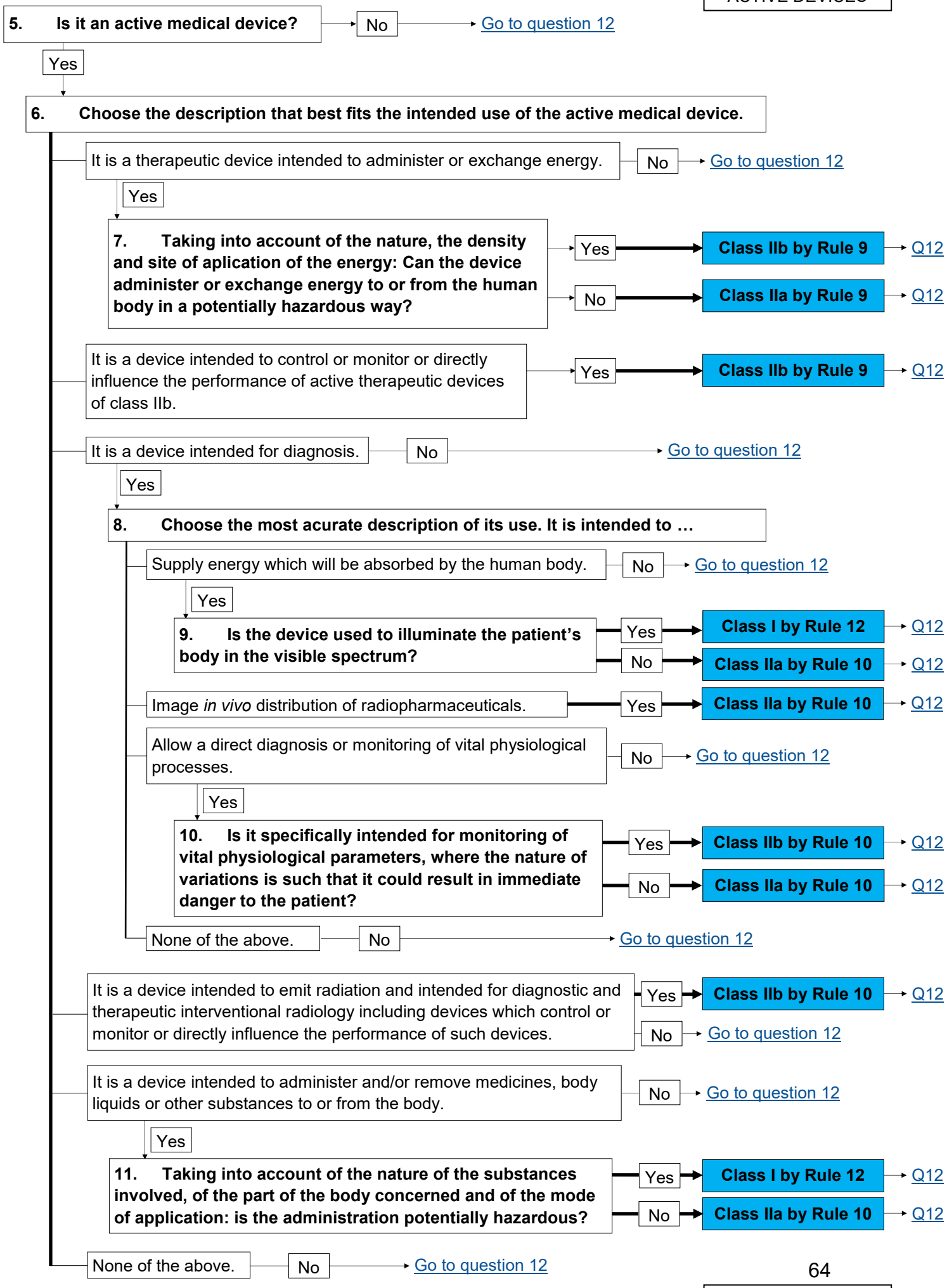
and which does not achieve its principal intended action in or on the human body by pharmaceutical, immunological or metabolic means, but which may be assisted in its function by such means. *(Defined according to Directive 93/42/ EEC)*

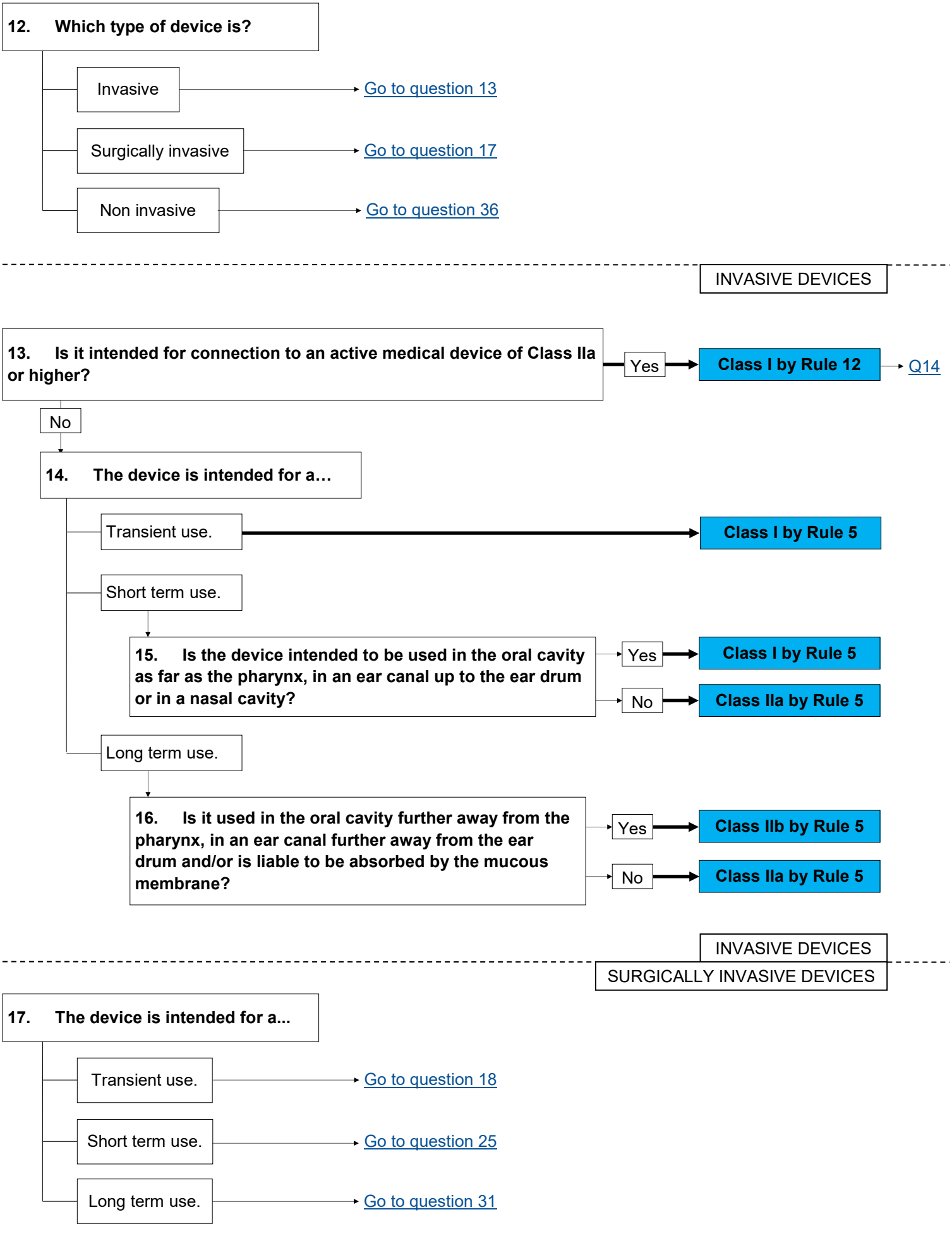
Medicinal Product: any substance or combination of substances presented as having properties for treating or preventing disease in human beings, or any substance or combination of subtances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. The substance can be of any matter irrespective of origin, which may be: human, animal, vegetable or chemical. *(Defined according to Directive 2001/83/EC)*

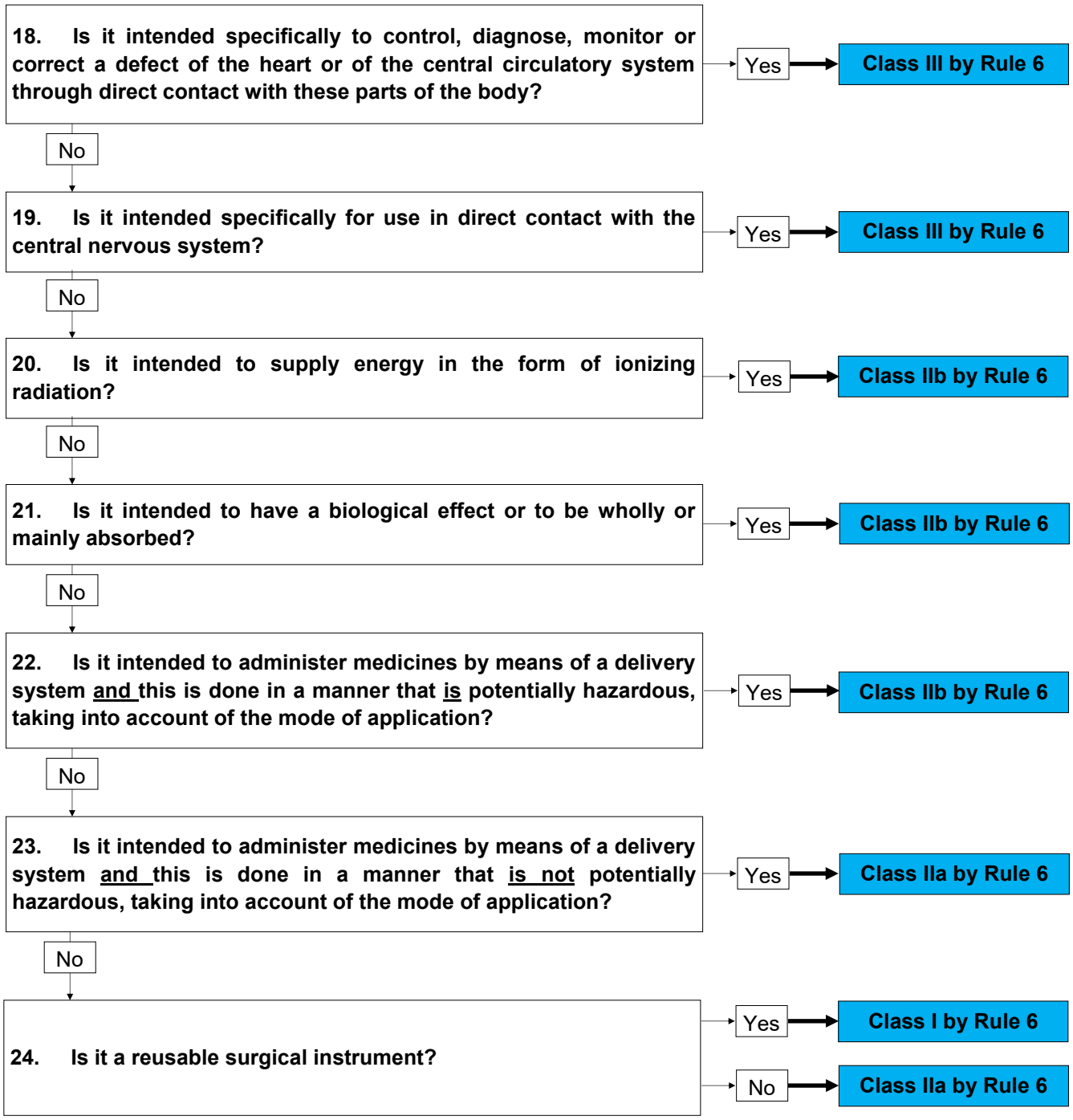
Reusable surgical instrument: Insturment intended for surgical use by cutting, drilling, sawing, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out. *(Defined according to Directive 93/42/EEC)*

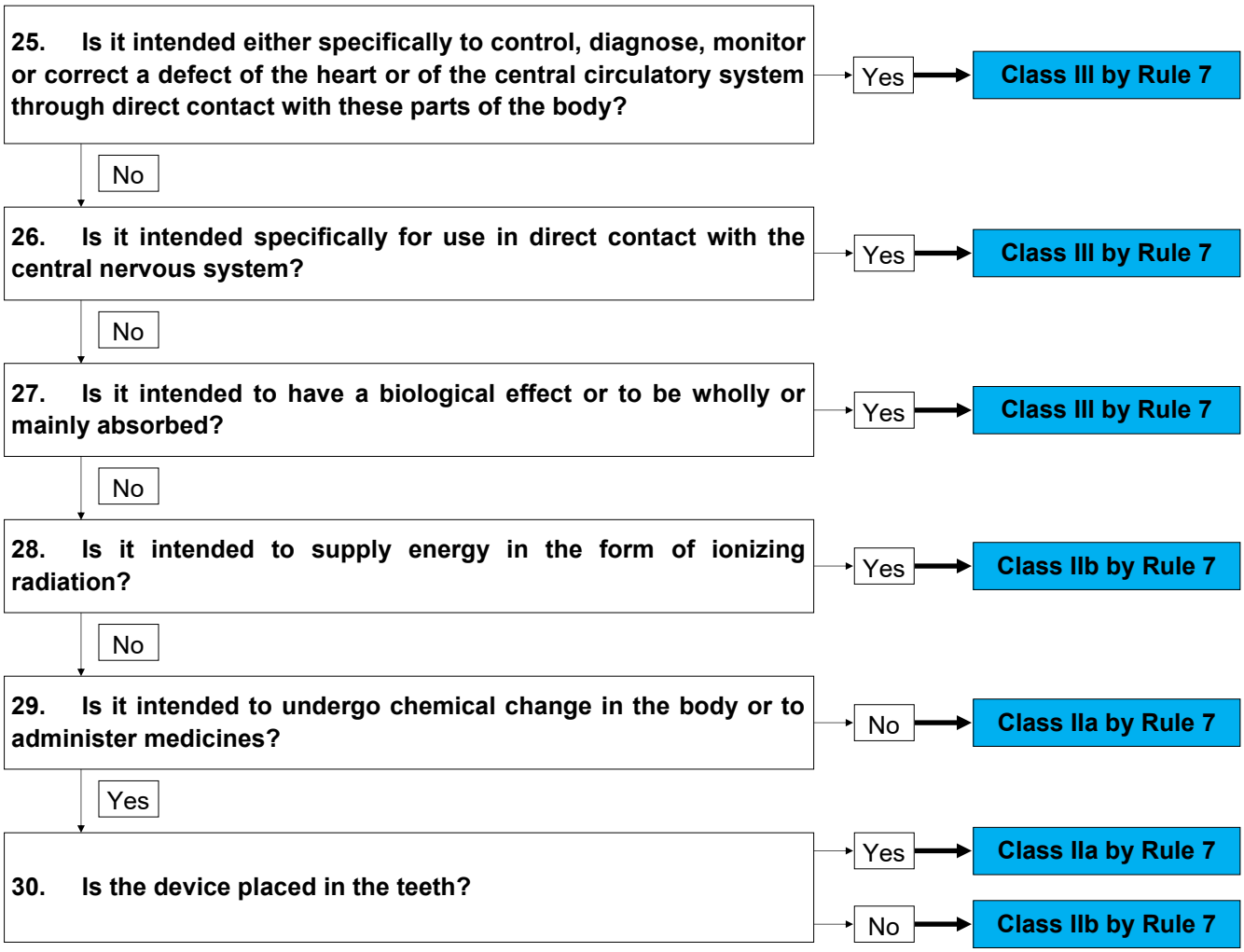
Surgically Invasive Device: An invasive device that penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation. Those that produce penetration other than through an established body orifice. *(Defined according to Directive 93/42/EEC)*

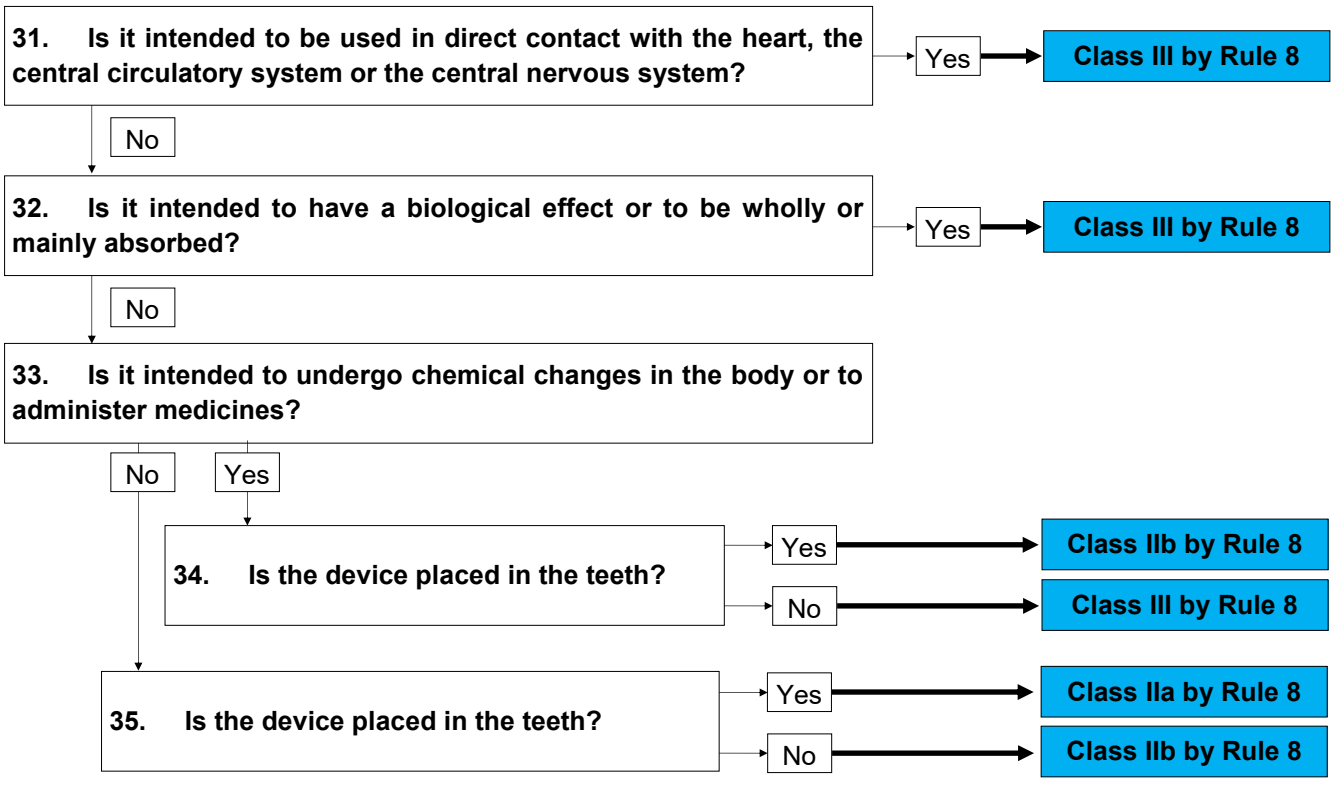

1. Choose the option that best describes the medical device.
The device is a blood bag.
Class IIb by Rule 18
The device is manufactured utilizing animal tissues or derivatives rendered non-viable.
2. Is the device intended to come into contat with intact skin only?
Yes
Go to question 5
No
Class III by Rule 17
The device incorporates, as an integral part, a human blood derivative.
Class III by Rule 13
The device incorporates, as an integral part, a substance which if used separately, can be considered to be a medicinal product and it is liable to act upon the human body with action ancillary to that of the device.
Class III by Rule 13
The device is specifically intended for recording X-ray diagnostic images.
Class IIa by Rule 16
Q5
The device is used for contraception or prevention of the transmission of sexually transmitted diseases.
3. Is the device implantable or a long term invasive device?
Yes
Class III by Rule 14
No
Class IIb by Rule 14
Q5
The device is intended specifically to be used for disinfecting.
4. The device is intended to be used for:
Disinfecting medical devices.
Class IIa by Rule 15
Disinfecting invasive medical devices.
Class IIb by Rule 15
Disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses.
Class IIb by Rule 15
None of the above.
Go to question 5

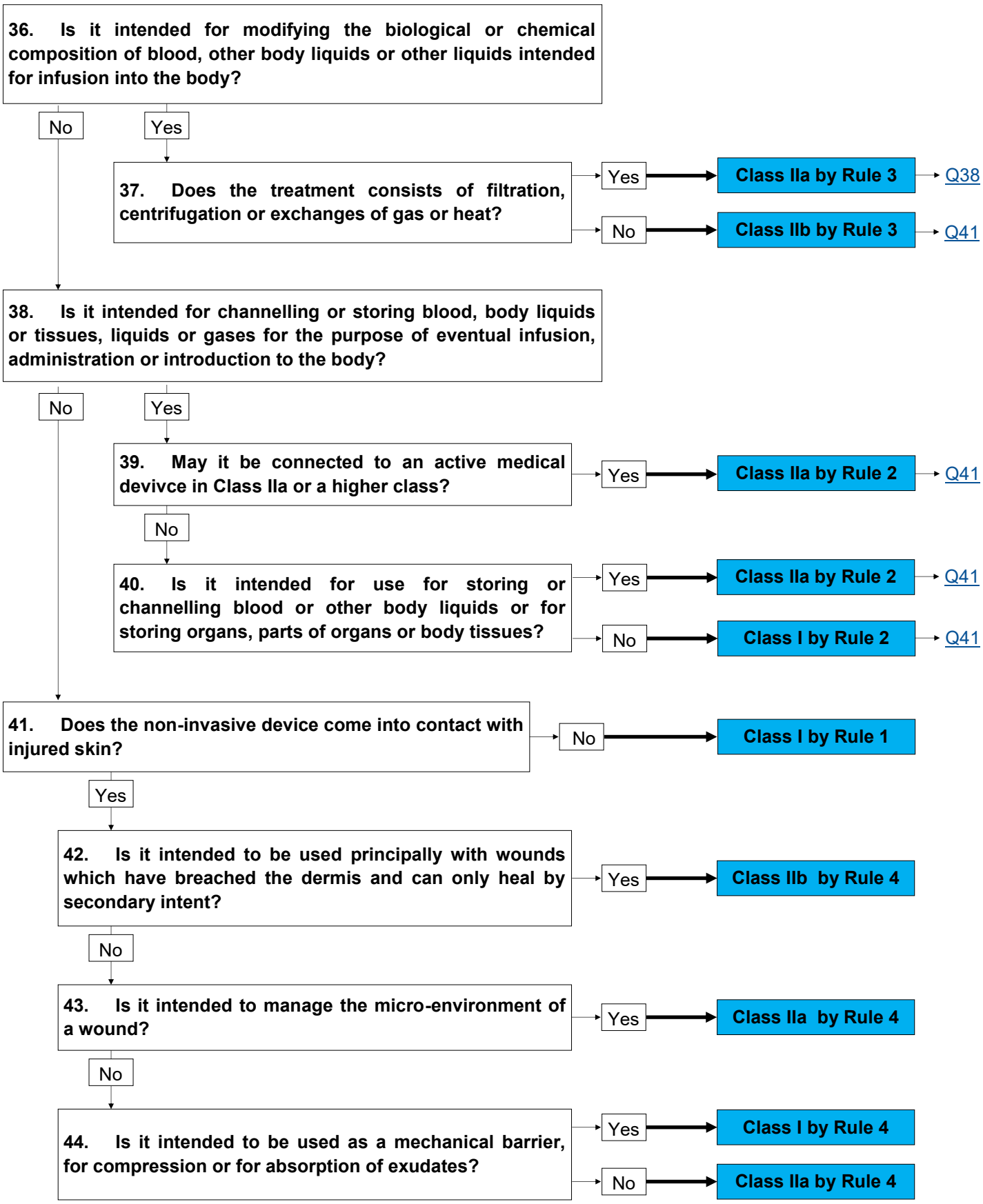

5. Is it an active medical device?
No
Go to question 12
Yes
6. Choose the description that best fits the intended use of the active medical device.
It is a therapeutic device intended to administer or exchange energy.
No
Go to question 12
Yes
7. Taking into account of the nature, the density and site of aplication of the energy: Can the device administer or exchange energy to or from the human body in a potentially hazardous way?
Yes
Class IIb by Rule 9
Q12
No
Class IIa by Rule 9
Q12
It is a device intended to control or monitor or directly influence the performance of active therapeutic devices of class IIb.
Yes
Class IIb by Rule 9
Q12
It is a device intended for diagnosis.
No
Go to question 12
Yes
8. Choose the most acurate description of its use. It is intended to …
Supply energy which will be absorbed by the human body.
No
Go to question 12
Yes
9. Is the device used to illuminate the patient's body in the visible spectrum?
Yes
Class I by Rule 12
Q12
No
Class IIa by Rule 10
Q12
Image *in vivo* distribution of radiopharmaceuticals.
Yes
Class IIa by Rule 10
Q12
Allow a direct diagnosis or monitoring of vital physiological processes.
No
Go to question 12
Yes
10. Is it specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient?
Yes
Class IIb by Rule 10
Q12
No
Class IIa by Rule 10
Q12
None of the above.
No
Go to question 12
It is a device intended to emit radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor or directly influence the performance of such devices.
Yes
Class IIb by Rule 10
Q12
No
Go to question 12
It is a device intended to administer and/or remove medicines, body liquids or other substances to or from the body.
No
Go to question 12
Yes
11. Taking into account of the nature of the substances involved, of the part of the body concerned and of the mode of application: is the administration potentially hazardous?
Yes
Class I by Rule 12
Q12
No
Class IIa by Rule 10
Q12
None of the above.
No
Go to question 12


12. Which type of device is?
Invasive
Go to question 13
Surgically invasive
Go to question 17
Non invasive
Go to question 36
INVASIVE DEVICES
13. Is it intended for connection to an active medical device of Class IIa or higher?
Yes
Class I by Rule 12
Q14
No
14. The device is intended for a…
Transient use.
Class I by Rule 5
Short term use.
15. Is the device intended to be used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity?
Yes
Class I by Rule 5
No
Class IIa by Rule 5
Long term use.
16. Is it used in the oral cavity further away from the pharynx, in an ear canal further away from the ear drum and/or is liable to be absorbed by the mucous membrane?
Yes
Class IIb by Rule 5
No
Class IIa by Rule 5
INVASIVE DEVICES
SURGICALLY INVASIVE DEVICES
17. The device is intended for a...
Transient use.
Go to question 18
Short term use.
Go to question 25
Long term use.
Go to question 31


18. Is it intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body?
Yes
Class III by Rule 6
No
19. Is it intended specifically for use in direct contact with the central nervous system?
Yes
Class III by Rule 6
No
20. Is it intended to supply energy in the form of ionizing radiation?
Yes
Class IIb by Rule 6
No
21. Is it intended to have a biological effect or to be wholly or mainly absorbed?
Yes
Class IIb by Rule 6
No
22. Is it intended to administer medicines by means of a delivery system and this is done in a manner that is potentially hazardous, taking into account of the mode of application?
Yes
Class IIb by Rule 6
No
23. Is it intended to administer medicines by means of a delivery system and this is done in a manner that is not potentially hazardous, taking into account of the mode of application?
Yes
Class IIa by Rule 6
No
24. Is it a reusable surgical instrument?
Yes
Class I by Rule 6
No
Class IIa by Rule 6


25. Is it intended either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body?
Yes
Class III by Rule 7
No
26. Is it intended specifically for use in direct contact with the central nervous system?
Yes
Class III by Rule 7
No
27. Is it intended to have a biological effect or to be wholly or mainly absorbed?
Yes
Class III by Rule 7
No
28. Is it intended to supply energy in the form of ionizing radiation?
Yes
Class IIb by Rule 7
No
29. Is it intended to undergo chemical change in the body or to administer medicines?
No
Class IIa by Rule 7
Yes
30. Is the device placed in the teeth?
Yes
Class IIa by Rule 7
No
Class IIb by Rule 7


31. Is it intended to be used in direct contact with the heart, the central circulatory system or the central nervous system?
Yes
Class III by Rule 8
No
32. Is it intended to have a biological effect or to be wholly or mainly absorbed?
Yes
Class III by Rule 8
No
33. Is it intended to undergo chemical changes in the body or to administer medicines?
No
Yes
34. Is the device placed in the teeth?
Yes
Class IIb by Rule 8
No
Class III by Rule 8
35. Is the device placed in the teeth?
Yes
Class IIa by Rule 8
No
Class IIb by Rule 8


36. Is it intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body?
No
Yes
37. Does the treatment consists of filtration, centrifugation or exchanges of gas or heat?
Yes
Class IIa by Rule 3
Q38
No
Class IIb by Rule 3
Q41
38. Is it intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction to the body?
No
Yes
39. May it be connected to an active medical devivce in Class IIa or a higher class?
Yes
Class IIa by Rule 2
Q41
No
40. Is it intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues?
Yes
Class IIa by Rule 2
Q41
No
Class I by Rule 2
Q41
41. Does the non-invasive device come into contact with injured skin?
No
Class I by Rule 1
Yes
42. Is it intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent?
Yes
Class IIb by Rule 4
No
43. Is it intended to manage the micro-environment of a wound?
Yes
Class IIa by Rule 4
No
44. Is it intended to be used as a mechanical barrier, for compression or for absorption of exudates?
Yes
Class I by Rule 4
No
Class IIa by Rule 4

Annex 4: Medical Devices CODES list

Codes and its description for all types of Medical Devices (according to MD 93/42/EEC) and Active Implantable Medical Devices (according to 90/385/EEC).

CODE	MD SCOPE EXPRESSIONS, NON-ACTIVE MEDICAL DEVICES (Non-active Medical Devices, 93/42/EEC)
MD 0100 General non-active, non-implantable medical devices	
MD 0101	Non-active devices for anaesthesia, emergency and intensive care
MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
MD 0103	Non-active orthopaedic and rehabilitation devices
MD 0104	Non-active medical devices with measuring function
MD 0105	Non-active ophthalmologic devices
MD 0106	Non-active instruments
MD 0107	Contraceptive medical devices
MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
MD 0109	Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
MD 0200 Non-active implants	
MD 0201	Non-active cardiovascular implants
MD 0202	Non-active orthopaedic implants
MD 0203	Non-active functional implants
MD 0204	Non-active soft tissue implants
MD 0300 Devices for wound care	
MD 0301	Bandages and wound dressings
MD 0302	Suture material and clamps
MD 0303	Other medical devices for wound care
MD 0400 Non-active dental devices and accessories	
MD 0401	Non-active dental equipment and instruments
MD 0402	Dental materials
MD 0403	Dental implants

CODE	MD SCOPE EXPRESSIONS, ACTIVE (NON-IMPLANTABLE) (Active Medical Devices, 93/42/EEC)
MD 1100 General active medical devices	
MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
MD 1102	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
MD 1103	Devices for stimulation or inhibition
MD 1104	Active surgical devices
MD 1105	Active ophthalmologic devices
MD 1106	Active dental devices
MD 1107	Active devices for disinfection and sterilisation
MD 1108	Active rehabilitation devices and active prostheses
MD 1109	Active devices for patient positioning and transport
MD 1110	Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
MD 1111	Software
MD 1112	Medical gas supply systems and parts thereof
MD 1200 Devices for imaging	
MD 1201	Imaging devices utilizing ionizing radiation
MD 1202	Imaging devices utilising non-ionizing radiation
MD 1300 Monitoring devices	
MD 1301	Monitoring devices of non-vital physiological parameters
MD 1302	Monitoring devices of vital physiological parameters
MD 1400 Devices for radiation therapy and thermo therapy	
MD 1401	Devices utilising ionizing radiation
MD 1402	Devices utilising non-ionizing radiation
MD 1403	Devices for hyperthermia / hypothermia
MD 1404	Devices for (extracorporal) shock-wave therapy (lithotripsy)

Table A4- 1. List of codes for Medical Devices. MD: Medical Device

CODE	AIMD SCOPE EXPRESSIONS (Active Implantable Medical Devices, 90/385/EEC)
AIMD 0100 General active implantable medical devices	
AIMD 0101	Active implantable medical devices for stimulation/inhibition
AIMD 0102	Active implantable medical devices delivering drugs or other substances
AIMD 0103	Active implantable medical devices substituting or replacing organ functions

Table A4- 2. List of codes for Active Implantable Medical Devices AIMD: Active Implantable Medical Devices

Others

CODE	MD AND AIMD SCOPE EXPRESSIONS, ADDITIONS (Specifics of MD 93/42/EEC and AIMD 90/385/EEC)
MDS 7000 MD /AIMD Specifics	
MDS 7001	Medical Devices incorporating medicinal substances, according to Directive 2001/83/EC
MDS 7002	Medical devices utilizing tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)
MDS 7003	Medical devices incorporating derivatives of human blood according to Directive 2000/70/EC
MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
MDS 7006	Medical Devices in sterile condition
MDS 7007	Medical devices utilizing micromechanics
MDS 7008	Medical devices utilizing nanomaterials
MDS 7009	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed
MDS 7010	Medical devices incorporating software /utilizing software / controlled by software

Table A4- 3. List of codes for both Medical Devices and Active Implantable Medical Devices.

Annex 5: How to perform a Risk Analysis - GUIDE

Risk management is necessary to ensure device usability, safety and regulatory compliance. A **risk analysis** is the assessment of the estimated risks related to a well-defined product or situation and a recognized potential source of harm known as **hazard**. Risk analysis is required to obtain the CE marking, it ensures safety of the device, it eliminates costs associated with recalls and, of course, it demonstrates that the manufacturer is providing safe devices.

> A risk is considered to be the probability of occurrence of harm and the severity of that harm.

Risk management involves: identifying, understanding, controlling and preventing failures that can result in hazards when a device is used. Manufacturers are expected to identify those risks (in both normal and fault conditions), evaluate the risks (estimating a measure risk) and take the corresponding measures in order to eliminate them or reduce it as much as possible. Figure A5-1 shows the overall process.[27]

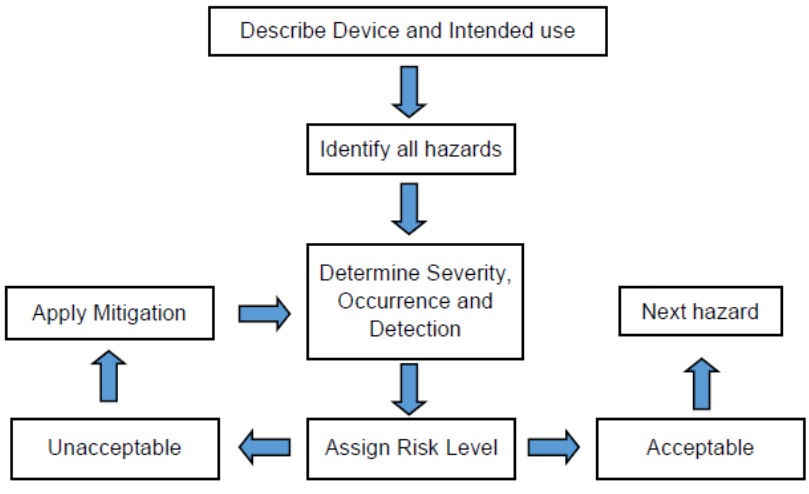


Figure A5-1. Overall Risk Analysis Process

[27] Basic Principles of Risk Management for Medical Device Design - Wipro

Define the Intended Use of the Device

First of all, the **intended use** of the device needs to be stated, Annex C and H of ISO 14791:2012 are useful at this point. This statement helps define the scope and will be instrumental as the user identifies hazards, harms, etc.

Think about your device and answer the following questions: What will it be used for? In which way must be used? When must be used? How must use it?

Identify all hazards

Identifying all hazards is not an easy thing; you need to take into account risks from the product being correctly used and as intended, and also risks from foreseeable misuse. Annex E and H (IVD) of the same ISO are of great use.

Now think about everything that could possibly go wrong. What could happen if the user does not read the instructions for use? Or they are written in a language unknown to the user? What happens if it is used after the expiration date? What happens if the device is used more times that intended? What could happen if it comes into contact with water? What could possibly happen if the user misunderstands the units of measurement?

Some examples of risks are:

- Energy (ionizing radiation, heat, …)
- Biological (biocompatibility, toxicity, …)
- Viruses or bacteria (wrong sterilization, …)
- Environmental (pollution, …)
- Functional failure
- Manufacturing process (traceability, devices out of calibration, …)
- Inappropriate user interface (errors, …)
- Maintenance and aging (improper maintenance, reuse, …)

Estimation of the risk

It is necessary to identify all the possible harms for each hazardous situation. As said, Risk is defined in ISO 14791 as the combination of the probability of occurrence of harm and the severity of that harm. Therefore it requires identifying: severity and probability of occurrence. To do so, first it is necessary to define descriptions for various **levels of both severity and probability**. A common technique is:[28]

SEVERITY (S)		
Rating	Severity	Criteria
5	Catastrophic	Likely to result in death.
4	Critical	Potential for severe injury.
3	Moderate	Potential for moderate injury.
2	Minor	Potential for minor injury.
1	Negligible	No significant risk of injury.

Table A5- 1. Qualitative Severity Scaling

FREQUENCY OF OCCURRENCE (O)		
Rating	Probability	Criteria
5	Frequent	Hazard expected to occur frequently.
4	Probable	Hazard will be experienced several times in the life of a product.
3	Occasional	Some manifestations of the hazard are likely to occur.
2	Remote	Manifestations of the hazard are possible but not likely.
1	Improbable	So unlikely, it can be assumed occurrence may not be experienced.

Table A5- 2. Qualitative Probability Scaling.

Some methods also take into account **detection**. Detection is a significant measure to consider as it alters the probability of the harm actually occurring (assuming the detection is effectively acted on).

[28] Risk Analysis: Beyond Probability and Severity – Medical Device And Diagnostic Industry.

DETECTION (D)	
Rating	Probability
6	There is no possible detection of the failure.
5	The failure may only be detected with further testing.
4	The failure is difficult to detect.
3	Failure is easily detected with someone of experience.
2	Failure is clearly visible and would be detected with some attention to detail.
1	Failure is obvious and always detected.

Table A5- 3. Qualitative Detection Scaling.

Assign risk level

Now that the risk criteria has been defined, the next step is to estimate the risk of each hazard. Which means: rate each hazard according to severity (S), occurrence (O) and detection (D) and obtain a **risk priority number (RPN)** by multiplying the three scores.

$$RPN = S \times O \times D$$

With the variables a risk space is created (it can be created with 2 or 3 variables, obtaining a two-dimensional or a three-dimensional matrix respectively). It must be said that if it is of two variables this have to be: Severity and Occurrence; the risk level is here called Criticality. This risk space indicates three regions, which classify the risk in order to know if changes must be applied. The regions are:

- Generally acceptable (GA)
- Generally unacceptable (GU)
- As low as reasonably practicable (ALARP)

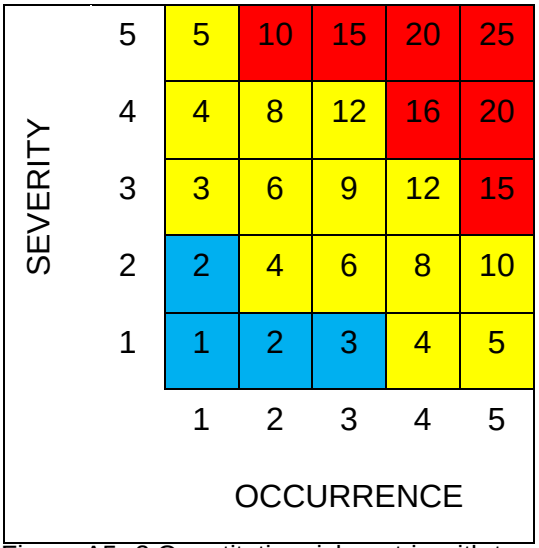


Figure A5- 2.Quantitative risk matrix with two variables. Criticality value in each case (obtained by Criticality=SxO). In blue the low-risk zone (generally accepted), in yellow the ALARP region, and in red the high-risk zone (generally unaccepted).

Risk Controls / Mitigation

In the past, the ALARP zone was accepted, but currently a risk reduced ‘as low as reasonable possible’ is not acceptable: risks have to be reduced to the maximum. If a risk is not reduced to the maximum possible level, the Notified Body can consider it as a ‘no conformity’, which means that the device does not comply with the European regulation and the CE marking will not be obtained before fixing the no conformity.

Therefore, risks situated in both the GU and the ALARP zone are considered unacceptable and need to be mitigated. How are risks mitigated? Risk controls are about reducing identified risks to acceptable levels. It is possible to reduce the severity of an identified harm with Risk Control, but it mainly impacts on the probability of occurrence of a harm.

Risk controls should be decided according to the following priority: 1) Inherent safety by design, 2) Protective measures in the device and/or manufacturing process and, lastly, 3) Adding information for safety, such as instructions for use and labeling.

Risk Controls may include: Design Controls, Design Outputs, Design Verifications and/or Design Validations.

The procedure is: to identify the necessary risk controls and implement them. Then the manufacturer needs to keep record the changes that had been made (in order to implement them) and determine the effectiveness of the new measures.

Residual Risk Evaluation

The last step is to re-evaluate the risks using the same criteria as the first time. This is done to see if the risk level for each hazard has been reduced to the maximum limit (or if not, they have been reduced as far as possible, according to EN ISO 14971:2012).

Overall Residual Risk Acceptability

Previously, individual risks have been identified. In this step, an overall risk is assessed taking into account the whole entirety of the device. The risk level and criteria has to be the same throughout the entire process.

Two possible results arise:

- The overall residual risk is acceptable: document the decision and support it.
- The overall residual risk is unacceptable: conduct a risk/benefit analysis.

Risk Benefit Analysis (RBA)

Do the medical benefits of the device outweigh the residual risk?

Production and Post-Production Information.

As all risks have been considered throughout the whole lifecycle of the device, the Risk Management is also constant. Therefore, the Risk Management File needs to be continuously updated with data obtained from post-production information.

The manufacturer needs to ensure that all production and post-production information is fed again into the risk analysis.[29]

[29] The definitive Guide to ISO 14971 Risk Management for Medical Devices. Written by Joan Speer, greenlight.guru

Annex 6: Risk Management File - TEMPLATE

RISK MANAGEMENT FILE

Name	Insert name of the product.
Model	Insert model of the device.
Type of device	Insert class of Medical Device.
Company	Insert name of the company.
Direction	Direction of the company.
Year of Creation	Year of creation of the Risk File.

APPROVAL

The signatures below certify that this risk management file has been reviewed and accepted, and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision.

	Name	Signature	Position	Date
Prepared by				
Reviewed by				
Approved by				

REVISION HISTORIAL

This risk management file is reviewed to ensure its continuing relevance to the systems and process that it describes. All the revisions are stated below:

Rev	Description of changes	Reviewed by		Approved by	
		Date	Signature	Date	Signature
A	*Initial Release*				

COMPANY PROPRIETARY INFORMATION

The electronic version of this document is the latest version. It is responsibility of the individual to ensure that any paper material is the current revision. The printed version of this file is uncontrolled, except when provided with a document reference number and a revision in the field below:

Document Ref: _____ Rev: _____

Uncontrolled copy ☐ Controlled Copy ☐ Date: _____

1. PURPOSE

Name of the company has created a Risk Management File to define the Risk Management Plan protocol which are the activities planned during the product development process for Insert product(s) name(s).

2. SCOPE

The scope of the risk management plan relates to the activities and documentation pertaining to the product risks. The scope of risk management is limited to insert product(s), its interface with other products and components, and use during list type of use procedures.

3. RESPONSIBILITY

RA/QA	• Establishing and maintaining risk management documentation
Project Team	• Participating in risk management activities
Project Manager	• Assuring that all risks are identified, documented and mitigated to an acceptable level. • Obtaining Executive Management approval for risk management activities. • Maintaining the Risk Management File (RMF)
Executive Manager	• Approval of Risk Management Plan

Table 1. Responsibilities according to RMF by Position

4. DEVICE DESCRIPTION

Describe the product (brief background). Include the **intended use** and describe how the device is used. Describe the overview of the procedure. Define who has to use the device. Describe the duration of use. Include information of foreseeable misuse, any defined limits and characteristic that could impact safety.

5. Risk Management Plan

The risk management activities coincide with the product development and design control process.

Project Phase	Risk Management Deliverables
Planning	• Risk Management Plan
Design and Development	• System Risk Analysis (hazard identification) • System Risk Evaluation • Risk Assessment (product and process)
Design Verification	• Risk Control • Residual Rick Acceptance
Design Validation	• Risk Management Report
Market Release	• Product and Post-Production Risk Management • Revised Risk Management Report

Table 2. Risk Management Deliverables by Project Phase

Risk management deliverables are reviewed and approved during design reviews for each project phase. EN ISO 14971:2012 shall be used for instructions and as guidelines during risk management documentation.

Risk is defined as the combination of severity of harm and the occurrence of that harm. In order to estimate risks of hazardous situations relating to insert product family, severity of harm, probability of occurrence and detection of harm are described in the tables below.

Rating	Severity	Criteria
5	Catastrophic	Likely to result in death.
4	Critical	Potential for severe injury.
3	Moderate	Potential for moderate injury.
2	Minor	Potential for minor injury.
1	Negligible	No significant risk of injury.

Table 3. Qualitative Severity Scaling.

Rating	Probability	Criteria
5	Frequent	Hazard expected to occur frequently.
4	Probable	Hazard will be experienced several times in the life of a product.
3	Occasional	Some manifestations of the hazard are likely to occur.
2	Remote	Manifestations of the hazard are possible but not likely.
1	Improbable	So unlikely, it can be assumed occurrence may not be experienced.

Table 4. Qualitative Probability Scaling (also known as Frequency of Occurrence)

Rating	Probability
6	There is no possible detection of the failure.
5	The failure may only be detected with further testing.
4	The failure is difficult to detect.
3	Failure is easily detected with someone of experience.
2	Failure is clearly visible and would be detected with some attention to detail.
1	Failure is obvious and always detected.

Table 5. Qualitative Detection Scaling

Risk Level is determined based on the Risk Priority Number. In this case, RPN values can go from 1 (lower-level risk) to 150 (highest-level risk). Risks for product name are identified as Low, Medium and High:

- Risk levels between 1 and highest value for the low-risk range are in the low-risk range and, therefore are generally accepted.
- Risk levels between lowest and highest values for medium-risk range are in the medium-risk range, also known as low reasonably practicable (ALARP). Risks may be mitigated but it is not strictly necessary.
- Risk levels higher than value are in the high-risk range, are unacceptable and require risk reduction by risk control.

6. Risk Response Planning

Each major risk (medium and high risks) will be assigned to a project team member for monitoring purposes to implement any of the following approaches:

- Avoid – eliminate the threat by eliminating the cause.
- Mitigate – identify ways to reduce the probability or the impact of the risk.
- Accept – Nothing will be done
- Transfer – Make another party responsible for the risk (buy insurance, etc.)

For each risk that will be mitigated, the project team will identify ways to prevent the risk from occurring or reduce its impact or probability of occurring. For each mitigated or accepted risk, a course of action will be outlined for the event that the risk does materialize in order to minimize its impact.

7. PRODUCTION AND POST-PRODUCTION INFORMATION

The level of risk on a project will be tracked, monitored and reported throughout the project lifecycle.

A list will be maintained by the project team and will be reported as a component of the project status reporting process for this project. All project change requests will be analyzed for their possible impact to the project risks. Management will be notified of important changes to risk status as a component to the Executive Project Status Report.

8. RISK ANALYSIS

#	Identification of Known or Foreseeable Risks			Estimation of Risk - BEFORE					AFTER Mitigation				
	Source	**Potential Hazard**	**Potential Cause**	**Effect of failure**	**S1**	**O1**	**C1**	**RPN**	**Preventing Measures**	**S2**	**O2**	**D2**	**RPN**
1	IFU.	The device is used after is use by date.	User unaware of the use by date of the device.	Does not perform as exected.	3	3	2	18	Add bigger label with use by date in each individual device.	3	2	1	6
2													
…													

Annex 7: Technical File - GUIDE

The manufacturer needs to prepare the technical file prior to affixing the CE mark. The manufacturer or its authorized representative must make this documentation. And most importantly, needs to keep the document up-to-date and demonstrate how is maintained.

All technical documentation can be maintained in any EU language (being English and French the most used). Other information such as instructions for use, labels, user manuals, may be strictly required (by directives or European national laws) to be written in all the official languages where a device is sold. Although there is the possibility that, if the technical file needs to be read by an entity with another official language, the whole file (or just parts of it) have to be translated.

According to the Blue Guide, the TF must be kept for at least **10 years** from the last date of manufacturing, in some cases, directives may provide a later day. Talking about Medical Devices, MDD states that the documentation of implantable devices must be kept for at least **15 years** from the last date of manufacturing.

A copy must be kept in either hard or electronic format (or both) and must be made available to the EU Competent Authorities. Manufacturers based outside the EEA must make the copy available at the address of their Authorized Representative.

What to include in the Technical File

The technical documentation holds information about the medical device. When appropriate, the use of photograms and diagrams is recommended. There are no clear rules on a **TF for medical devices**, but below there are guides to support the manufacturer.

- **Administrative information:** Manufacturer name and address, EU Representative and subcontractors, file date and issue number,

directive(s) that apply, device identification and classification and accessories.

- **Technical documentation**
    - **Device description**: Describe the design, packaging and sterilization among other characteristics. Pictures and schematics should be provided.
    - **Intended use**: Describe the condition intended to treat or monitor, its installation, preparation for use, pre-use checks and maintenance, calibration and servicing as appropriate to the particular medical devices involved).
    - **Market history, sales, complaints and vigilance:** For an already existing device: add a market history, sales complaints and vigilance data for the last 5 years (include sales outside EU). If the device is new please state it.
    - **Draft Declaration of Conformity**. See section 2.8 and Annex 9.
    - **Technical standards**: Documentation should demonstrate that standards have been considered. List of applicable standards.
    - **Essential requirements**: Provide Essential Requirement Checklist (ERC) to show how compliance has been achieved.
    - **Manufacturing process and subcontractors**: Detailed overview of the manufacturing processes. Identify any subcontracted processes.
    - **User information**: Labels, instructions for use (IFU), patient implant cards, surgical manuals, brochures, etc. Provide drawings of the packaging configuration. (Read Point 13 in Annex I to MDD.) Instructions of use are not needed for devices in Class I or IIa if they can be used safely without any instructions. Read Point 13.6 of Annex I to MDD to know what to include in the instructions for use. Labels must bear a following set of particular things. Please carefully read Point 13.3 of Annex I of the MDD. Information may take the form of symbols.

- **Design verification and validation**: Product design specifications: outline key functional characteristics and technical performance specifications. Test reports
- **Risk Management**. Conduct a Risk Management assessment for the entire life-cycle of the device. Indicate controls, criteria for the risk analysis and risk acceptability. See Annexes 5 and 6.
- **Clinical Evaluation**: For devices with suitable equivalents: literature can be provided. For devices without suitable equivalents or insufficient data in the literature, a pre-market clinical investigation is required. See Annex X of directive 93/42/EEC.
- **PMS and PMCF**: Post-Marketing Surveillance Plan (PMS Plan) with the product risk, lifetime and available clinical data. Also add a Post-Market Clinical Plan Follow-up (PMCF).
- **Biological safety**: In accordance with ISO 10993-1 (see Clause 7 of the mentioned standard). Specific document types include: **sterilization validation**, **shelf life validation**, **radiation validation**. For those, some of the required documentation is: protocol, testing method, test report. **End user sterilization product documentation** is also necessary. Explain how the user must sterilize it (conditions and parameters).
- **Packaging**: Packaging testing in accordance with relevant standards.
- **Shelf life and stability testing**: accelerated age testing results. Plan for a real time testing.
- **Product lifetime.** Define lifetime of the product taking into account: risk management, clinical evaluation, PMS…
- **Medicinal substances/human blood derivative and recombinant protein/peptides**: Clearly indicate or not if the device contains any medicinal substances and/or blood derivatives and/or recombinant peptides/proteins. Provide full justification and evidence that the components are ancillary.

- **Animal derived substances**: clearly indicate if the devices is used in, utilizes or incorporates any materials of animal origin.
- **Software**: Add a rationale for why the software is a medical device and for its classification. Documentation on medical device software life-cycle processes implemented.

Take into account that the more specific the documents supporting compliance are, the faster the review by the Notified Body can be conducted.

Structure of the Technical File

It is proposed that the technical documentation is divided into two parts, as it enables a more effective management of the file.

- **Part A:** Summary of the essential technical data relevant to the conformity assessment procedure.
  - Name and address of the manufacturer and the Authorized Representative (if applies).
  - Identification of the device(s): include trade or proprietary name (if applicable), common or usual name(s), device classification and rule(s) assigned by the manufacturer in accordance with Annex IX.
  - Name and address of the facility(es): include all facilities involved in the design and manufacture of the particular device(s)
  - Name and address of any Notified Body involved
  - A statement of the conformity assessment procedure being followed
  - The declaration of conformity: with the essential requirements.
  - Brief description of the device: intended purpose, and indications for use. Add list of accessories (if applies).
  - Label and Instructions for use.
  - Statement of relevant regulations.
  - Identification of technical standards with which compliance is claimed.
  - Brief statement of the testing performed and clinical data obtained.

- **Part B**: remaining technical documentation as detailed as in the previous part.
    - Risk analysis
    - Test reports
    - Quality manual
    - Plans, descriptions of the product and processes
    - Standards applied

Annex 8: Technical File - TEMPLATE

TECHNICAL FILE

Name of the Device

Name	Insert name of the product.
Model	Insert model of the device.
Type of device	Insert class of Medical Device.
Company	Insert name of the company.
Direction	Direction of the company.
Year of Creation	Year of creation of the Risk File.

APPROVAL

The signatures below certify that this technical file has been reviewed and accepted, and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision.

	Name	Signature	Position	Date
Prepared by				
Reviewed by				
Approved by				

REVISION HISTORIAL

This technical file is reviewed to ensure its continuing relevance to the systems and process that it describes. All the revisions are stated below:

Rev	Description of changes	Reviewed by		Approved by	
		Date	Signature	Date	Signature
A	*Initial Release*				

COMPANY PROPRIETARY INFORMATION

The electronic version of this document is the latest version. It is responsibility of the individual to ensure that any paper material is the current revision. The printed version of this file is uncontrolled, except when provided with a document reference number and a revision in the field below:

Document Ref: _____ Rev: _____

Uncontrolled copy ☐ Controlled Copy ☐ Date: _____

0. INTRODUCTION

Name of the Company has created a technical file for its new medical device Name of the medical device, it provides information on the design, manufacture and operation of the product. This device fulfils the requirements in Council Directive 93/42/CEE concerning medical devices. If any other directive applies, state it.

1. ADMINISTRATIVE INFORMATION

Manufacturer's name, address, phone number, email address, website.

If applicable, European Authorized Representative name, address, phone number, email address. .

Subcontractors information.

2. PRODUCT DESCRIPTION

2.1. GENERAL DESCRIPTION OF THE DEVICE(S)

Brief description of the device.

Why has been designed, which condition(s) treat.

If the device has variants (for example, different lengths) mention them all and how to distinguish the variants (the name of the models may be sufficient). Recommendation: make a table.

According to annex IX of Directive 93/42/CEE, is the device is a sterile/non-sterile transient/short term/long term active/non-active device for diagnosis/for treatment. If not self-evident, document why the product is classified as a medical device and falls under directive 94/42/EEC.

The device is of a class Class of the device device by rule rule number. Briefly explain the reason of the classification (and the rule).

The regulation has been defined by annex annex(es) by which conformity assessment is done.

2.2. CONCEPTUAL DESIGN

Explain the parts of the medical device.

Insert diagrams to understand the design and characteristics of the device. If needed add those as an annex. Number each of the parts, name them and give a description for each.

If the device includes a medicinal substance with action ancillary to that of the device: explain the purpose of including it, its mode of action.

If the device incorporates non-viable materials of animal origin:.

Make a table explaining the origin of each **purchased** component: Company you bought it from, Manufacturer, Model you bought and brief description of each component.

2.3. DESCRIPTION OF THE INTENDED USE AND OPERATION OF THE DEVICE (S)

The following information can be found in the "Instructions for Use" in annex number of annex where the IFUs are and/or (if applicable) in the operating manual for the device in annex number of annex where the operating manual is.

Clear description of the inputs and outputs associated with the intended operation of the device. For example, in the case of a thermometer, inputs are to do with temperature. The output therefore has to include a display of the temperature.

2.4. DESCRIPTION OF THE ACCESSORIES

Describe other devices or equipment which the device is intended to be used with.

Describe the important parameters or interfaces for safe and proper use.

3. MANUFACTURING

Explain the type of manufacturing method. State all the significant subcontractors.

Explain the method of sterilization (if applicable).

4. ESSENTIAL REQUIREMENTS

Essential Requirement Checklist: demonstrate how each of the applicable essential requirements have been met. Where harmonized standards are used, demonstrate it complies with the relevant clauses. Use test reports or records of application of Standard Operating Procedures to assure the compliance.

If harmonized standards have been used: make clear if they have been fully applied or in part. If the device does not comply with relevant published standards a rationale should be given.

5. Design Verification

5.1. Risk Analysis

Show results of the risk analysis. Download the guide and template from CEEASY's website.

Provide proof that the remaining risks are acceptable when weighed against the intended benefits to the patient.

Example: After doing the risk assessment (shown in Annex X), some checkpoints in the production process where established. Labelling was also reconsidered (seen in section X).

5.2. Materials

Specify all the materials used. Its biological safety and biocompatibility of materials that are to come into contact with the body.

Environmental conditions for production.

Specify any 'special processes' as sterilization. .

5.3. Production Validation

Procedures relating to the conduct of checks, test and trials as part of the routine production. Part of the manufacturer's quality system.

5.4. Validation Test Reports

Results of tests related to: sterility, packaging (transport and storage)., aging tests, tests for material resistance, …

Define Shelf-life and life time of the device. With that, define the 'use by' date.

5.5. Clinical Data

Data from market experience of similar devices.

Information from the scientific literature. Establish the extent to which the literature is relevant to the device.

This has been done according to Annex X of directive 93/42/EEC.

Make clear where clinical data is being used to demonstrate conformity with the applicable essential requirements.

6. LABELLING

Show drawings or pictures of the labels of the packaging; if more than unit comes in one package, show the individual label too.

ANNEX # – MEDICAL DEVICE DESIGN

(If applicable) Insert all necessary documentation according to the design. Graphs, schematic figures, pictures…

ANNEX # – INSTRUCTIONS FOR USE

Insert Instructions for Use (In all the languages you have).

Short description of the **intended purpose**/application. Include: intended patient(s), intended medical condition(s).

Short description of the **intended purpose**/application. Include: intended patient(s), intended medical condition(s).

Include a graphical representation of the use

Annex 9: Declaration of Conformity – TEMPLATE

EC DECLARATION OF CONFORMITY

No number *rev* 00

MANUFACTURER: **NAME OF THE COMPANY**
address, street.
Postal Code, City.
Country.

EUROPEAN REPRESENTATIVE: **NAME OF THE COMPANY** (if applies)
address, street.
Postal Code, City.
Country.

PRODUCT(S): Name of the product. If variants, include them (a table can be useful). If too many variables, add an annex.

CLASSIFICATION: Class I/Is/Im/IIa/IIb/III by rule number.

CONFORMITY ASSESSMENT ROUTE: Annex II/III/IV/V/VI/VII of Directive 93/42/EEC concerning Medical Devices.

APPLIED STANDARDS: List of applied standards, you can list it them 'topic'.

We hereby declare that the above mentioned devices have been classified according to the classification rules and conform to the Essential Requirements for Safety and Performance as laid out in the Council Directive 93/42/EEC on Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

NOTIFIED BODY: Name, Number.
Address

YEAR OF CE MARKING: Year.
Issued at city, country: Month day, year.

Signature: _____
Name / Title

Annex 10: MiWEndo – Notified Body Selection Process

In order to choose an appropriate Notified Body for our case, the NB needs to:

1. Be accredited for Directive 93/42/EEC.

All of the 59 currently competent NB in Table S3 comply with this first requirement.

2. Be able to certificate a **Class IIa** medical devices.
3. Be accredited to certificate the devices under codes MD 1202 (**Imaging device utilising non-ionizing radiation**) and MD 1111(**Software**). It is preferable to work with a NB that also knows how to certify Software.
4. Be able to certify devices according to the conformity assessment set out in **Annex II (excluding point 4) of MDD**.

Notified Bodies complying with all this three previous requirements (#2, 3 and 4) are listed in the first column of the Table 1 in this Annex. This step has been done with the use of the Table 2 in Annex 13 in Excel format (thanks to the filtering option).

As in this case, the device also needs to comply with Directive 2014/30/EU concerning electromagnetic compatibility:

5. We will choose a notified body that is also accredited for such directive. (NBs accredited for such directive are highlighted in bold.)

Manufacturers need to choose a NB not just thinking in a concrete medical device but in all the possible medical devices they would like to manufacturer. Therefore if better to leave doors open:

6. Out of these NB, we will take out those that have some kind of limitation. (Column 2 of the Table)

At this point, all the results which are not in grey in the table, are valid to be the NB of choice. But there are still a lot of them, so we will try to shorten the list a little more.

7. We will use the CEEASY rating of the NBs (Table 1 in Annex 13). According to the results, just NBs with three stars or more will be considered (threshold set at the middle). Results are highlighted in Blue.

Language should be taken into account. Although all papers can be written in any official language the most common ones are English and French. Still, I believe choosing a NB with an official language that you do understand is a plus. (Column 4 of the Table below)

NBs (#2, 3, 4)	**Limitations (#5)**	**Rating (#6)**	**Country**
0044		★★★★☆	Germany
0050		★★★☆☆	Ireland
0068	Exclusion of Class III devices		
0086		★★★★★	UK
0088		★★☆☆☆	UK
0120		★★★☆☆	UK
0123		★★★★★	**Germany**
0124		☆☆☆☆☆	Germany
0197		★★★★★	**Germany**
0297		★☆☆☆☆	Germany
0318		★★☆☆☆	Spain
0344		★★★★☆	**Netherlands**
0402		★★★★☆	**Sweden**
0408		★★☆☆☆	**Austria**
0413		★☆☆☆☆	**Sweden**
0459		★★★☆☆	France
0476	Excluding class III and devices for MR		

0477	**Excluding class III and devices for MR**		
0482		★☆☆☆☆	Germany
0483		★☆☆☆☆	Germany
0494	**Excluding class III**		
0537	Excluding class III		
0543		★☆☆☆☆	Denmark
0598	**Up to Class IIb for Annex II. Only MRI devices for other Annexes.**		
0633		☆☆☆☆☆	Germany
0805		★☆☆☆☆	Australia (MRA)
0843	No class III or implants		
1011		★☆☆☆☆	Hungary
1014		★★☆☆☆	Czech Republic
1023	**No class III**		
1304		★★☆☆☆	**Slovenia**
1434		★★★★☆	**Poland**
1639	No class III devices		
1783		★★★☆☆	Turkey
1984		★☆☆☆☆	Turkey
2195		★★☆☆☆	Turkey
2265		★☆☆☆☆	Slovakia
2274		★☆☆☆☆	Poland
2409		★★☆☆☆	Hungary
2460		★☆☆☆☆	Norway

Table A11- 1. Selection process for an appropriate Notified Bodies (NB). Notified Bodies highlighted in grey are not eligible due some limitations. Those highlighted in blue are considered to be the best possible options. Those not highlighted are perfectly accredited for certifying

After this selection criteria, out of 59 NBs, 11 are considered to be the ‘best options’. Those are classified into two groups:

- 5 of them are accredited for directive 2014/30/EU concerning electromagnetic compatibility. Which are:

  0123 0197 0344 0402 1434

- The other 6 are not accredited for this concrete directive, but are also valid. Those are:

  0044 0050 0086 0120 0459 1783

Now it is time to get in contact with the Notified Bodies and talk about quotes and time. For most of the NB this consult is free of charge. Choosing the NB is sole responsibility of the manufacturer.

Annex 11: MiWEndo – List of all applicable essential requirements

According to the Essential Requirements set out in Annex I of MDD, MiWEndo must be designed in such a way that:

- The device does not compromise the clinical condition or safety of the patients when used as intended.
- Any risks associated and undesirable side-effects may constitute acceptable risks when weighed against benefits.
- Consider technical knowledge, experience, education and training of the intended user.
- The risk of use error due ergonomic features is reduced as far as possible.
- The device performance (when subjected to stresses) is not affected to such a degree that patients and other persons are compromised during the lifetime of the device.
- The used materials are safe (especial care for toxicity and flammability).
- Materials and biological tissues are compatible (taking account of the intended purpose).
- The design ensures that the device can be used safely with the materials, substances and gases with which they enter into contact during the normal use of the device.
- Design and manufacturing processes eliminate or reduce as far as possible the risk of infection to the patient, user or third parties.
- (If delivered sterile) The device is designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed into the market. The device remains sterile after storage and transport until the protective packaging is opened or damaged.
- (If delivered sterile) The device is manufactured and sterilized by an appropriate validated method and conditions.

- (If delivered non-sterile but has to be sterilized prior to use) The packaging keeps the product without deterioration, at level of cleanliness and minimizes the risk of microbial contamination.
- (If non-sterile) The packaging keeps the product without deterioration, at level of cleanliness.
- (If intended to use in combination with other devices or equipment) The whole combination is safe and does not impair the specified performances of the devices.
- The device is designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy (taking account of the intended purpose).
- Measurement, monitoring and display scale are design in line with ergonomic principles, taking account of the intended purpose.
- Measurements are expressed in legal units conforming to Directive 80/181/EEC.
- Exposure of patients, users and other persons to radiation is reduced as far as possible compatible with the intended purpose.
- (If devices are intended to emit potentially hazardous, visible and/or invisible radiation). The device is fitted with visual displays and/or audible warnings.
- (Devices incorporating electronic programmable systems). The design ensures the repeatability, reliability and performance of the system according to its intended use.
- Software is validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.
- Risk of accidental electric shocks during normal use (when the device is correctly installed) is completely avoided (or as far as possible).
- Terminals and connectors to the electricity are designed and constructed in such a way as to minimize all possible risks.

According to Annex I in Directive 2014/30/EU concerning electromagnetic compatibility, the essential requirements the device must meet are:

- The equipment is designed and manufactured to ensure that the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended.
- The equipment is designed and manufactured to ensure that it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

Annex 12: MiWEndo – Gantt chart of the upcoming regulatory events

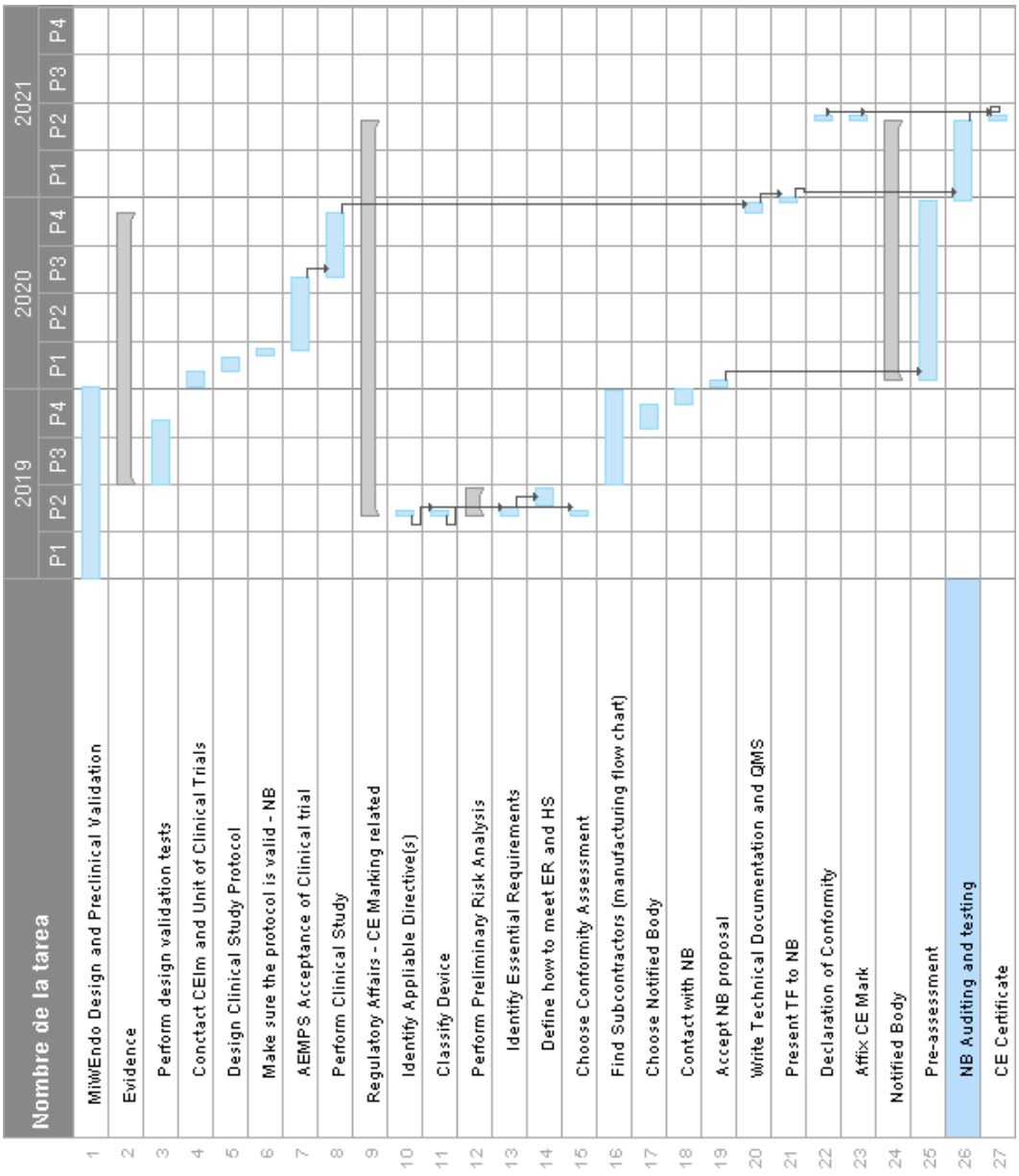


Figure A12- 1. Gantt chart for MiWEndo Regulatory Affairs from the present moment to the certification. (Gantt Chart created with: Smartsheet, and exported to an image). CEIm: Comité de Ética de la Investigación con medicamentos. AEMPS: Agencia Española de Medicamentos y Productos Sanitarios. ER: Essential Requirements. TF: Technical File. NB: Notified Body.

Annex 13: List of all Notified Bodies accredited for Directive 93/42/EEC

BN	NAME	COUNTRY	AIMD	IVD	R	NR	RATING
0044	TÜV NORD CERT GmbH	Germany	✓		✓	✓	★★★★☆
0050	National Standards Authority of Ireland (NSAI)	Ireland	✓	✓		✓	★★★☆☆
0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy	✓		✓	✓	★★★☆☆
0068	Mit International Testing S.r.l.	Italy			✓	✓	★★☆☆☆
0086	BSI	United Kingdom	✓	✓	✓	✓	★★★★★
0088	LLOYD'S REGISTER QUALITY ASSURANCE LTD (0088)	United Kingdom		✓	✓	✓	★★☆☆☆
0120	SGS United Kingdom Limited	United Kingdom		✓	✓	✓	★★★☆☆
0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany	✓	✓	✓	✓	★★★★★
0124	DEKRA Certification GmbH	Germany					☆☆☆☆☆
0197	TÜV Rheinland LGA Products GmbH	Germany	✓	✓	✓	✓	★★★★★
0297	DQS Medizinprodukte GmbH	Germany					★☆☆☆☆
0318	AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS	Spain	✓	✓			★★☆☆☆
0344	DEKRA Certification B.V.	Netherlands	✓	✓	✓	✓	★★★★☆
0373	ISTITUTO SUPERIORE DI SANITA'	Italy		✓			★☆☆☆☆

0402	RISE Research Institutes of Sweden AB	Sweden			✓	✓	★★★★☆
0408	TÜV AUSTRIA SERVICES GMBH	Austria		✓	✓	✓	★★☆☆☆
0413	INTERTEK SEMKO AB	Sweden			✓	✓	★☆☆☆☆
0425	ICIM S.P.A.	Italy			✓	✓	★★☆☆☆
0426	ITALCERT SRL	Italy			✓	✓	★★☆☆☆
0459	Laboratoire national de métrologie et d'essais / G-MED	France	✓	✓			★★★☆☆
0473	AMTAC CERTIFICATION SERVICES LTD	United Kingdom					☆☆☆☆☆
0476	KIWA CERMET ITALIA S.P.A.	Italy			✓	✓	★★☆☆☆
0477	Eurofins Product Testing Italy S.r.l.	Italy			✓	✓	★★☆☆☆
0481	ecm-Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH	Germany					☆☆☆☆☆
0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany	✓				★☆☆☆☆
0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany		✓			★☆☆☆☆
0494	SLG PRÜF UND ZERTIFIZIERUNGS GMBH	Germany			✓	✓	★☆☆☆☆
0537	VTT Expert Services Oy	Finland		✓	✓	✓	★★☆☆☆
0543	Presafe Denmark A/S	Denmark		✓			★☆☆☆☆
0546	CERTIQUALITY S.R.L. - ISTITUTO DI	Italy				✓	★☆☆☆☆

	CERTIFICAZIONE DELLA QUALITA'						
0598	SGS FIMKO OY	Finland			✓	✓	★☆☆☆☆
0633	Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH	Germany					☆☆☆☆☆
0636	PRÜFSTELLE FÜR MEDIZINPRODUKTE GRAZ	Austria*					-
0653	NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A.- EKAPTY	Greece*					-
0681	Eurofins Product Service GmbH	Germany			✓	✓	★☆☆☆☆
0805	THERAPEUTIC GOODS ADMINISTRATION	Australia**(MRA)**					★☆☆☆☆
0843	UL INTERNATIONAL (UK) LTD	United Kingdom		✓	✓	✓	★★☆☆☆
1011	Országos Gógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság (National Institute of Pharmacy and Nutrition)	Hungary		✓			★☆☆☆☆
1014	ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV, s.p.	Czech Republic	✓		✓	✓	★★☆☆☆
1023	INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s.	Czech Republic		✓	✓	✓	★★★☆☆
1250	Schweizerische Vereinigung für Qualitäts- und Managementsysteme	Switzerland**(MRA)**				✓	★☆☆☆☆
1254	QS Zürich AG	Switzerland**(MRA)**				✓	★☆☆☆☆
1282	ENTE CERTIFICAZIONE MACCHINE SRL	Italy			✓	✓	★★☆☆☆

1304	SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ	Slovenia			✓	✓	★★☆☆☆
1370	BUREAU VERITAS ITALIA S.P.A.	Italy			✓	✓	★★☆☆☆
1434	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.	Poland	✓	✓	✓	✓	★★★★☆
1639	SGS Belgium NV	Belgium				✓	★☆☆☆☆
1783	TURKISH STANDARDS INSTITUTION (TSE)	Turkey		✓	✓	✓	★★★☆☆
1912	DARE!! Certifications	Netherlands			✓		★☆☆☆☆
1936	TUV Rheinland Italia SRL	Italy				✓	★☆☆☆☆
1984	Kiwa Belgelendirme Hizmetleri A.Ş.	Turkey			✓	✓	★☆☆☆☆
2195	Szutest Uygunluk Değerlendirme A.Ş.	Turkey			✓	✓	★★☆☆☆
2265	3EC International a.s.	Slovakia		✓			★☆☆☆☆
2274	TUV NORD Polska Sp. z o.o	Poland				✓	★☆☆☆☆
2282	DQS Polska Sp. z o.o	Poland					☆☆☆☆☆
2292	UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.	Turkey			✓	✓	★☆☆☆☆
2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary	✓	✓			★★☆☆☆
2460	DNV GL Nemko Presafe AS	Norway				✓	★☆☆☆☆

2764	Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim Şirketi	Turkey			✓		★☆☆☆☆

*Notified Bodies 0636 and 0653 are not rated as "the Commission has not received assurance of the continuing competence of this NB concerning its tasks under 93/42/EEC Medical devices"
MD: Medical Device
AIMD: Active Implantable Medical Device
IVD: *In vitro* diagnostic Medical Devices
R: other related directives to MD, AIMD, IVD.
NR: other directives not related to MD, AIMD, IVD.

Table A13- 1. Conformity assessment procedures that all accredited Notified Bodies can perform for each type of medical device (defined by Codes, shown in table 3). There is also a rating for 0 to 5 stars (from worst to best, respectively) according to the directive.

The table above shows whether the NB complies with AIMD and IVD too. It also states if it complies with other directives related to medical devices as directives concerning: machinery, electromagnetic compatibility, personal protective equipment and measuring instruments. Other non-related directives, as toy safety, are considered. The information has been as well extracted from the NANDO database. With all that, a scoring for 0 to 5 stars has been performed in the following way:

- Being accredited for AIMD = 1 star
- Being accredited for IVD = 1 star
- Being accredited for Related directives but not non-related = 1 star
- Being accredited for non-related directives but not related ones = 1 star
- Being accredited for both related and non-related: If the sum of both numbers of directives is
    - Higher than 4 = 2 stars
    - Smaller or equal than 4 = 1 star
- The fifth star is obtained according to table S3, a star is given is the NB is accredited for most of the MD product-types (codes) and modules (Annexes).

This score just takes into account the technical competences of the NB, but it does not take into account the expertise of the NB. Assessing the expertise of all the 59 notified has not been possible, as 1) not all NB have a website, 2) as tuition fees are paid, all of their websites aim to say they are 'the best', and 3) external results on performance or expertise could not be found; making the assessment completely partial.

The following table shows all the conformity assessment paths that all notified bodies are accredited for each type of devices (known as codes). It also says the limitations of each kind for a given code.

Notified Bodies 0636 and 0653 are not considered as “the Commission has not received assurance of the continuing competence of this NB concerning its tasks under 93/42/EEC Medical devices”.

The Excel format of the table is provided in CEEASY's website.

Code	NB	II	III	IV	V	VI	Limitations
MD 0101	NB 0044	II			V	VI	
MD 0102	NB 0044	II			V	VI	
MD 0103	NB 0044	II			V	VI	
MD 0104	NB 0044	II			V	VI	
MD 0105	NB 0044	II			V	VI	
MD 0106	NB 0044	II			V	VI	
MD 0107	NB 0044	II			V	VI	
MD 0108	NB 0044	II			V	VI	
MD 0109	NB 0044	II			V	VI	
MD 0110	NB 0044	II			V	VI	
MD 0201	NB 0044	II			V	VI	
MD 0202	NB 0044	II			V	VI	
MD 0203	NB 0044	II			V	VI	
MD 0204	NB 0044	II			V	VI	
MD 0301	NB 0044	II			V	VI	
MD 0302	NB 0044	II			V	VI	
MD 0303	NB 0044	II			V	VI	
MD 0401	NB 0044	II			V	VI	
MD 0402	NB 0044	II			V	VI	
MD 0403	NB 0044	II			V	VI	
MD 1101	NB 0044	II	III	IV	V	VI	
MD 1102	NB 0044	II	III	IV	V	VI	
MD 1103	NB 0044	II	III	IV	V	VI	
MD 1104	NB 0044	II	III	IV	V	VI	
MD 1105	NB 0044	II	III	IV	V	VI	
MD 1106	NB 0044	II	III	IV	V	VI	
MD 1107	NB 0044	II	III	IV	V	VI	
MD 1108	NB 0044	II	III	IV	V	VI	
MD 1109	NB 0044	II	III	IV	V	VI	
MD 1111	NB 0044	II	III	IV	V	VI	
MD 1112	NB 0044	II	III	IV	V	VI	
MD 1201	NB 0044	II	III	IV	V	VI	
MD 1202	NB 0044	II	III	IV	V	VI	
MD 1301	NB 0044	II	III	IV	V	VI	
MD 1302	NB 0044	II	III	IV	V	VI	
MD 1401	NB 0044	II	III	IV	V	VI	
MD 1402	NB 0044	II	III	IV	V	VI	
MD 0101	NB 0050	II			V	VI	

MD 0102	NB 0050	II			V	VI	
MD 0103	NB 0050	II			V	VI	
MD 0104	NB 0050	II			V	VI	
MD 0105	NB 0050	II			V	VI	
MD 0106	NB 0050	II			V	VI	
MD 0107	NB 0050	II			V	VI	
MD 0108	NB 0050	II			V	VI	
MD 0109	NB 0050	II			V	VI	
MD 0201	NB 0050	II			V	VI	
MD 0202	NB 0050	II			V	VI	
MD 0203	NB 0050	II			V	VI	
MD 0204	NB 0050	II			V	VI	
MD 0301	NB 0050	II			V	VI	
MD 0302	NB 0050	II			V	VI	
MD 0303	NB 0050	II			V	VI	
MD 0401	NB 0050	II			V	VI	
MD 0402	NB 0050	II			V	VI	
MD 0403	NB 0050	II			V	VI	
MD 1101	NB 0050	II			V	VI	
MD 1102	NB 0050	II			V	VI	
MD 1103	NB 0050	II			V	VI	
MD 1104	NB 0050	II			V	VI	
MD 1105	NB 0050	II			V	VI	
MD 1106	NB 0050	II			V	VI	
MD 1107	NB 0050	II			V	VI	
MD 1108	NB 0050	II			V	VI	
MD 1109	NB 0050	II			V	VI	
MD 1111	NB 0050	II			V	VI	
MD 1201	NB 0050	II			V	VI	
MD 1202	NB 0050	II			V	VI	
MD 1301	NB 0050	II			V	VI	
MD 1302	NB 0050	II			V	VI	
MD 1402	NB 0050	II			V	VI	
MD 1403	NB 0050	II			V	VI	
MD 1404	NB 0050	II			V	VI	
MD 0101	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0102	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0103	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0104	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0105	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0106	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0107	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0108	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0202	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0301	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0302	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0303	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0401	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0402	NB 0051	II			V	VI	Exclusion of MD Class III
MD 0403	NB 0051	II			V	VI	Exclusion of MD Class III
MD 1101	NB 0051	II	III	IV	V	VI	
MD 1102	NB 0051	II	III	IV	V	VI	
MD 1103	NB 0051	II	III	IV	V	VI	
MD 1104	NB 0051	II	III	IV	V	VI	

MD 1105	NB 0051	II	III	IV	V	VI	
MD 1106	NB 0051	II	III	IV	V	VI	
MD 1107	NB 0051	II	III	IV	V	VI	
MD 1108	NB 0051	II	III	IV	V	VI	
MD 1109	NB 0051	II	III	IV	V	VI	
MD 1111	NB 0051	II			V	VI	
MD 1112	NB 0051	II	III	IV	V	VI	
MD 1301	NB 0051	II	III	IV	V	VI	
MD 1302	NB 0051	II	III	IV	V	VI	
MD 1401	NB 0051	II	III	IV	V	VI	
MD 1402	NB 0051	II	III	IV	V	VI	
MD 1403	NB 0051	II	III	IV	V	VI	
MD 1404	NB 0051	II	III	IV	V	VI	
MD 0101	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0102	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0104	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0105	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0106	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0108	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0202	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0301	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0401	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0402	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0403	NB 0068	II			V	VI	Exclusion of MD Class III
MD 1101	NB 0068	II			V	VI	Exclusion of MD Class III
MD 1102	NB 0068	II	III		V	VI	Exclusion of MD Class III and hyperbaric chambers
MD 1103	NB 0068	II		IV	V	VI	Exclusion of MD Class III
MD 1104	NB 0068	II	III		V	VI	Exclusion of MD Class III
MD 1106	NB 0068	II			V	VI	Exclusion of MD Class III
MD 1107	NB 0068	II	III		V	VI	Exclusion of MD Class III
MD 1108	NB 0068	II	III	IV	V	VI	Exclusion of MD Class III
MD 1111	NB 0068	II			V	VI	Exclusion of MD Class III
MD 1112	NB 0068	II			V	VI	Exclusion of MD Class III
MD 1201	NB 0068	II			V	VI	Exclusion of MD Class III
MD 1202	NB 0068	II			V	VI	Exclusion of MD Class III
MD 1301	NB 0068	II			V	VI	Exclusion of MD Class III
MD 1302	NB 0068	II			V	VI	Exclusion of MD Class III
MD 1402	NB 0068	II	III	IV	V	VI	Exclusion of MD Class III
MD 1403	NB 0068	II			V	VI	Exclusion of MD Class III
MD 0101	NB 0086	II	III	IV	V	VI	
MD 0102	NB 0086	II	III	IV	V	VI	
MD 0103	NB 0086	II	III	IV	V	VI	
MD 0104	NB 0086	II	III	IV	V	VI	
MD 0105	NB 0086	II	III	IV	V	VI	
MD 0106	NB 0086	II	III	IV	V	VI	
MD 0107	NB 0086	II	III	IV	V	VI	
MD 0108	NB 0086	II	III	IV	V	VI	
MD 0109	NB 0086	II	III	IV	V	VI	
MD 0110	NB 0086	II	III	IV	V	VI	
MD 0201	NB 0086	II	III	IV	V	VI	
MD 0202	NB 0086	II	III	IV	V	VI	
MD 0203	NB 0086	II	III	IV	V	VI	
MD 0204	NB 0086	II	III	IV	V	VI	
MD 0301	NB 0086	II	III	IV	V	VI	

MD 0302	NB 0086	II	III	IV	V	VI	
MD 0303	NB 0086	II	III	IV	V	VI	
MD 0401	NB 0086	II	III	IV	V	VI	
MD 0402	NB 0086	II	III	IV	V	VI	
MD 0403	NB 0086	II	III	IV	V	VI	
MD 1101	NB 0086	II	III	IV	V	VI	
MD 1102	NB 0086	II	III	IV	V	VI	
MD 1103	NB 0086	II	III	IV	V	VI	
MD 1104	NB 0086	II	III	IV	V	VI	
MD 1105	NB 0086	II	III	IV	V	VI	
MD 1106	NB 0086	II	III	IV	V	VI	
MD 1107	NB 0086	II	III	IV	V	VI	
MD 1108	NB 0086	II	III	IV	V	VI	
MD 1109	NB 0086	II	III	IV	V	VI	
MD 1110	NB 0086	II	III	IV	V	VI	
MD 1111	NB 0086	II	III	IV	V	VI	
MD 1112	NB 0086	II	III	IV	V	VI	
MD 1201	NB 0086	II	III	IV	V	VI	
MD 1202	NB 0086	II	III	IV	V	VI	
MD 1301	NB 0086	II	III	IV	V	VI	
MD 1302	NB 0086	II	III	IV	V	VI	
MD 1401	NB 0086	II	III	IV	V	VI	
MD 1402	NB 0086	II	III	IV	V	VI	
MD 1403	NB 0086	II	III	IV	V	VI	
MD 1404	NB 0086	II	III	IV	V	VI	
MD 0101	NB 0120	II			V	VI	
MD 0102	NB 0120	II			V	VI	
MD 0103	NB 0120	II			V	VI	
MD 0104	NB 0120	II			V	VI	
MD 0105	NB 0120	II			V	VI	
MD 0106	NB 0120	II			V	VI	
MD 0107	NB 0120	II			V	VI	
MD 0108	NB 0120	II			V	VI	
MD 0109	NB 0120	II			V	VI	
MD 0110	NB 0120	II			V	VI	
MD 0201	NB 0120	II			V	VI	
MD 0202	NB 0120	II			V	VI	
MD 0203	NB 0120	II			V	VI	
MD 0204	NB 0120	II			V	VI	Excluding Breast Implants
MD 0301	NB 0120	II			V	VI	
MD 0302	NB 0120	II			V	VI	
MD 0303	NB 0120	II			V	VI	
MD 0401	NB 0120	II			V	VI	
MD 0402	NB 0120	II			V	VI	
MD 0403	NB 0120	II			V	VI	
MD 1101	NB 0120	II			V	VI	
MD 1102	NB 0120	II			V	VI	
MD 1103	NB 0120	II			V	VI	
MD 1104	NB 0120	II			V	VI	
MD 1105	NB 0120	II			V	VI	
MD 1106	NB 0120	II			V	VI	
MD 1107	NB 0120	II			V	VI	
MD 1108	NB 0120	II			V	VI	
MD 1109	NB 0120	II			V	VI	

MD 1110	NB 0120	II			V	VI
MD 1111	NB 0120	II			V	VI
MD 1112	NB 0120	II			V	VI
MD 1201	NB 0120	II			V	VI
MD 1202	NB 0120	II			V	VI
MD 1301	NB 0120	II			V	VI
MD 1302	NB 0120	II			V	VI
MD 1401	NB 0120	II			V	VI
MD 1402	NB 0120	II			V	VI
MD 1403	NB 0120	II			V	VI
MD 1404	NB 0120	II			V	VI
MD 0101	NB 0123	II	III	IV	V	VI
MD 0102	NB 0123	II	III	IV	V	VI
MD 0103	NB 0123	II			V	VI
MD 0104	NB 0123	II			V	VI
MD 0105	NB 0123	II			V	VI
MD 0106	NB 0123	II			V	VI
MD 0107	NB 0123	II			V	VI
MD 0108	NB 0123	II			V	VI
MD 0109	NB 0123	II	III	IV	V	VI
MD 0110	NB 0123	II	III	IV	V	VI
MD 0201	NB 0123	II	III	IV	V	VI
MD 0202	NB 0123	II			V	VI
MD 0203	NB 0123	II			V	VI
MD 0204	NB 0123	II			V	VI
MD 0301	NB 0123	II			V	VI
MD 0302	NB 0123	II			V	VI
MD 0303	NB 0123	II			V	VI
MD 0401	NB 0123	II			V	VI
MD 0402	NB 0123	II			V	VI
MD 0403	NB 0123	II			V	VI
MD 1101	NB 0123	II	III	IV	V	VI
MD 1102	NB 0123	II	III	IV	V	VI
MD 1103	NB 0123	II	III	IV	V	VI
MD 1104	NB 0123	II	III	IV	V	VI
MD 1105	NB 0123	II	III	IV	V	VI
MD 1106	NB 0123	II	III	IV	V	VI
MD 1107	NB 0123	II	III	IV	V	VI
MD 1108	NB 0123	II	III	IV	V	VI
MD 1109	NB 0123	II	III	IV	V	VI
MD 1110	NB 0123	II	III	IV	V	VI
MD 1111	NB 0123	II	III	IV	V	VI
MD 1112	NB 0123	II	III	IV	V	VI
MD 1201	NB 0123	II	III	IV	V	VI
MD 1202	NB 0123	II	III	IV	V	VI
MD 1301	NB 0123	II	III	IV	V	VI
MD 1302	NB 0123	II	III	IV	V	VI
MD 1401	NB 0123	II	III	IV	V	VI
MD 1402	NB 0123	II	III	IV	V	VI
MD 1403	NB 0123	II	III	IV	V	VI
MD 1404	NB 0123	II	III	IV	V	VI
MD 0101	NB 0124	II			V	VI
MD 0102	NB 0124	II			V	VI
MD 0103	NB 0124	II			V	VI

MD 0104	NB 0124	II			V	VI
MD 0105	NB 0124	II			V	VI
MD 0106	NB 0124	II			V	VI
MD 0107	NB 0124	II			V	VI
MD 0108	NB 0124	II			V	VI
MD 0109	NB 0124	II			V	VI
MD 0201	NB 0124	II			V	VI
MD 0202	NB 0124	II			V	VI
MD 0203	NB 0124	II			V	VI
MD 0204	NB 0124	II			V	VI
MD 0301	NB 0124	II			V	VI
MD 0302	NB 0124	II			V	VI
MD 0303	NB 0124	II			V	VI
MD 0401	NB 0124	II			V	VI
MD 0402	NB 0124	II			V	VI
MD 0403	NB 0124	II			V	VI
MD 1101	NB 0124	II			V	VI
MD 1102	NB 0124	II			V	VI
MD 1103	NB 0124	II			V	VI
MD 1104	NB 0124	II			V	VI
MD 1105	NB 0124	II			V	VI
MD 1106	NB 0124	II			V	VI
MD 1107	NB 0124	II			V	VI
MD 1108	NB 0124	II			V	VI
MD 1109	NB 0124	II			V	VI
MD 1111	NB 0124	II			V	VI
MD 1112	NB 0124	II			V	VI
MD 1201	NB 0124	II			V	VI
MD 1202	NB 0124	II			V	VI
MD 1301	NB 0124	II			V	VI
MD 1302	NB 0124	II			V	VI
MD 1401	NB 0124	II			V	VI
MD 1402	NB 0124	II			V	VI
MD 1403	NB 0124	II			V	VI
MD 1404	NB 0124	II			V	VI
MD 0101	NB 0197	II			V	VI
MD 0102	NB 0197	II			V	VI
MD 0103	NB 0197	II			V	VI
MD 0104	NB 0197	II	III	IV	V	VI
MD 0105	NB 0197	II	III	IV	V	VI
MD 0106	NB 0197	II			V	VI
MD 0107	NB 0197	II	III	IV	V	VI
MD 0108	NB 0197	II			V	VI
MD 0109	NB 0197	II			V	VI
MD 0110	NB 0197	II			V	VI
MD 0201	NB 0197	II	III	IV	V	VI
MD 0202	NB 0197	II			V	VI
MD 0203	NB 0197	II			V	VI
MD 0204	NB 0197	II	III	IV	V	VI
MD 0301	NB 0197	II			V	VI
MD 0302	NB 0197	II	III	IV	V	VI
MD 0303	NB 0197	II			V	VI
MD 0401	NB 0197	II	III	IV	V	VI
MD 0402	NB 0197	II			V	VI

MD 0403	NB 0197	II			V	VI
MD 1101	NB 0197	II	III	IV	V	VI
MD 1102	NB 0197	II	III	IV	V	VI
MD 1103	NB 0197	II	III	IV	V	VI
MD 1104	NB 0197	II	III	IV	V	VI
MD 1105	NB 0197	II	III	IV	V	VI
MD 1106	NB 0197	II	III	IV	V	VI
MD 1107	NB 0197	II	III	IV	V	VI
MD 1108	NB 0197	II	III	IV	V	VI
MD 1109	NB 0197	II	III	IV	V	VI
MD 1110	NB 0197	II	III	IV	V	VI
MD 1111	NB 0197	II	III	IV	V	VI
MD 1112	NB 0197	II	III	IV	V	VI
MD 1201	NB 0197	II	III	IV	V	VI
MD 1202	NB 0197	II	III	IV	V	VI
MD 1301	NB 0197	II	III	IV	V	VI
MD 1302	NB 0197	II	III	IV	V	VI
MD 1401	NB 0197	II	III	IV	V	VI
MD 1402	NB 0197	II	III	IV	V	VI
MD 1403	NB 0197	II	III	IV	V	VI
MD 1404	NB 0197	II	III	IV	V	VI
MD 1101	NB 0279	II			V	VI
MD 1102	NB 0279	II			V	VI
MD 1103	NB 0279	II			V	VI
MD 1104	NB 0279	II			V	VI
MD 1105	NB 0279	II			V	VI
MD 1106	NB 0279	II			V	VI
MD 1107	NB 0279	II			V	VI
MD 1108	NB 0279	II			V	VI
MD 1109	NB 0279	II			V	VI
MD 1111	NB 0279	II			V	VI
MD 1112	NB 0279	II			V	VI
MD 1201	NB 0279	II			V	VI
MD 1202	NB 0279	II			V	VI
MD 1301	NB 0279	II			V	VI
MD 1302	NB 0279	II			V	VI
MD 1401	NB 0279	II			V	VI
MD 1402	NB 0279	II			V	VI
MD 1404	NB 0279	II			V	VI
MD 0101	NB 0318	II	III	IV	V	VI
MD 0102	NB 0318	II	III	IV	V	VI
MD 0103	NB 0318	II	III	IV	V	VI
MD 0104	NB 0318	II	III	IV	V	VI
MD 0105	NB 0318	II	III	IV	V	VI
MD 0106	NB 0318	II	III	IV	V	VI
MD 0107	NB 0318	II	III	IV	V	VI
MD 0108	NB 0318	II	III	IV	V	VI
MD 0109	NB 0318	II	III	IV	V	VI
MD 0201	NB 0318	II	III	IV	V	VI
MD 0202	NB 0318	II	III	IV	V	VI
MD 0203	NB 0318	II	III	IV	V	VI
MD 0204	NB 0318	II	III	IV	V	VI
MD 0301	NB 0318	II	III	IV	V	VI
MD 0302	NB 0318	II	III	IV	V	VI

MD 0303	NB 0318	II	III	IV	V	VI
MD 0401	NB 0318	II	III	IV	V	VI
MD 0402	NB 0318	II	III	IV	V	VI
MD 0403	NB 0318	II	III	IV	V	VI
MD 1101	NB 0318	II	III	IV	V	VI
MD 1102	NB 0318	II	III	IV	V	VI
MD 1103	NB 0318	II	III	IV	V	VI
MD 1104	NB 0318	II	III	IV	V	VI
MD 1105	NB 0318	II	III	IV	V	VI
MD 1106	NB 0318	II	III	IV	V	VI
MD 1107	NB 0318	II	III	IV	V	VI
MD 1108	NB 0318	II	III	IV	V	VI
MD 1109	NB 0318	II	III	IV	V	VI
MD 1110	NB 0318	II	III	IV	V	VI
MD 1111	NB 0318	II	III	IV	V	VI
MD 1201	NB 0318	II	III	IV	V	VI
MD 1202	NB 0318	II	III	IV	V	VI
MD 1301	NB 0318	II	III	IV	V	VI
MD 1302	NB 0318	II	III	IV	V	VI
MD 1401	NB 0318	II	III	IV	V	VI
MD 1402	NB 0318	II	III	IV	V	VI
MD 1403	NB 0318	II	III	IV	V	VI
MD 1404	NB 0318	II	III	IV	V	VI
MD 0101	NB 0344	II	III	IV	V	VI
MD 0102	NB 0344	II	III	IV	V	VI
MD 0103	NB 0344	II	III	IV	V	VI
MD 0104	NB 0344	II	III	IV	V	VI
MD 0105	NB 0344	II	III	IV	V	VI
MD 0106	NB 0344	II	III	IV	V	VI
MD 0107	NB 0344	II	III	IV	V	VI
MD 0108	NB 0344	II	III	IV	V	VI
MD 0109	NB 0344	II	III	IV	V	VI
MD 0201	NB 0344	II	III	IV	V	VI
MD 0202	NB 0344	II	III	IV	V	VI
MD 0203	NB 0344	II	III	IV	V	VI
MD 0204	NB 0344	II	III	IV	V	VI
MD 0301	NB 0344	II	III	IV	V	VI
MD 0302	NB 0344	II	III	IV	V	VI
MD 0303	NB 0344	II	III	IV	V	VI
MD 0401	NB 0344	II	III	IV	V	VI
MD 0402	NB 0344	II	III	IV	V	VI
MD 0403	NB 0344	II	III	IV	V	VI
MD 1101	NB 0344	II	III	IV	V	VI
MD 1102	NB 0344	II	III	IV	V	VI
MD 1103	NB 0344	II	III	IV	V	VI
MD 1104	NB 0344	II	III	IV	V	VI
MD 1105	NB 0344	II	III	IV	V	VI
MD 1106	NB 0344	II	III	IV	V	VI
MD 1107	NB 0344	II	III	IV	V	VI
MD 1108	NB 0344	II	III	IV	V	VI
MD 1109	NB 0344	II	III	IV	V	VI
MD 1110	NB 0344	II	III	IV	V	VI
MD 1111	NB 0344	II	III	IV	V	VI
MD 1112	NB 0344	II	III	IV	V	VI

MD 1201	NB 0344	II	III	IV	V	VI	
MD 1202	NB 0344	II	III	IV	V	VI	
MD 1301	NB 0344	II	III	IV	V	VI	
MD 1302	NB 0344	II	III	IV	V	VI	
MD 1401	NB 0344	II	III	IV	V	VI	
MD 1402	NB 0344	II	III	IV	V	VI	
MD 1403	NB 0344	II	III	IV	V	VI	
MD 1404	NB 0344	II	III	IV	V	VI	
MD 0105	NB 0373	II	III		V	VI	Annex III limited to ophthalmic solutions
MD 0101	NB 0402	II			V	VI	
MD 0102	NB 0402	II			V	VI	
MD 0103	NB 0402	II			V	VI	
MD 0104	NB 0402	II			V	VI	
MD 0106	NB 0402	II			V	VI	
MD 0108	NB 0402	II			V	VI	
MD 0202	NB 0402	II			V	VI	
MD 0203	NB 0402	II			V	VI	Bone-anchored implants for dental and cranio-facial reconstruction.
MD 0301	NB 0402	II			V	VI	
MD 0303	NB 0402	II			V	VI	
MD 0401	NB 0402	II			V	VI	
MD 0402	NB 0402	II			V	VI	
MD 0403	NB 0402	II			V	VI	Bone-anchored implants for dental and cranio-facial reconstruction.
MD 1102	NB 0402	II			V	VI	
MD 1103	NB 0402	II			V	VI	
MD 1104	NB 0402	II			V	VI	
MD 1106	NB 0402	II			V	VI	
MD 1107	NB 0402	II			V	VI	
MD 1108	NB 0402	II			V	VI	
MD 1111	NB 0402	II			V	VI	
MD 1201	NB 0402	II			V	VI	
MD 1202	NB 0402	II			V	VI	
MD 1301	NB 0402	II			V	VI	
MD 0101	NB 0408	II	III	IV	V	VI	
MD 0102	NB 0408	II	III	IV	V	VI	
MD 0103	NB 0408	II	III	IV	V	VI	
MD 0104	NB 0408	II	III	IV	V	VI	
MD 0105	NB 0408	II	III	IV	V	VI	
MD 0106	NB 0408	II	III	IV	V	VI	
MD 0107	NB 0408	II	III	IV	V	VI	
MD 0108	NB 0408	II	III	IV	V	VI	
MD 0109	NB 0408	II	III	IV	V	VI	
MD 0202	NB 0408	II	III	IV	V	VI	
MD 0203	NB 0408	II	III	IV	V	VI	Neurological and neurosurgical implants excluded.
MD 0301	NB 0408	II	III	IV	V	VI	
MD 0302	NB 0408	II	III	IV	V	VI	
MD 0303	NB 0408	II	III	IV	V	VI	
MD 0401	NB 0408	II	III	IV	V	VI	
MD 0402	NB 0408	II	III	IV	V	VI	
MD 0403	NB 0408	II	III	IV	V	VI	
MD 1101	NB 0408	II	III	IV	V	VI	
MD 1102	NB 0408	II	III	IV	V	VI	
MD 1103	NB 0408	II	III	IV	V	VI	

MD 1104	NB 0408	II	III	IV	V	VI	
MD 1105	NB 0408	II	III	IV	V	VI	
MD 1106	NB 0408	II	III	IV	V	VI	
MD 1107	NB 0408	II	III	IV	V	VI	
MD 1108	NB 0408	II	III	IV	V	VI	
MD 1109	NB 0408	II	III	IV	V	VI	
MD 1110	NB 0408	II	III	IV	V	VI	
MD 1111	NB 0408	II	III	IV	V	VI	
MD 1201	NB 0408	II	III	IV	V	VI	
MD 1202	NB 0408	II	III	IV	V	VI	
MD 1301	NB 0408	II	III	IV	V	VI	
MD 1302	NB 0408	II	III	IV	V	VI	
MD 1401	NB 0408	II	III	IV	V	VI	
MD 1402	NB 0408	II	III	IV	V	VI	
MD 1403	NB 0408	II	III	IV	V	VI	
MD 1404	NB 0408	II	III	IV	V	VI	
MD 0101	NB 0413	II			V	VI	
MD 0102	NB 0413	II			V	VI	
MD 0103	NB 0413	II			V	VI	
MD 0104	NB 0413	II			V	VI	
MD 0105	NB 0413	II			V	VI	
MD 0106	NB 0413	II			V	VI	
MD 0107	NB 0413	II			V	VI	
MD 0108	NB 0413	II			V	VI	
MD 0202	NB 0413	II			V	VI	
MD 0203	NB 0413	II			V	VI	
MD 0204	NB 0413	II			V	VI	
MD 0301	NB 0413	II			V	VI	
MD 0302	NB 0413	II			V	VI	
MD 0303	NB 0413	II			V	VI	
MD 0401	NB 0413	II			V	VI	
MD 0402	NB 0413	II			V	VI	
MD 0403	NB 0413	II			V	VI	
MD 1101	NB 0413	II			V	VI	
MD 1102	NB 0413	II			V	VI	
MD 1103	NB 0413	II			V	VI	
MD 1104	NB 0413	II			V	VI	
MD 1105	NB 0413	II			V	VI	
MD 1106	NB 0413	II			V	VI	
MD 1107	NB 0413	II			V	VI	
MD 1108	NB 0413	II			V	VI	
MD 1109	NB 0413	II			V	VI	
MD 1111	NB 0413	II			V	VI	
MD 1201	NB 0413	II			V	VI	
MD 1202	NB 0413	II			V	VI	
MD 1301	NB 0413	II			V	VI	
MD 1302	NB 0413	II			V	VI	
MD 1401	NB 0413	II			V	VI	
MD 1402	NB 0413	II			V	VI	
MD 1403	NB 0413	II			V	VI	
MD 0101	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0102	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0104	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0105	NB 0425	II			V	VI	Exclusion of class III medical devices

MD 0106	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0301	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0302	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0303	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0401	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0402	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0403	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 1102	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 1106	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 1107	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 1111	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 1112	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 1301	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 1302	NB 0425	II			V	VI	Exclusion of class III medical devices
MD 0101	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0102	NB 0426	II			V	VI	Exclusion of class III medical devices, except surgically devices, intended for transient use, in direct contact with central nervous system
MD 0103	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0104	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0105	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0106	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0108	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0110	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0202	NB 0426	II			V	VI	
MD 0203	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0204	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0301	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0302	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0303	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0401	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0402	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0403	NB 0426	II			V	VI	
MD 1101	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1102	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1103	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1104	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1105	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1106	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1107	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1108	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1111	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1112	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1301	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1402	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 1403	NB 0426	II			V	VI	Exclusion of class III medical devices
MD 0101	NB 0459	II	III	IV	V	VI	
MD 0102	NB 0459	II	III	IV	V	VI	
MD 0103	NB 0459	II	III	IV	V	VI	
MD 0104	NB 0459	II	III	IV	V	VI	
MD 0105	NB 0459	II	III	IV	V	VI	
MD 0106	NB 0459	II	III	IV	V	VI	
MD 0107	NB 0459	II	III	IV	V	VI	
MD 0108	NB 0459	II	III	IV	V	VI	

MD 0109	NB 0459	II	III	IV	V	VI	
MD 0110	NB 0459	II	III	IV	V	VI	
MD 0201	NB 0459	II	III	IV	V	VI	
MD 0202	NB 0459	II	III	IV	V	VI	
MD 0203	NB 0459	II	III	IV	V	VI	
MD 0204	NB 0459	II	III	IV	V	VI	
MD 0301	NB 0459	II	III	IV	V	VI	
MD 0302	NB 0459	II	III	IV	V	VI	
MD 0303	NB 0459	II	III	IV	V	VI	
MD 0401	NB 0459	II	III	IV	V	VI	
MD 0402	NB 0459	II	III	IV	V	VI	
MD 0403	NB 0459	II	III	IV	V	VI	
MD 1101	NB 0459	II	III	IV	V	VI	
MD 1102	NB 0459	II	III	IV	V	VI	
MD 1103	NB 0459	II	III	IV	V	VI	
MD 1104	NB 0459	II	III	IV	V	VI	
MD 1105	NB 0459	II	III	IV	V	VI	
MD 1106	NB 0459	II	III	IV	V	VI	
MD 1107	NB 0459	II	III	IV	V	VI	
MD 1108	NB 0459	II	III	IV	V	VI	
MD 1109	NB 0459	II	III	IV	V	VI	
MD 1110	NB 0459	II	III	IV	V	VI	
MD 1111	NB 0459	II	III	IV	V	VI	
MD 1112	NB 0459	II	III	IV	V	VI	
MD 1201	NB 0459	II	III	IV	V	VI	
MD 1202	NB 0459	II	III	IV	V	VI	
MD 1301	NB 0459	II	III	IV	V	VI	
MD 1302	NB 0459	II	III	IV	V	VI	
MD 1401	NB 0459	II	III	IV	V	VI	
MD 1402	NB 0459	II	III	IV	V	VI	
MD 1403	NB 0459	II	III	IV	V	VI	
MD 1404	NB 0459	II	III	IV	V	VI	
MD 0101	NB 0473	II			V	VI	
MD 0102	NB 0473	II			V	VI	
MD 0103	NB 0473	II			V	VI	
MD 0104	NB 0473	II			V	VI	
MD 0105	NB 0473	II			V	VI	
MD 0106	NB 0473	II			V	VI	Excluding Breast Implants
MD 0108	NB 0473	II			V	VI	
MD 0201	NB 0473	II			V	VI	
MD 0202	NB 0473	II			V	VI	
MD 0203	NB 0473	II			V	VI	
MD 0204	NB 0473	II			V	VI	Excluding Breast Implants
MD 0301	NB 0473	II			V	VI	
MD 0303	NB 0473	II			V	VI	
MD 0401	NB 0473	II			V	VI	
MD 0402	NB 0473	II			V	VI	Excluding Class III
MD 0403	NB 0473	II			V	VI	Excluding Class III
MD 0101	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 0102	NB 0476	II			V	VI	
MD 0104	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 0105	NB 0476	II			V	VI	
MD 0106	NB 0476	II			V	VI	
MD 0107	NB 0476	II			V	VI	Excluding Class III Medical Devices

MD 0108	NB 0476	II			V	VI	
MD 0110	NB 0476	II			V	VI	
MD 0202	NB 0476	II			V	VI	
MD 0203	NB 0476	II			V	VI	
MD 0204	NB 0476	II			V	VI	
MD 0301	NB 0476	II			V	VI	
MD 0302	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 0303	NB 0476	II			V	VI	
MD 0401	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 0402	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 0403	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1101	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1102	NB 0476	II			V	VI	Excluding Class III Medical Devices and hyperbaric chambers for oxygen therapy
MD 1103	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1104	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1105	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1106	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1107	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1108	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1109	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1111	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1112	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1202	NB 0476	II			V	VI	Excluding Class III Medical Devices and devices for magnetic resonance
MD 1301	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1302	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 1403	NB 0476	II			V	VI	Excluding Class III Medical Devices
MD 0101	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 0102	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0103	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 0104	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 0105	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0106	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0107	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0108	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0202	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 0204	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0301	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0302	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0303	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0401	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0402	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 0403	NB 0477	II	III	IV	V	VI	Excluding Class III Medical Devices
MD 1101	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 1102	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 1103	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 1104	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 1105	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 1106	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 1107	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 1108	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 1109	NB 0477	II			V	VI	Excluding Class III Medical Devices
MD 1111	NB 0477	II			V	VI	Excluding Class III Medical Devices

MD 1201	NB 0477	II		V	VI	Excluding Class III Medical Devices
MD 1202	NB 0477	II		V	VI	Excluding Class III Medical Devices and devices for magnetic resonance
MD 1301	NB 0477	II		V	VI	Excluding Class III Medical Devices
MD 1401	NB 0477	II		V	VI	Excluding Class III Medical Devices
MD 1402	NB 0477	II		V	VI	Excluding Class III Medical Devices
MD 1404	NB 0477	II		V	VI	Excluding Class III Medical Devices
MD 0101	NB 0481	II		V	VI	
MD 0102	NB 0481	II	III	V	VI	Annex III: Only infusion sets, transfusion sets, catheters, tubing systems for extra-corporal circulation
MD 0103	NB 0481	II		V	VI	
MD 0104	NB 0481	II		V	VI	
MD 0105	NB 0481	II		V	VI	
MD 0106	NB 0481	II		V	VI	
MD 0107	NB 0481	II		V	VI	
MD 0108	NB 0481	II		V	VI	
MD 0109	NB 0481	II		V	VI	
MD 0110	NB 0481	II		V	VI	
MD 0201	NB 0481	II	III	V	VI	Only stents, implantable catheters, vascular grafts, occlusion systems
MD 0202	NB 0481	II		V	VI	
MD 0203	NB 0481	II		V	VI	Only introcular lenses
MD 0204	NB 0481	II		V	VI	
MD 0301	NB 0481	II		V	VI	
MD 0302	NB 0481	II		V	VI	
MD 0303	NB 0481	II		V	VI	
MD 0401	NB 0481	II		V	VI	
MD 0402	NB 0481	II		V	VI	
MD 0403	NB 0481	II		V	VI	
MD 1101	NB 0481	II		V	VI	Only products, which are based on spring tension (pre-loaded) or gas release for pressure build-up, e.g. drug dosers
MD 1104	NB 0481	II		V	VI	Only wound drainage systems and accessories for HF surgery (e.g. scissors, pliers)
MD 1403	NB 0481	II		V	VI	Only medical devices in small pressure vessels (e.g. coolant sprays) for focalized application and medical devices, where heat or cold is generated by chemical or physical processes (e.g. hot/cold packs) for focalized application.
MD 0101	NB 0482	II	III	V	VI	
MD 0102	NB 0482	II	III	V	VI	
MD 0103	NB 0482	II		V	VI	
MD 0104	NB 0482	II		V	VI	
MD 0105	NB 0482	II		V	VI	
MD 0106	NB 0482	II		V	VI	
MD 0107	NB 0482	II	III	V	VI	
MD 0108	NB 0482	II		V	VI	
MD 0109	NB 0482	II		V	VI	
MD 0110	NB 0482	II		V	VI	
MD 0201	NB 0482	II	III	V	VI	
MD 0202	NB 0482	II		V	VI	
MD 0203	NB 0482	II	III	V	VI	
MD 0204	NB 0482	II		V	VI	

MD 0301	NB 0482	II	III	V	VI	
MD 0302	NB 0482	II		V	VI	
MD 0303	NB 0482	II		V	VI	
MD 0401	NB 0482	II		V	VI	
MD 0402	NB 0482	II		V	VI	
MD 0403	NB 0482	II	III	V	VI	
MD 1101	NB 0482	II		V	VI	
MD 1102	NB 0482	II		V	VI	
MD 1103	NB 0482	II		V	VI	
MD 1104	NB 0482	II		V	VI	
MD 1105	NB 0482	II		V	VI	
MD 1106	NB 0482	II		V	VI	
MD 1107	NB 0482	II		V	VI	
MD 1108	NB 0482	II		V	VI	
MD 1109	NB 0482	II		V	VI	
MD 1111	NB 0482	II		V	VI	
MD 1112	NB 0482	II		V	VI	
MD 1201	NB 0482	II		V	VI	
MD 1202	NB 0482	II		V	VI	
MD 1301	NB 0482	II		V	VI	
MD 1302	NB 0482	II		V	VI	
MD 1401	NB 0482	II		V	VI	
MD 1402	NB 0482	II		V	VI	
MD 1403	NB 0482	II		V	VI	
MD 1404	NB 0482	II		V	VI	
MD 0101	NB 0483	II		V	VI	
MD 0102	NB 0483	II		V	VI	
MD 0103	NB 0483	II		V	VI	
MD 0104	NB 0483	II		V	VI	
MD 0105	NB 0483	II		V	VI	
MD 0106	NB 0483	II		V	VI	
MD 0107	NB 0483	II		V	VI	
MD 0108	NB 0483	II		V	VI	
MD 0109	NB 0483	II		V	VI	
MD 0110	NB 0483	II		V	VI	
MD 0201	NB 0483	II		V	VI	
MD 0202	NB 0483	II		V	VI	
MD 0203	NB 0483	II		V	VI	
MD 0204	NB 0483	II		V	VI	
MD 0301	NB 0483	II		V	VI	
MD 0302	NB 0483	II		V	VI	
MD 0303	NB 0483	II		V	VI	
MD 0401	NB 0483	II		V	VI	
MD 0402	NB 0483	II		V	VI	
MD 0403	NB 0483	II		V	VI	
MD 1101	NB 0483	II		V	VI	
MD 1102	NB 0483	II		V	VI	Except hyperbaric chambers
MD 1103	NB 0483	II		V	VI	Except external pacemakers and heart defibrilators
MD 1104	NB 0483	II		V	VI	
MD 1105	NB 0483	II		V	VI	
MD 1106	NB 0483	II		V	VI	
MD 1107	NB 0483	II		V	VI	
MD 1108	NB 0483	II		V	VI	
MD 1109	NB 0483	II		V	VI	

MD 1111	NB 0483	II			V	VI	
MD 1112	NB 0483	II			V	VI	
MD 1201	NB 0483	II			V	VI	
MD 1202	NB 0483	II			V	VI	
MD 1301	NB 0483	II			V	VI	
MD 1302	NB 0483	II			V	VI	
MD 1401	NB 0483	II			V	VI	
MD 1402	NB 0483	II			V	VI	
MD 1403	NB 0483	II			V	VI	
MD 1102	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1103	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1104	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1105	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1106	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1108	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1109	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1111	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1112	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1201	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1202	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1301	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1302	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1402	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 1403	NB 0494	II	III	IV	V	VI	Excluding Class III Devices
MD 0101	NB 0537	II			V	VI	Excluding Class III Devices
MD 0102	NB 0537	II			V	VI	Excluding Class III Devices
MD 0103	NB 0537	II			V	VI	Excluding Class III Devices
MD 0104	NB 0537	II			V	VI	Excluding Class III Devices
MD 0105	NB 0537	II			V	VI	Excluding Class III Devices
MD 0106	NB 0537	II			V	VI	Excluding Class III Devices
MD 0108	NB 0537	II			V	VI	Excluding Class III Devices
MD 0202	NB 0537	II			V	VI	Excluding Class III Devices
MD 0301	NB 0537	II			V	VI	Excluding Class III Devices
MD 0303	NB 0537	II			V	VI	Excluding Class III Devices
MD 0401	NB 0537	II			V	VI	Excluding Class III Devices
MD 0402	NB 0537	II			V	VI	Excluding Class III Devices
MD 0403	NB 0537	II			V	VI	Excluding Class III Devices
MD 1103	NB 0537	II			V	VI	Excluding Class III Devices
MD 1104	NB 0537	II			V	VI	Excluding Class III Devices
MD 1105	NB 0537	II			V	VI	Excluding Class III Devices
MD 1106	NB 0537	II			V	VI	Excluding Class III Devices
MD 1107	NB 0537	II			V	VI	Excluding Class III Devices
MD 1108	NB 0537	II			V	VI	Excluding Class III Devices
MD 1111	NB 0537	II			V	VI	Excluding Class III Devices
MD 1201	NB 0537	II			V	VI	Excluding Class III Devices
MD 1202	NB 0537	II			V	VI	Excluding Class III Devices
MD 1301	NB 0537	II			V	VI	Excluding Class III Devices
MD 1302	NB 0537	II			V	VI	Excluding Class III Devices
MD 1402	NB 0537	II			V	VI	Excluding Class III Devices
MD 1403	NB 0537	II			V	VI	Excluding Class III Devices
MD 0101	NB 0543	II			V	VI	
MD 0102	NB 0543	II			V	VI	
MD 0104	NB 0543	II			V	VI	
MD 0105	NB 0543	II			V	VI	

MD 0106	NB 0543	II	V	VI	
MD 0108	NB 0543	II	V	VI	
MD 0109	NB 0543	II	V	VI	
MD 0202	NB 0543	II	V	VI	Excluding orthopaedic implants ref. 2005/50/EEC and bone cement.
MD 0203	NB 0543	II	V	VI	
MD 0204	NB 0543	II	V	VI	
MD 0301	NB 0543	II	V	VI	
MD 0302	NB 0543	II	V	VI	
MD 0303	NB 0543	II	V	VI	
MD 1101	NB 0543	II	V	VI	
MD 1102	NB 0543	II	V	VI	
MD 1103	NB 0543	II	V	VI	
MD 1104	NB 0543	II	V	VI	
MD 1106	NB 0543	II	V	VI	
MD 1107	NB 0543	II	V	VI	
MD 1110	NB 0543	II	V	VI	
MD 1111	NB 0543	II	V	VI	
MD 1201	NB 0543	II	V	VI	
MD 1202	NB 0543	II	V	VI	
MD 1301	NB 0543	II	V	VI	
MD 1302	NB 0543	II	V	VI	
MD 1402	NB 0543	II	V	VI	
MD 0101	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 0102	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 0104	NB 0546	II	V	VI	Exclusion of Class III medical devices
MD 0105	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 0106	NB 0546	II	V	VI	Exclusion of Class III medical devices
MD 0108	NB 0546	II	V	VI	Exclusion of Class III medical devices
MD 0110	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC
MD 0202	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.

MD 0203	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 0204	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 0301	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 0302	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 0303	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 0401	NB 0546	II	V	VI	Exclusion of Class III medical devices
MD 0402	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 0403	NB 0546	II	V	VI	Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed.
MD 1102	NB 0546	II	V	VI	Excluding hyperbaric chambers and all devices depending on a source of electrical energy. Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC.
MD 1111	NB 0546	II	V	VI	Exclusion of Class III medical devices
MD 1112	NB 0546	II	V	VI	Exclusion of Class III medical devices
MD 1403	NB 0546	II	V	VI	Excluding medical devices depending on a source of electrical energy. Exclusion of Class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC.
MD 0101	NB 0598	II	V	VI	II: Up to class IIb only
MD 0103	NB 0598	II	V	VI	II: Up to class IIb only
MD 0104	NB 0598	II	V	VI	II: Up to class IIb only
MD 0106	NB 0598	II	V	VI	II: Up to class IIb only

MD 0108	NB 0598	II			V	VI	II: Up to class IIb only
MD 0202	NB 0598	II			V	VI	II: Up to class IIb only
MD 0401	NB 0598	II			V	VI	II: Up to class IIb only
MD 0402	NB 0598	II			V	VI	II: Up to class IIb only
MD 0403	NB 0598	II			V	VI	II: Up to class IIb only
MD 1103	NB 0598	II	III	IV	V	VI	II: Up to class IIb only, III, IV: Nerve and muscle stimulator only
MD 1105	NB 0598	II	III	IV	V	VI	II: Up to class IIb only
MD 1106	NB 0598	II	III	IV	V	VI	II: Up to class IIb only; III, IV: Dental units and dental patient chairs only.
MD 1107	NB 0598	II			V	VI	II: Up to class IIb only
MD 1108	NB 0598	II	III	IV	V	VI	II: Up to class IIb only; III, IV: Neurological and muscular rehabilitation devices only.
MD 1109	NB 0598	II	III	IV	V	VI	II: Up to class IIb only
MD 1111	NB 0598	II			V	VI	II: Up to class IIb only
MD 1201	NB 0598	II	III	IV	V	VI	II: Up to class IIb only; III, IV: X-ray devies only
MD 1202	NB 0598	II	III	IV	V	VI	II: Up to class IIb only; III, IV: Magnetic resonance imaging (MRI) devices only
MD 1301	NB 0598	II	III	IV	V	VI	II: Up to class IIb only
MD 1302	NB 0598	II	III	IV	V	VI	II: Up to class IIb only
MD 1401	NB 0598	II			V	VI	II: Up to class IIb only
MD 1402	NB 0598	II	III	IV	V	VI	II: Up to class IIb only; III, IV: Surgical ultrasound devices only
MD 1403	NB 0598	II			V	VI	II: Up to class IIb only
MD 0103	NB 0633	II		IV	V	VI	
MD 0106	NB 0633	II		IV	V	VI	
MD 1101	NB 0633	II		IV	V	VI	
MD 1102	NB 0633	II		IV	V	VI	
MD 1103	NB 0633	II		IV	V	VI	
MD 1104	NB 0633	II		IV	V	VI	
MD 1105	NB 0633	II		IV	V	VI	
MD 1106	NB 0633	II		IV	V	VI	
MD 1107	NB 0633	II		IV	V	VI	
MD 1108	NB 0633	II		IV	V	VI	
MD 1109	NB 0633	II		IV	V	VI	
MD 1111	NB 0633	II		IV	V	VI	
MD 1112	NB 0633	II		IV	V	VI	
MD 1202	NB 0633	II		IV	V	VI	
MD 1301	NB 0633	II		IV	V	VI	
MD 1302	NB 0633	II		IV	V	VI	
MD 0103	NB 0681	II	III	IV	V	VI	Excluding class II devices
MD 1108	NB 0681	II	III	IV	V	VI	Excluding class II devices
MD 1109	NB 0681	II	III	IV	V	VI	Excluding class II devices
MD 0101	NB 0805	II			V	VI	
MD 0102	NB 0805	II			V	VI	
MD 0103	NB 0805	II			V	VI	
MD 0104	NB 0805	II			V	VI	
MD 0105	NB 0805	II			V	VI	
MD 0106	NB 0805	II			V	VI	
MD 0108	NB 0805	II			V	VI	
MD 0109	NB 0805	II			V	VI	
MD 0301	NB 0805	II			V	VI	
MD 0302	NB 0805	II			V	VI	
MD 0303	NB 0805	II			V	VI	

MD 0401	NB 0805	II		V	VI	
MD 0402	NB 0805	II		V	VI	
MD 0403	NB 0805	II		V	VI	
MD 1101	NB 0805	II		V	VI	
MD 1102	NB 0805	II		V	VI	
MD 1103	NB 0805	II		V	VI	
MD 1104	NB 0805	II		V	VI	
MD 1105	NB 0805	II		V	VI	
MD 1106	NB 0805	II		V	VI	
MD 1107	NB 0805	II		V	VI	
MD 1108	NB 0805	II		V	VI	
MD 1109	NB 0805	II		V	VI	
MD 1110	NB 0805	II		V	VI	
MD 1111	NB 0805	II		V	VI	
MD 1201	NB 0805	II		V	VI	
MD 1202	NB 0805	II		V	VI	
MD 1301	NB 0805	II		V	VI	
MD 1302	NB 0805	II		V	VI	
MD 1401	NB 0805	II		V	VI	
MD 1402	NB 0805	II		V	VI	
MD 1403	NB 0805	II		V	VI	
MD 1404	NB 0805	II		V	VI	
MD 0101	NB 0843	II		V	VI	Limited to sterile single use devices, class IIb and below
MD 0102	NB 0843	II		V	VI	Limited to sterile single use devices and surgical instruments, class IIb and below
MD 0104	NB 0843	II		V	VI	Class IIb and below
MD 0106	NB 0843	II		V	VI	Class IIb and below
MD 0108	NB 0843	II		V	VI	Class IIb and below
MD 0301	NB 0843	II		V	VI	Class IIb and below
MD 0302	NB 0843	II		V	VI	Class IIb and below
MD 0303	NB 0843	II		V	VI	Limited to sterile single use devices, class IIb and below
MD 1101	NB 0843	II		V	VI	No class III or implants
MD 1102	NB 0843	II		V	VI	No class III or implants
MD 1103	NB 0843	II		V	VI	No class III or implants
MD 1104	NB 0843	II		V	VI	No class III or implants
MD 1105	NB 0843	II		V	VI	No class III or implants
MD 1106	NB 0843	II		V	VI	No class III or implants
MD 1107	NB 0843	II		V	VI	No class III or implants
MD 1108	NB 0843	II		V	VI	No class III or implants
MD 1109	NB 0843	II		V	VI	No class III or implants
MD 1111	NB 0843	II		V	VI	No class III or implants
MD 1201	NB 0843	II		V	VI	No class III or implants
MD 1202	NB 0843	II		V	VI	No class III or implants
MD 1301	NB 0843	II		V	VI	No class III or implants
MD 1302	NB 0843	II		V	VI	No class III or implants
MD 1401	NB 0843	II		V	VI	No class III or implants
MD 1402	NB 0843	II		V	VI	No class III or implants
MD 1403	NB 0843	II		V	VI	No class III or implants
MD 1404	NB 0843	II		V	VI	No class III or implants
MD 0101	NB 1011	II	III	V	VI	
MD 0102	NB 1011	II	III	V	VI	
MD 0103	NB 1011	II	III	V	VI	

MD 0104	NB 1011	II	III		V	VI	
MD 0106	NB 1011	II	III		V	VI	
MD 0107	NB 1011	II	III		V	VI	
MD 0108	NB 1011	II	III		V	VI	Annex III designation excluding materials of desinfecting, cleaning and rinsing. For Annex II, V, VI there are no limitations.
MD 0109	NB 1011	II	III		V	VI	
MD 0301	NB 1011	II	III		V	VI	
MD 0302	NB 1011	II	III		V	VI	
MD 0303	NB 1011	II			V	VI	
MD 0401	NB 1011	II	III		V	VI	
MD 0402	NB 1011	II			V	VI	
MD 0403	NB 1011	II	III		V	VI	
MD 1101	NB 1011	II	III		V	VI	
MD 1102	NB 1011	II	III		V	VI	
MD 1103	NB 1011	II	III		V	VI	
MD 1104	NB 1011	II	III		V	VI	
MD 1106	NB 1011	II	III		V	VI	
MD 1107	NB 1011	II	III		V	VI	
MD 1108	NB 1011	II	III		V	VI	
MD 1109	NB 1011	II	III		V	VI	
MD 1110	NB 1011	II	III		V	VI	
MD 1111	NB 1011	II	III		V	VI	
MD 1112	NB 1011	II	III		V	VI	
MD 1202	NB 1011	II	III		V	VI	
MD 1301	NB 1011	II	III		V	VI	
MD 1302	NB 1011	II	III		V	VI	
MD 1402	NB 1011	II	III		V	VI	
MD 1403	NB 1011	II	III		V	VI	
MD 0101	NB 1014	II			V	VI	
MD 0102	NB 1014	II			V	VI	
MD 0103	NB 1014	II			V	VI	
MD 0104	NB 1014	II			V	VI	
MD 0105	NB 1014	II			V	VI	
MD 0106	NB 1014	II			V	VI	
MD 0107	NB 1014	II			V	VI	
MD 0108	NB 1014	II			V	VI	
MD 0201	NB 1014	II			V	VI	
MD 0202	NB 1014	II			V	VI	
MD 0203	NB 1014	II			V	VI	
MD 0204	NB 1014	II			V	VI	
MD 0301	NB 1014	II			V	VI	
MD 0302	NB 1014	II			V	VI	
MD 0303	NB 1014	II			V	VI	
MD 0401	NB 1014	II			V	VI	
MD 0402	NB 1014	II			V	VI	
MD 0403	NB 1014	II			V	VI	
MD 1101	NB 1014	II	III	IV	V	VI	
MD 1102	NB 1014	II	III	IV	V	VI	
MD 1103	NB 1014	II	III	IV	V	VI	
MD 1104	NB 1014	II	III	IV	V	VI	
MD 1105	NB 1014	II	III	IV	V	VI	
MD 1106	NB 1014	II	III	IV	V	VI	
MD 1107	NB 1014	II	III	IV	V	VI	

MD 1108	NB 1014	II	III	IV	V	VI	
MD 1109	NB 1014	II	III	IV	V	VI	
MD 1111	NB 1014	II	III	IV	V	VI	
MD 1112	NB 1014	II	III	IV	V	VI	
MD 1201	NB 1014	II	III	IV	V	VI	
MD 1202	NB 1014	II	III	IV	V	VI	
MD 1301	NB 1014	II	III	IV	V	VI	
MD 1302	NB 1014	II	III	IV	V	VI	
MD 1401	NB 1014	II	III	IV	V	VI	
MD 1402	NB 1014	II	III	IV	V	VI	
MD 1403	NB 1014	II	III	IV	V	VI	
MD 1404	NB 1014	II	III	IV	V	VI	
MD 0101	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb plus baloon catheters plus stent delivery systems
MD 0102	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb plus epidural sets
MD 0104	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 0105	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 0106	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 0108	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 0201	NB 1023	II			V	VI	Limited to cardiovascular stents including stent inserting tools plus cardiac valves not containing animal tissues.
MD 0202	NB 1023	II			V	VI	Limited to devices of Class IIb
MD 0203	NB 1023	II			V	VI	Limited to devices of Class IIb oesophageal, ureteral and biliary stents
MD 0204	NB 1023	II			V	VI	Limited to devices of Class IIb plus injection implants based on hyaluronic acid and hyaluronic acid derivates
MD 0301	NB 1023	II			V	VI	Limited to devices of Class Is, IIa, IIb plus wound dressing, being wholly or mainly absorbed and/or incorporating medicinal substances
MD 0302	NB 1023	II			V	VI	Limited to devices of Class Is, IIa, IIb plus devices being wholly or mainly absorbed plus sutures for the central circulatory system
MD 0303	NB 1023	II			V	VI	Limited to devices of Class Is, IIa, IIb plus wound care devices being wholly or mainly absorbed and/or incorporating medicinal substances.
MD 0401	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 0402	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 0403	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1101	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1102	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1103	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1104	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1105	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1106	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1107	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1108	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1111	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1201	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1202	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1302	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb
MD 1402	NB 1023	II			V	VI	Limited to devices of Classes Im, Is, IIa, IIb

MD 1403	NB 1023	II	V	VI	Limited to devices of Classes Im, Is, Ila, llb
MD 0102	NB 1250	II	V	VI	
MD 0103	NB 1250	II	V	VI	
MD 0104	NB 1250	II	V	VI	
MD 0106	NB 1250	II	V	VI	
MD 0108	NB 1250	II	V	VI	
MD 0202	NB 1250	II	V	VI	
MD 0301	NB 1250	II	V	VI	
MD 0303	NB 1250	II	V	VI	
MD 0401	NB 1250	II	V	VI	
MD 0402	NB 1250	II	V	VI	
MD 0403	NB 1250	II	V	VI	
MD 1101	NB 1250	II	V	VI	Excluding heart-lung machine
MD 1103	NB 1250	II	V	VI	Excluding life sustaining devices
MD 1104	NB 1250	II	V	VI	
MD 1106	NB 1250	II	V	VI	
MD 1111	NB 1250	II	V	VI	
MD 1112	NB 1250	II	V	VI	
MD 1301	NB 1250	II	V	VI	
MD 1302	NB 1250	II	V	VI	Without devices specifically intended for monitoring of vital physiological parameters where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS
MD 1404	NB 1250	II	V	VI	
MD 0101	NB 1254	II	V	VI	Single-use medical devices
MD 0102	NB 1254	II	V	VI	Single-use medical devices
MD 0103	NB 1254	II	V	VI	
MD 0104	NB 1254	II	V	VI	Reusable instruments
MD 0105	NB 1254	II	V	VI	Single-use medical devices
MD 0106	NB 1254	II	V	VI	
MD 0107	NB 1254	II	V	VI	Single-use medical devices
MD 0108	NB 1254	II	V	VI	Single-use medical devices
MD 0110	NB 1254	II	V	VI	
MD 0202	NB 1254	II	V	VI	
MD 0203	NB 1254	II	V	VI	
MD 0301	NB 1254	II	V	VI	
MD 0302	NB 1254	II	V	VI	
MD 0303	NB 1254	II	V	VI	
MD 0401	NB 1254	II	V	VI	
MD 0402	NB 1254	II	V	VI	
MD 0403	NB 1254	II	V	VI	
MD 1106	NB 1254	II	V	VI	
MD 1109	NB 1254	II	V	VI	
MD 1202	NB 1254	II	V	VI	
MD 1301	NB 1254	II	V	VI	
MD 0101	NB 1282	II	V	VI	Excluding class III devices
MD 0102	NB 1282	II	V	VI	Excluding class III devices
MD 0106	NB 1282	II	V	VI	Excluding class III devices
MD 0108	NB 1282	II	V	VI	Excluding class III devices
MD 0301	NB 1282	II	V	VI	Excluding class III devices
MD 1101	NB 1282	II	V	VI	Excluding class III devices
MD 1103	NB 1282	II	V	VI	Excluding class III devices

MD 1104	NB 1282	II			V	VI	Excluding class III devices
MD 1107	NB 1282	II			V	VI	Excluding class III devices
MD 1108	NB 1282	II			V	VI	Excluding class III devices
MD 1109	NB 1282	II			V	VI	Excluding class III devices
MD 1111	NB 1282	II			V	VI	Excluding class III devices
MD 1301	NB 1282	II			V	VI	Excluding class III devices
MD 1302	NB 1282	II			V	VI	Excluding class III devices
MD 1402	NB 1282	II			V	VI	Excluding class III devices
MD 0101	NB 1304	II			V	VI	
MD 0102	NB 1304	II			V	VI	Included only devices for injection, infusion and transfusion
MD 0103	NB 1304	II			V	VI	
MD 0104	NB 1304	II			V	VI	
MD 0105	NB 1304	II			V	VI	
MD 0106	NB 1304	II			V	VI	
MD 0301	NB 1304	II			V	VI	
MD 0302	NB 1304	II			V	VI	
MD 0303	NB 1304	II			V	VI	
MD 0401	NB 1304	II			V	VI	
MD 1101	NB 1304	II			V	VI	Only infant incubators included
MD 1102	NB 1304	II			V	VI	Included only devices for respiratory devices
MD 1103	NB 1304	II	III	IV	V	VI	
MD 1104	NB 1304	II			V	VI	
MD 1105	NB 1304	II	III	IV	V	VI	Annex III and IV lasers only
MD 1106	NB 1304	II	III	IV	V	VI	Annex III and IV lasers only
MD 1107	NB 1304	II			V	VI	
MD 1109	NB 1304	II			V	VI	
MD 1111	NB 1304	II			V	VI	
MD 1201	NB 1304	II			V	VI	
MD 1202	NB 1304	II	III	IV	V	VI	
MD 1301	NB 1304	II	III	IV	V	VI	
MD 1302	NB 1304	II	III	IV	V	VI	
MD 1402	NB 1304	II			V	VI	
MD 0101	NB 1370	II			V	VI	Excluding class III medical devices
MD 0102	NB 1370	II			V	VI	Excluding class III medical devices
MD 0103	NB 1370	II			V	VI	Excluding class III medical devices
MD 0105	NB 1370	II			V	VI	Excluding class III medical devices
MD 0106	NB 1370	II			V	VI	Excluding class III medical devices
MD 0108	NB 1370	II			V	VI	Excluding class III medical devices
MD 0301	NB 1370	II			V	VI	Excluding class III medical devices
MD 0302	NB 1370	II			V	VI	Excluding class III medical devices
MD 0303	NB 1370	II			V	VI	Excluding class III medical devices
MD 0401	NB 1370	II			V	VI	Excluding class III medical devices
MD 0402	NB 1370	II			V	VI	Excluding class III medical devices
MD 0403	NB 1370	II			V	VI	Excluding class III medical devices
MD 1102	NB 1370	II			V	VI	Excluding class III medical devices, hyperbaric chambers for oxygen therapy and medical gas pipeline systems
MD 1103	NB 1370	II			V	VI	Excluding class III medical devices
MD 1104	NB 1370	II			V	VI	Excluding class III medical devices
MD 1106	NB 1370	II			V	VI	Excluding class III medical devices
MD 1107	NB 1370	II			V	VI	Excluding class III medical devices
MD 1108	NB 1370	II			V	VI	Excluding class III medical devices
MD 1111	NB 1370	II			V	VI	Excluding class III medical devices

MD 1201	NB 1370	II			V	VI	Excluding class III medical devices
MD 1301	NB 1370	II			V	VI	Excluding class III medical devices
MD 1302	NB 1370	II			V	VI	Excluding class III medical devices
MD 1403	NB 1370	II			V	VI	Excluding class III medical devices
MD 0101	NB 1434	II	III	IV	V	VI	
MD 0102	NB 1434	II	III	IV	V	VI	
MD 0103	NB 1434	II	III	IV	V	VI	
MD 0104	NB 1434	II	III	IV	V	VI	
MD 0105	NB 1434	II	III	IV	V	VI	
MD 0106	NB 1434	II	III	IV	V	VI	
MD 0107	NB 1434	II	III	IV	V	VI	
MD 0108	NB 1434	II	III	IV	V	VI	
MD 0110	NB 1434	II	III	IV	V	VI	
MD 0201	NB 1434	II	III	IV	V	VI	
MD 0202	NB 1434	II	III	IV	V	VI	
MD 0203	NB 1434	II	III	IV	V	VI	
MD 0204	NB 1434	II	III	IV	V	VI	
MD 0301	NB 1434	II	III	IV	V	VI	
MD 0302	NB 1434	II	III	IV	V	VI	
MD 0303	NB 1434	II	III	IV	V	VI	
MD 0401	NB 1434	II	III	IV	V	VI	
MD 0402	NB 1434	II	III	IV	V	VI	
MD 0403	NB 1434	II	III	IV	V	VI	
MD 1101	NB 1434	II	III	IV	V	VI	
MD 1102	NB 1434	II	III	IV	V	VI	
MD 1103	NB 1434	II	III	IV	V	VI	
MD 1104	NB 1434	II	III	IV	V	VI	
MD 1105	NB 1434	II	III	IV	V	VI	
MD 1106	NB 1434	II	III	IV	V	VI	
MD 1107	NB 1434	II	III	IV	V	VI	
MD 1108	NB 1434	II	III	IV	V	VI	
MD 1109	NB 1434	II	III	IV	V	VI	
MD 1111	NB 1434	II	III	IV	V	VI	
MD 1112	NB 1434	II	III	IV	V	VI	
MD 1201	NB 1434	II	III	IV	V	VI	
MD 1202	NB 1434	II	III	IV	V	VI	
MD 1301	NB 1434	II	III	IV	V	VI	
MD 1302	NB 1434	II	III	IV	V	VI	
MD 1401	NB 1434	II	III	IV	V	VI	
MD 1402	NB 1434	II	III	IV	V	VI	
MD 1403	NB 1434	II	III	IV	V	VI	
MD 0101	NB 1936	II			V	VI	Excluding class II medical devices
MD 0102	NB 1936	II			V	VI	
MD 0103	NB 1936	II			V	VI	Excluding class II medical devices
MD 0104	NB 1936	II			V	VI	Excluding class II medical devices
MD 0105	NB 1936	II			V	VI	Excluding class II medical devices
MD 0106	NB 1936	II			V	VI	
MD 0108	NB 1936	II			V	VI	Excluding class II medical devices
MD 0110	NB 1936	II			V	VI	Excluding class II medical devices
MD 0202	NB 1936	II			V	VI	
MD 0204	NB 1936	II			V	VI	Excluding class II medical devices
MD 0301	NB 1936	II			V	VI	Excluding class II medical devices
MD 0302	NB 1936	II			V	VI	
MD 0303	NB 1936	II			V	VI	Excluding class II medical devices

MD 0401	NB 1936	II			V	VI	Excluding class II medical devices
MD 0402	NB 1936	II			V	VI	Excluding class II medical devices
MD 0403	NB 1936	II			V	VI	Excluding class II medical devices
MD 1101	NB 1936	II	III	IV	V	VI	Excluding class II medical devices
MD 1102	NB 1936	II	III	IV	V	VI	Excluding class II medical devices and hyperbaric chambers for oxygen therapy
MD 1103	NB 1936	II	III	IV	V	VI	
MD 1104	NB 1936	II	III	IV	V	VI	
MD 1105	NB 1936	II			V	VI	Excluding class II medical devices
MD 1106	NB 1936	II	III	IV	V	VI	Excluding class II medical devices
MD 1107	NB 1936	II			V	VI	Excluding class II medical devices
MD 1108	NB 1936	II	III	IV	V	VI	Excluding class II medical devices
MD 1109	NB 1936	II	III	IV	V	VI	Excluding class II medical devices
MD 1111	NB 1936	II			V	VI	Excluding class II medical devices
MD 1112	NB 1936	II			V	VI	Excluding class II medical devices
MD 1201	NB 1936	II			V	VI	Excluding class II medical devices
MD 1301	NB 1936	II	III	IV	V	VI	Excluding class II medical devices
MD 1302	NB 1936	II	III	IV	V	VI	
MD 1401	NB 1936	II			V	VI	Excluding class II medical devices
MD 1402	NB 1936	II		IV	V	VI	Excluding class II medical devices
MD 1403	NB 1936	II			V	VI	Excluding class II medical devices
MD 0101	NB 2265	II			V	VI	
MD 0102	NB 2265	II			V	VI	
MD 0103	NB 2265	II			V	VI	
MD 0104	NB 2265	II			V	VI	
MD 0105	NB 2265	II			V	VI	
MD 0106	NB 2265	II			V	VI	
MD 0107	NB 2265	II			V	VI	
MD 0108	NB 2265	II			V	VI	
MD 0109	NB 2265	II			V	VI	
MD 0110	NB 2265	II			V	VI	
MD 0201	NB 2265	II			V	VI	
MD 0202	NB 2265	II			V	VI	
MD 0203	NB 2265	II			V	VI	
MD 0204	NB 2265	II			V	VI	
MD 0301	NB 2265	II			V	VI	
MD 0302	NB 2265	II			V	VI	
MD 0303	NB 2265	II			V	VI	
MD 0401	NB 2265	II			V	VI	
MD 0402	NB 2265	II			V	VI	
MD 0403	NB 2265	II			V	VI	
MD 1101	NB 2265	II			V	VI	
MD 1102	NB 2265	II			V	VI	
MD 1103	NB 2265	II			V	VI	
MD 1104	NB 2265	II			V	VI	
MD 1105	NB 2265	II			V	VI	
MD 1106	NB 2265	II			V	VI	
MD 1107	NB 2265	II			V	VI	
MD 1108	NB 2265	II			V	VI	
MD 1109	NB 2265	II			V	VI	
MD 1110	NB 2265	II			V	VI	
MD 1111	NB 2265	II			V	VI	
MD 1201	NB 2265	II			V	VI	
MD 1202	NB 2265	II			V	VI	

MD 1301	NB 2265	II	V	VI	
MD 1302	NB 2265	II	V	VI	
MD 1401	NB 2265	II	V	VI	
MD 1402	NB 2265	II	V	VI	
MD 1403	NB 2265	II	V	VI	
MD 1404	NB 2265	II	V	VI	
MD 0101	NB 2274	II	V	VI	
MD 0102	NB 2274	II	V	VI	
MD 0103	NB 2274	II	V	VI	
MD 0104	NB 2274	II	V	VI	
MD 0106	NB 2274	II	V	VI	
MD 0108	NB 2274	II	V	VI	
MD 0301	NB 2274	II	V	VI	
MD 0303	NB 2274	II	V	VI	
MD 1101	NB 2274	II	V	VI	
MD 1102	NB 2274	II	V	VI	
MD 1103	NB 2274	II	V	VI	
MD 1104	NB 2274	II	V	VI	
MD 1106	NB 2274	II	V	VI	
MD 1107	NB 2274	II	V	VI	
MD 1108	NB 2274	II	V	VI	Without active protheses
MD 1109	NB 2274	II	V	VI	
MD 1111	NB 2274	II	V	VI	
MD 1112	NB 2274	II	V	VI	
MD 1201	NB 2274	II	V	VI	
MD 1202	NB 2274	II	V	VI	
MD 1301	NB 2274	II	V	VI	
MD 1302	NB 2274	II	V	VI	
MD 1401	NB 2274	II	V	VI	
MD 1402	NB 2274	II	V	VI	
MD 0101	NB 2409	II	V	VI	
MD 0102	NB 2409	II	V	VI	
MD 0103	NB 2409	II	V	VI	
MD 0104	NB 2409	II	V	VI	
MD 0105	NB 2409	II	V	VI	
MD 0106	NB 2409	II	V	VI	
MD 0107	NB 2409	II	V	VI	
MD 0108	NB 2409	II	V	VI	
MD 0109	NB 2409	II	V	VI	
MD 0110	NB 2409	II	V	VI	
MD 0201	NB 2409	II	V	VI	
MD 0202	NB 2409	II	V	VI	
MD 0203	NB 2409	II	V	VI	
MD 0204	NB 2409	II	V	VI	
MD 0301	NB 2409	II	V	VI	
MD 0302	NB 2409	II	V	VI	
MD 0303	NB 2409	II	V	VI	
MD 0401	NB 2409	II	V	VI	
MD 0402	NB 2409	II	V	VI	
MD 0403	NB 2409	II	V	VI	
MD 1101	NB 2409	II	V	VI	
MD 1102	NB 2409	II	V	VI	
MD 1103	NB 2409	II	V	VI	
MD 1104	NB 2409	II	V	VI	

MD 1105	NB 2409	II	V	VI
MD 1106	NB 2409	II	V	VI
MD 1107	NB 2409	II	V	VI
MD 1108	NB 2409	II	V	VI
MD 1111	NB 2409	II	V	VI
MD 1202	NB 2409	II	V	VI
MD 1301	NB 2409	II	V	VI
MD 1302	NB 2409	II	V	VI
MD 1402	NB 2409	II	V	VI

Table A13-2. List of all notified bodies with all the medical device types (by MD code) by which are accredited, and by which conformity assessment procedures. Limitations are included.

Last updated: 28/05/2018