MDR Classification

Annex VIII

Classification Rules – MDR, Annex VIII

MDR

Rules 1 – 4: Non-invasive devices

Rules 5 – 8 : Invasive devices

Rules 9 – 13 : Active Devices

Rules 14 – 22 : Special rules

MDD

Rules 1 – 4 : Non-invasive devices

Rules 5 – 8 : Invasive devices

Rules 9 – 12 : Active devices

Rules 13 – 18 : Special rules

Rules 1 - 4: Non-invasive devices (in comparison with MDD)

Rule 1	Rule 2	Rule 3	Rule 4
• No change	• Addition of "cells and tissues" to the existing language • Blood bags moved to MDR Rule 2 from Rule 18 of MDD	• 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	• 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

Rules 5 – 8: Invasive devices (in comparison with MDD/AIMD)

Rule 5

- No change – clarifications only

Rule 6

- 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

Rule 7

- 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

Rule 8

- AIMD 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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Rules 9 – 13: Active Devices (in comparison with MDD/AIMD)

Rule 9

- 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.

Rule 10

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

Rule 11

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

Rule 12

- Rule 11 in MDD
- No change

Rule 13

- Rule 12 in MDD
- No change

Rules 14 – 18: Special rules

Rule 14 (Devices with medicinal substances)	Rule 15 (Contraceptive devices, Devices for prevention of transmission of STDs)	Rule 16 (Disinfectants, sterilizers)	Rule 17 (Devices for recording x-ray diagnostic images)	Rule 18 (Devices utilizing human or animal derivatives)
• Rule 13 in MDD • Clarification that medicinal product can be derived from human blood or plasma • "Liable to act" taken out	• Rule 14 in MDD • No change	• 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	• Rule 16 in MDD • No change – language clarified	• 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

Rules 19 – 22: Special rules

Rule 19 (Devices incorporating or consisting of nanomaterials)	Rule 20 (Body-orifice invasive devices intended to administer medicines by inhalation)	Rule 21 (Devices consisting of substances and introduced into the body via body orifice or skin and that are absorbed by or locally dispersed)	Rule 22 (Active therapeutic device with an integrated or incorporated diagnostic function)
• New rule • Classifications from III to IIa based on potential for internal exposure	• New rule • Classification IIa or IIb • IIb if they impact the safety and performance of the medicine or intended to treat life-threatening conditions	• New rule • Classification from IIa to III based on where they are used and whether they or their products of metabolism are absorbed	• New rule • Class III • Only applies if such devices significantly determine the patient management • Closed loop systems or automated external defibrillators

Conformity Assessment Procedures

Annex IX, X, XI

Classification & Conformity Assessment – MDD

Competent Authority Assessment

Notified Body Conformity Assessment

Self-Certification

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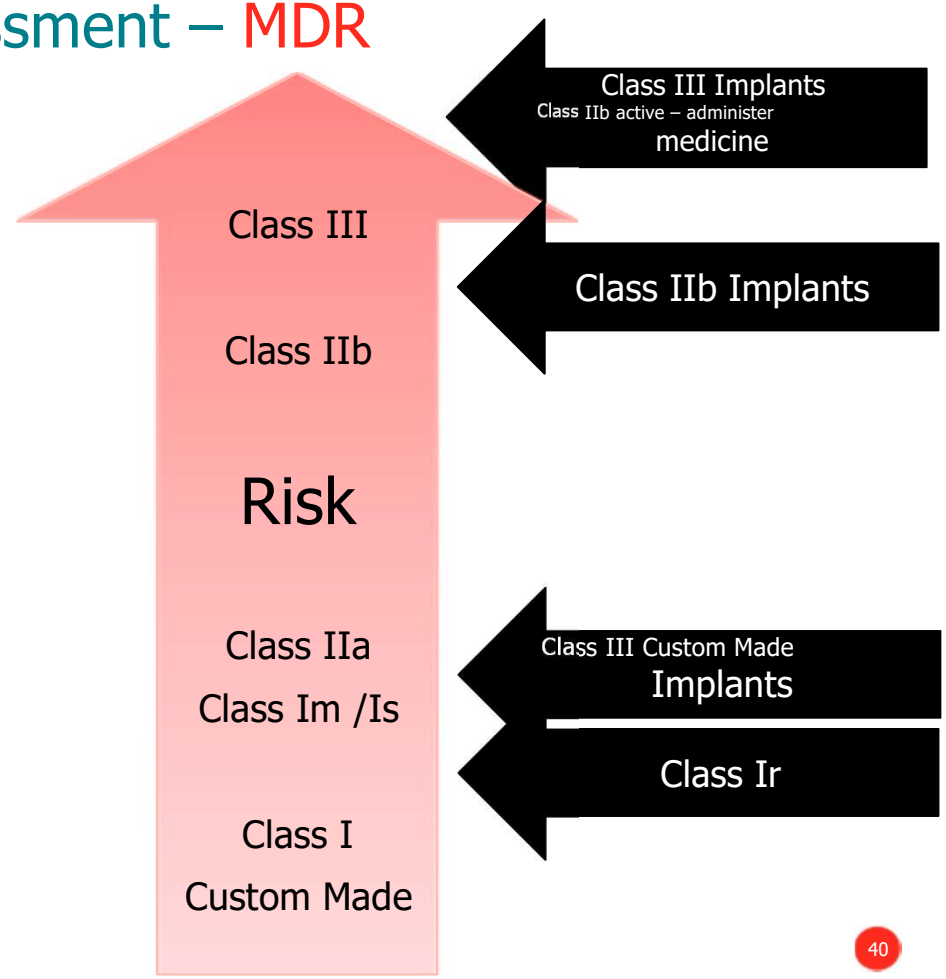
Classification & Conformity Assessment – MDR

Commission Assessment

Competent Authority Assessment

Notified Body Conformity Assessment

Self-Certification



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Regulation EU 2017/745 – Conformity Assessment

	Quality Management System	Microbiology	Technical Documentation	Unannounced Audit	Clinical Evaluation Consultation Procedure (CECP) (Article 54)	2001/83/EC EC/726/2004 2004/23/EC EU 722/2012	PSUR (Article 86) (*Annual)	SSCP (Article 32)
Class III Implants	✓	✓	✓	✓ 5 years	✓	✓	✓*	✓
Class III	✓	✓	✓	✓ 5 years		✓	✓*	✓
Class IIb Active Intended to administer and/or remove Medicines from the body	✓	✓	Sample per group	✓ 5 years	✓		✓* not submitted to NB	
Class IIb Implants	✓	✓	✓	✓ 5 years			✓*	✓
Sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins clips, connectors	✓	✓	Sample per group	✓ 5years			✓	✓
Class IIb	✓	✓	Sample per group	✓ 5years			✓* not submitted to NB	
Class IIa	✓	✓	Sample per category	✓ 5years			✓ not submitted to NB	

Regulation EU 2017/745 – Conformity Assessment

	Quality Management System	Microbiology	Technical Documentation	Unannounced Audit	Clinical Evaluation Consultation Procedure (CECP) (Article 54)	2001/83/EC EC/726/2004 2004/23/EC EU 722/2012	PSUR (Article 86) (*Annual)	SSCP (Article 32)
Class Is, Im, Ir	✓	✓		✓ 5years				
Class I								
Class III Custom Made Implants	✓	✓		✓ 5years			✓	
Custom Made								
Procedure Packs (Article 22)	✓	✓		✓ 5years				
Suppliers, Subcontractors	✓ *depends on certification held	✓ *depends on certification held		✓ 5years				
EU Authorised Representatives, Importers, Distributors (Article 16)	✓*impact sterile barrier, translate,	✓*impact sterile barrier, translate,		✓ 5years				
Drug Delivery Products (Arti