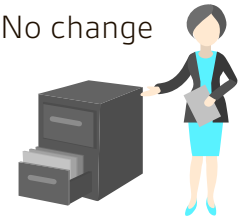
MDR Classification Rules

This document allows you to detail how you intend to meet the additional requirements of the new Regulation, so should be used in conjunction with Regulation (EU) 2017/745. It is NOT an exhaustive checklist, but contains summary statements of the significant changes. The list below is a top level summary of products that may have changed classification. Manufacturers are recommended to evaluate Annex VIII fully.

Non-invasive devices (in comparison with MDD)

1 RULE

- No change



2 RULE

- Addition of "cells and tissues" to the existing language
- Blood bags moved to MDR Rule 2 from Rule 18 of MDD

3 RULE

- Addition of human tissues and cells to blood, body liquids and other liquids
- Intended for implantation or administration vs Intended for infusion in MDD
- Inclusion of organ storage solutions, IVF media into the rule which are class III

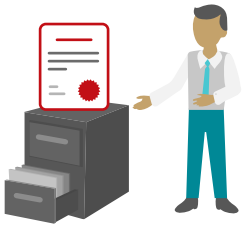
4 RULE

- Addition of injured mucous membrane to injured skin
- Replacement of 'wounds' with injuries to skin
- Also covers invasive devices that come into contact with injured mucous membrane

Invasive devices (in comparison with MDD/AIMDD)

5 RULE

- No change – clarifications only



6 RULE

- All devices intended specifically for direct contact with heart or central circulatory system now class III similar to devices in contact with central nervous system

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- All devices intended specifically for direct contact with heart or central circulatory system now class III similar to devices in contact with central nervous system

8 RULE

- AIMDD devices and accessories are class III
- Breast implants and surgical meshes are class III
- Total and partial joint replacements are class III
- Spinal disc replacement implants or implantable devices that come into contact with spinal column are class III with some exceptions (screws, wedges, plates and instruments)

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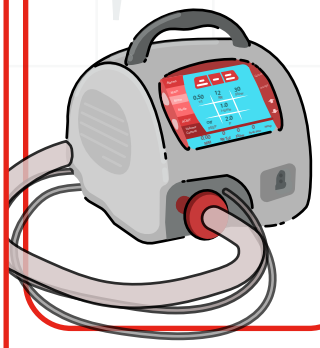
Active devices (in comparison with MDD/AIMDD)

9 RULE

- Addition of active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb
- Addition of active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III

10 RULE

- Addition of 'monitoring' to diagnosis
- Active devices intended for diagnosis in clinical situations where the patient is in immediate danger as class IIb

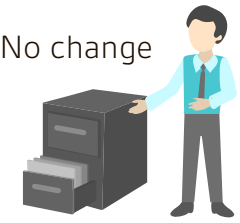


11 RULE

- New rule on software
- Classifications range from class III – class I

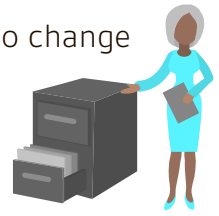
12 RULE

- Rule 11 in MDD
- No change



13 RULE

- Rule 12 in MDD
- No change



Special rules

14 RULE

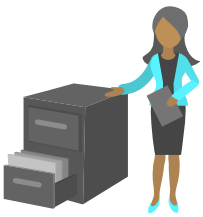
(Devices with medicinal substances)

- Rule 13 in MDD
- Clarification that medicinal product can be derived from human blood or plasma
- "Liable to act" taken out

15 RULE

(Contraceptive devices, devices for prevention of transmission of STDs)

- Rule 14 in MDD
- No change



16 RULE

(Disinfectants, sterilizers)

- Rule 15 in MDD
- Addition of sterilisers to disinfectants
- Disinfectants or sterilisers become IIb only if they are used for invasive devices and as the end point of processing

17 RULE

(Devices for recording x-ray diagnostic images)

- Rule 16 in MDD
- No change – language clarified

18 RULE

(Devices utilizing human or animal derivatives)

- Rule 17 in MDD
- Addition of cells (to tissues)
- Addition of human origin cells and tissues or derivatives
- The exception about contact with intact skin only, applies only to animal tissue and does not apply to human tissues or cells

19 RULE

(Devices incorporating or consisting of nanomaterials)

- New rule
- Classifications from III to IIa based on potential for internal exposure

20 RULE

(Body-orifice invasive devices intended to administer medicines by inhalation)

- New rule
- Classification IIa or IIb
- IIb if they impact the safety and performance of the medicine or intended to treat lifethreatening conditions

21 RULE

(Devices consisting of substances and introduced into the body via body orifice or skin and that are absorbed by or locally dispersed)

- New rule
- Classification from IIa to III based on where they are used and whether they or their products of metabolism are absorbed

22 RULE

(Active therapeutic device with an integrated or incorporated diagnostic function)

- New rule
- Class III
- Only applies if such devices significantly determine the patient management
- Closed loop systems or automated external defibrillators

Please note:

This document is a guide to help you to plan the changes for the MDR. This is not an exhaustive list and whilst BSI believes that it accurately reflects the regulatory environment at the time of publication, you should be aware that this is complex and can change. Therefore, this document is not to be considered as providing any legal advice and is not to be used as a substitute to reading the regulations directly or seeking advice from a qualified expert.

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