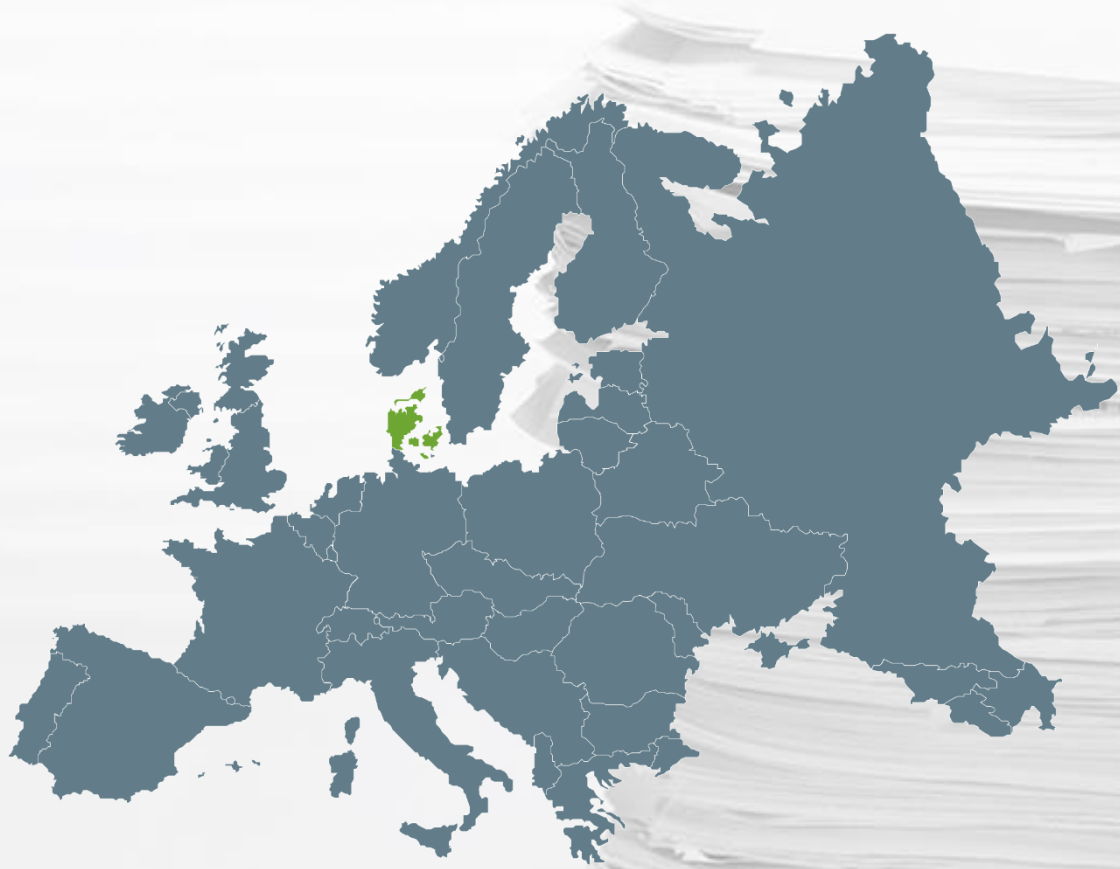
## Annex VIII

# Classification Rules

**Based on the classification of your device, you can lay down your regulatory pathway, and identify the appropriate conformity assessment route for your device to ensure fastest time to market by defining the best regulatory strategy.**

This strategy is to ensure performance of only the activities required, ensuring fastest track to compliance and CE marking of your device.



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# Annex VIII: Classification Rules

**The changes to the classification rules in the MDR will require manufacturers to make some important changes. Many of the changes in the MDR are a result of the MDD not taking into account the level of invasiveness and potential toxicity of some devices.**

- The Medical Device Directive (MDD) presented 18 classification rules
- The Medical Device Regulation (MDR) presents 22 classification rules
- Be aware many class I devices will need to be reclassified! Naturally, greatly increasing the Technical Documentation (TD) requirements, as well as requirements for NB approval

NEW

- The new MDR classification rules introduce a NEW device class: **Class Ir (reprocessing)**
- Further, products such as non-medical and cosmetic devices not previously regulated have been included in the MDR and must also be classified, e.g. products for cleaning, disinfection or sterilization of devices, contact lenses, liposuction equipment, or epilation lasers.

The MDR categorizes devices into four classes, as previous: class I, class IIa, class IIb and class III. Subclasses to class I has been expanded to cover, in addition to Im (measuring) and Is (sterile), reprocessed devices (Ir).

In the MDR there are 22 classification rules, vs 18 in the MDD, clearly indicating the magnitude of changes. The rules consider the device function, the risk to patients and the manufacturer's intended use.

There are specific sets of classification rules for four different categories of medical devices:

- Non-invasive (rule 1-4),
- Invasive (rule 5-8),
- Active (rule 9-13),
- Special rules (rule 14-22) for innovative devices that include other substances such as nanomaterial, medicinal products, disinfectants etc.

Manufacturers should be aware that it is absolutely critical to classify devices correctly from the beginning as it dictates the manufacturing requirements, clinical evaluation and conformity assessment. This is also where the possibility for the regulatory strategy starts. Classify correctly to ensure fastest track to market (CE mark).

This is also why, to ere on the side of caution, manufacturers should review all current and future devices to ensure compliance with the amended classification system.

As an example devices such as e.g. spinal disc replacement implants and other devices that come into contact with the spinal column are up-classified from IIb into class III. In addition, class I devices which are reprocessed may also have to be up-classified.

Software used to make decisions with diagnosis or for therapeutic purposes will also be reclassified as it is no longer classified as an active device.

Software does now have its own Rule 11.

# Annex VIII: Classification Rules

## Changes to the Classification Rules

The rules that have changed, and the relevant changes, are listed below. Rules with no changes are not listed (1, 5, 12, 13, 15, 17).

### Non-Invasive Devices

**Rule 2** Now includes cells and tissues. Blood bags are now contained in this rule (previously rule 18 MDD);

**Rule 3** Now includes human tissues or cells. Also, devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body (Class III);

**Rule 4** Addition of injured mucous membrane, as well as applicable to invasive devices.

### Invasive Devices

**Rule 6 and 7** Heart and circulatory system added for devices intended specifically for direct contact with (Class III);

**Rule 8** Addition of active implantable devices and accessories, breast implants, surgical mesh, total or partial joint or spinal disc replacement implants, or just implantable devices in contact with the spinal column (Class III). N/A for components, e.g. screws, wedges, plates or instruments.

### Active Devices

**Rule 9** All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance (Class IIb).

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices (Class III).

**Rule 10** Addition of devices intended for diagnosis in clinical situations where the patient is in immediate danger (Class IIb)

NEW

**Rule 11** on Software providing information used to take decisions with diagnosis or therapeutic purposes (Class IIa), except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health (Class III); or
- a serious deterioration of a person's state of health or a surgical intervention (Class IIb).
- Software intended to monitor physiological processes (Class IIa), except if it is intended for monitoring of vital physiological parameters,
- where the nature of variations of those parameters is such that it could result in immediate danger to the patient (Class IIb).
- All other software (Class I).

OBS: There will be hardly any stand-alone software left being classified as class I. Almost any software used for the purpose of diagnosis, monitoring, prediction, prognosis or treatment also provides information which is used to take decisions with diagnosis or therapeutic purposes.

**Rule 12 and 13** are the previous rule 11 and 12.

# Annex VIII: Classification Rules

## Changes to the Classification Rules

Cont.

### Special Rules

**Rule 14** (previous 13) including a medicinal product derived from human blood or human plasma (Class III). “liable to act” is removed.

**Rule 15 and 17** are the previous rule 14 and 16.

**Rule 16** (Previous 15) sterilizers included as addition to disinfectants (Class IIa). Also disinfecting solutions or washer-disinfectors for invasive devices, as the end point of processing (Class IIb)

**Rule 18** (Previous 17) Addition of cells of human/animal origin to tissue or derivatives (Class III). Devices manufactured using cells, tissue or derivatives of animal origin are excepted if contact is with intact skin only.

NEW

### Special Rules

**Rule 19** Devices incorporating or consisting of nanomaterial; Classified acc. to internal exposure potential;

- Class III; high or medium
- Class IIb; low
- Class IIa; negligible

**Rule 20** Invasive devices (body orifices, not surgically) for administration of medicinal products by inhalation (Class IIa), unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product, or they are intended to treat life-threatening conditions (Class IIb).

**Rule 21** Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:

- Class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
- Class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;
- Class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and
- Class IIb in all other cases.

**Rule 22** Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

# Annex VIII: Classification Rules

## Take Aways

**Correct Classification**
Ensures that the regulatory pathway is correct from the start and therefore facilitates a smoother process, and shortens time to market drastically

= Good business

**Incorrect Classification**
Can have serious repercussions which can result in project delays and significant budget overruns, loss of credibility and stakeholder disapproval and maybe even customer dissatisfaction (if they have been promised this new product

= Bad business

For low risk devices in class I which are self-certification (not Is, Im, or Ir), this is especially critical as the devices are placed on the market without NB approval. However if audited by the national authorities and the device is wrongly classified into class I, it can result in the CE mark being removed, recalls and other liabilities.

For more on classification, request our **Classification Tool** which will take you through the classification process in a systematic, yet simple way, and can help you in your reclassification process of your product portfolio.

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