



General Safety & Performance Requirements in the new MDR

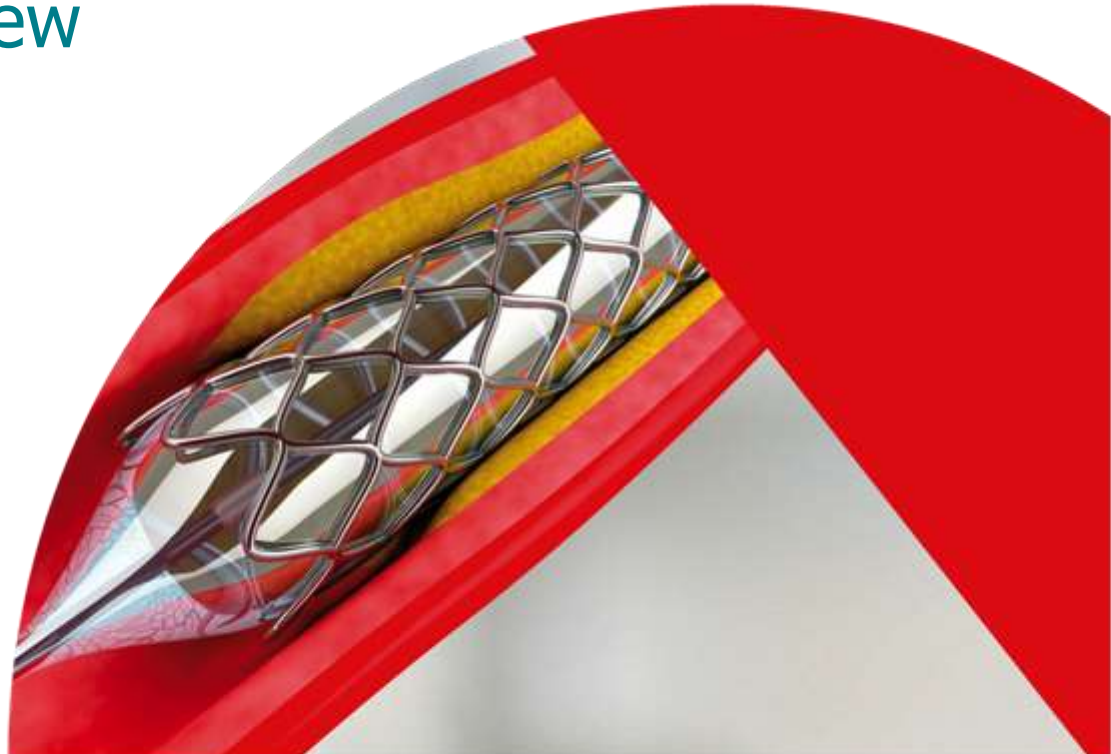
Maritza Carballo

Ronald Rakos

Alexandra Schroeder

BSI Webinars

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Introduction & Scope

- Focus of this webinar is the “ANNEX I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS” in new Regulation 2017-745 “MDR,” in comparison to Essential Requirements of the Medical Device Directive and Active Implantable Medical Device Directive
- There are many other areas of impact in the MDR outside the scope of this discussion, including (but not limited to):
 - Clinical data and evaluation requirements
 - Reclassification of some device types
 - Post-market requirements

Agenda

- Introduction
- Annex I, Chapter I: General Requirements
 - Performance & Lifetime
 - Risk Management
 - Devices without a Medical Purpose
- Annex II, Chapter II: Requirements Regarding Design and Manufacture
 - Packaging & Sterility
 - Medicinal and Biologically-Derived Substances
 - Chemical, Physical, and Biological Properties
 - Device-Specific Requirements
- Annex III, Chapter 3: Requirements Regarding the Information Supplied with the Device
 - Labeling
 - IFU
- Summary & Conclusions

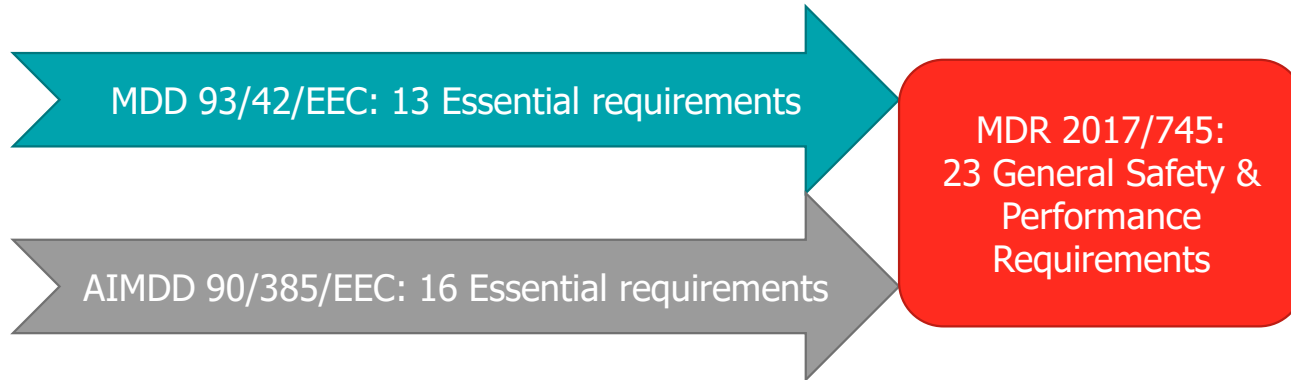


Essential
Requirements
(MDD/AIMD)

vs.

General Safety &
Performance
Requirements (MDR)

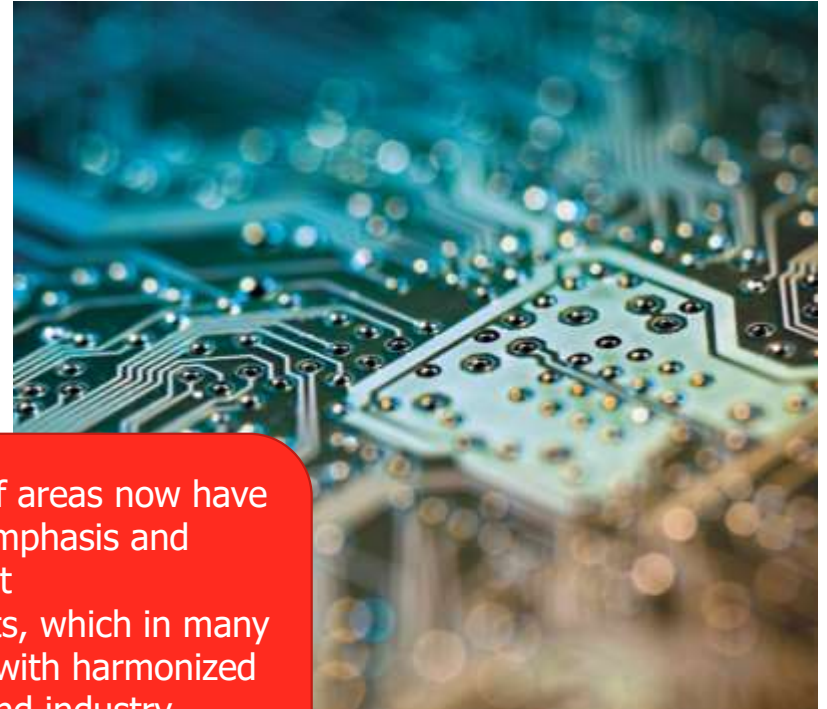
General Safety & Performance Requirements (Annex I)



- Similar to “Essential Requirements” in Directives.
 - Similar content and topics
 - Some numbering and organizational changes
 - Expanded requirements (Labeling, Risk)
 - New areas of emphasis (from standards and guidances, etc.)
 - Some additional requirements because of merging of MDD with AIMDD
 - Some topics move out of the SPR list into Articles/Annexes (clinical evaluation, medicinal consultation)
 - Some new topics introduced (devices without medical purpose, lay person use, etc.)

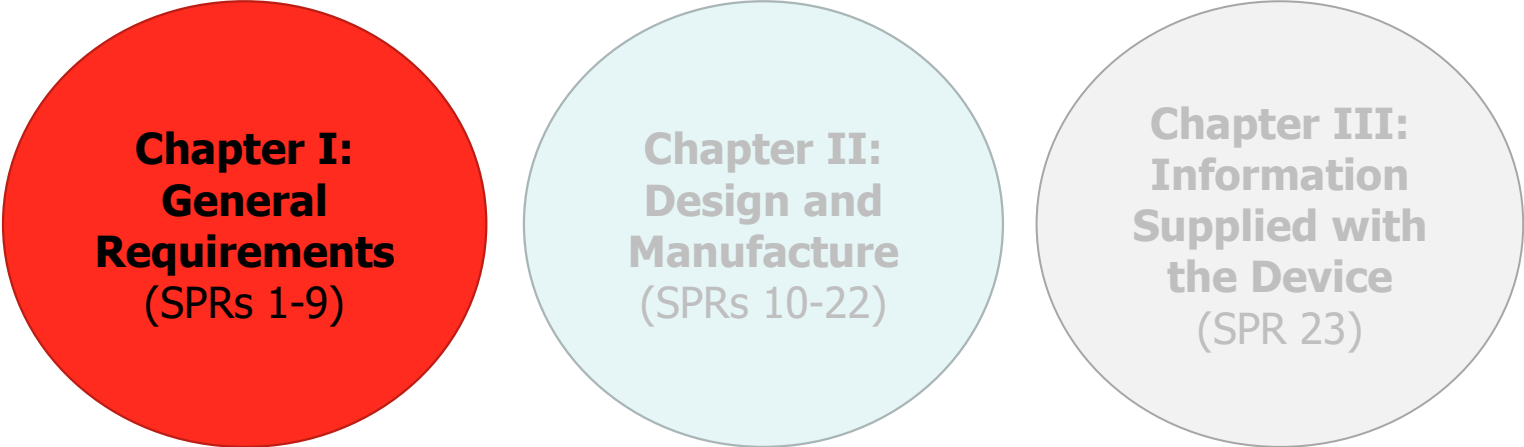
Areas of highest impact in Annex I

- Medicinal substances (and substances absorbed or locally dispersed)
- Devices incorporating materials of biological origin
- Substances of concern
- Labelling requirements
- Emphasis on cybersecurity



A number of areas now have increased emphasis and more explicit requirements, which in many cases align with harmonized standards and industry guidances

Annex I, Chapter I: General Requirements



**Chapter I:
General
Requirements**
(SPRs 1-9)

**Chapter II:
Design and
Manufacture**
(SPRs 10-22)

**Chapter III:
Information
Supplied with
the Device**
(SPR 23)

Performance & Lifetime – SPR 1, 6

- No major changes or new concepts
- “performance” intended brought in from ER 3 / 4 – into SPR 1
- ER 4 similar to SPR 6 (Lifetime)
- Performance now defined in Article 1: *‘performance’ means the ability of a device to achieve its intended purpose as claimed by the manufacturer;*
- Additional statement regarding Lifetime: *“has been properly maintained in accordance with the manufacturer’s instructions.”*
- ER 3 similar to SPR 6 → New : *“when the device is subjected to stresses”*

Reference Number			
SPR	MDD	AIMDD	Other
1	1, 2, 3	1, 2, 6	-
6	4	3	-

Legend:

Low Impact

Medium Impact

High Impact



Risk Management – SPR 1-5, 8

- The MDR is in alignment with EN ISO 14971:2012 and EN ISO 13485:2016
- Clarification statement SPR 2: *The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.*
- SPR 3 - Defines basics of Risk Management with many sub-parts.
- SPR 4 – similar to MDD ER 2 and AIMDD ER 6; **adds wording from EN ISO 14971:2012 Annex ZA/ZB (content deviations) and definitions of risk management procedure**
- SPR 5 – focus on risks related to use error, ergonomics
- SPR 8 - Risk-Benefit Ratio definition

Reference Number			
SPR	MDD	AIMDD	Other
1	1, 2, 3	1, 2, 6	-
2	2	8	-
3	-	-	EN ISO 14971
4	2	6	-
5	1	-	-
8	6	5	-

Legend:
Low Impact
Medium Impact
High Impact

Devices without a Medical Purpose – SPR 9

- SPR 9: New Requirement
- Devices without a medical purpose are new in scope of MDR, not in Directives
- Essentially clarifies how to apply/review the risk-benefit requirements when there is no medical benefit.
- *"For the devices referred to in Annex XVI, the general safety requirements set out in Sections [SPRs] 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons."*

SPR	Reference Number		
	MDD	AIMDD	Other
9	-	-	-

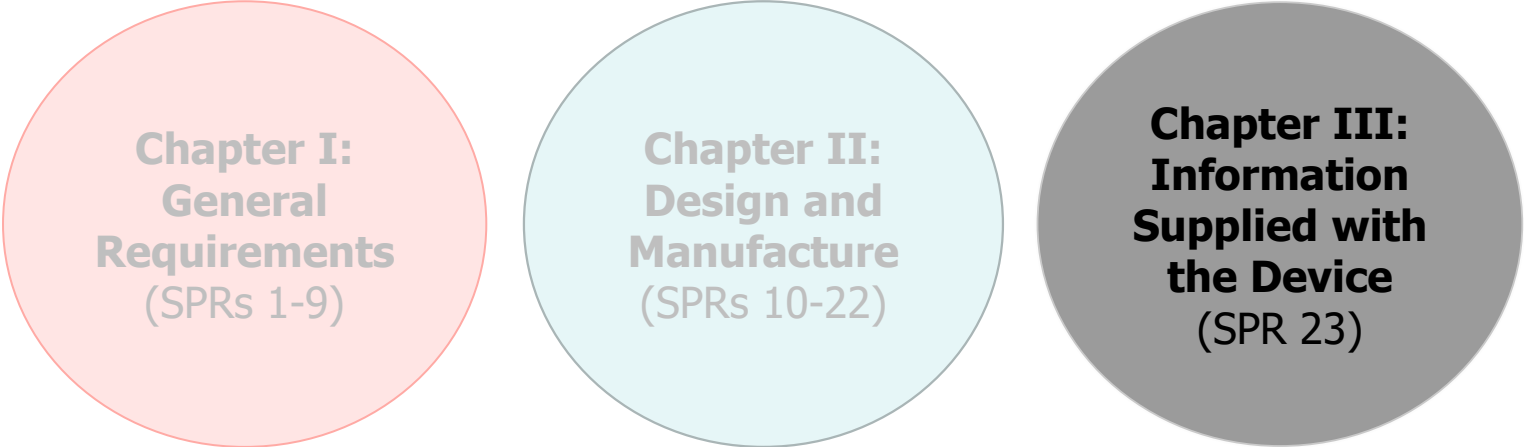


Clinical Evaluation Requirements – moved out of SPR list

- The explicit requirement for Clinical Evaluation is removed from the list of SPRs (current 6a/5a) – this shows up elsewhere.
 - No linkage from SPR list
- Aspects of performance, risk-benefit, etc., still tie to clinical evaluation
- **Annex XIV** “Clinical Evaluation and Post-Market Clinical Follow-Up”
- **Chapter VI, Article 61** – Clinical Evaluation
 - **Beyond the scope of the current ER / SPR discussion**

Reference Number			
SPR	MDD	AIMDD	Other
Absent	6a	5a	MDR Annex XIV

Annex I, Chapter II: Design and Manufacture



**Chapter I:
General
Requirements**
(SPRs 1-9)

**Chapter II:
Design and
Manufacture**
(SPRs 10-22)

**Chapter III:
Information
Supplied with
the Device**
(SPR 23)

Packaging Requirements – SPR 7, 11

- Overall very similar – not many changes
- SPR 7: “intended use will not be adversely affected during transport and storage (for example, fluctuations of temperature and humidity)”
 - SPR 7 similar to AIMDD ER 4, New : *Fluctuations*
 - ER 7 “storage and transport conditions stipulated by the manufacturer” is now also implemented in SPR 7 “instructions and information provided by the manufacturer”
- Clarification of ensuring integrity through whole product life cycle including handling, storage, delivery (SPR 11.4)
- Clearer requirements for packaging controls in manufacturing (SPR 11.6-11.7)
- Devices delivered sterile – *“These measures shall ensure that the integrity of the sterile packaging is clearly evident to the final user.”*
- Devices labelled as sterile shall be manufactured, packaged and sterilised by appropriate validated methods
- Devices intended to be sterilised shall be manufactured and packaged in ... controlled conditions and facilities
- Packaging for non-sterile devices shall maintain the integrity and cleanliness of the product

Reference Number			
SPR	MDD	AIMDD	Other
7	5	4	EN ISO 11607-2
11	8	7	EN ISO 13485 Sec. 7.5.7 EN ISO 11607-1/-2

Changes are primarily clarifications, and address gaps in language where packaging was not addressed

Infection and microbial contamination – SPR 11

- 11.1 (a) New: “reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries”
- 11.1 (c) New: “reduce as far as possible microbial leakage from the device and/or microbial exposure during use”
- 11.1(d) New: “prevent microbial contamination of the device or its content such as specimens or fluids.”
- 11.2: “Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.” – interpreted as only applying to devices designed for re-use
- 11.3: Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market, etc... - new requirement for devices with varying levels of microbial assurance; in addition to existing sterile requirements
- 11.4: Sterile packaging - “These measures shall ensure that the integrity of the sterile packaging is clearly evident to the final user.”
- Some of this wording is new to AIMDD: More explicit infection/microbial requirements

Reference Number			
SPR	MDD	AIMDD	Other
11.1	8.1	7	-
11.2	-	-	-
11.3	-	-	-
11.4	8.3	7	-
11.5	8.4	-	EN ISO 13485 Sec. 7.5.7 EN ISO 11607-1/-2
11.6	8.5	-	-
11.7	8.6	-	-
11.8	8.7	-	-



Chemical, physical and biological properties (Biological Safety) – SPR 10

- New wording but no major changes to how biological safety reviewed; text in line with EN ISO 10993
- Compatibility between materials and biological tissues, cells, fluids including "*absorption, distribution, metabolism, and excretion*"
- *the compatibility between the different parts of a device which consists of more than one implantable parts*" (SPR 10.1c)
- *Impact of processes on material properties*" – clarification / more explicit requirement (SPR 10.1d)
- Devices administering medicines – clarification that medicine is to be used within its approved indications (excluding "off-label" use) (SPR 10.3)
- New focuses: "Wear debris, degradation products, processing residues" (SPR 10.4.1)
- Risks linked to size and properties of particles (SPR 10.6) – considerations for nanomaterials or wear debris, etc.

Reference Number			
SPR	MDD	AIMDD	Other
10.1	7.1	9	ISO 10993 series
10.2	7.2	-	-
10.3	7.3	-	-
10.4	7.5	-	Regulation 1272/2008, Regulation 1907/2006, Regulation 528/2012
10.5	7.6	9	-
10.6	-	-	-

Substances [of concern] – SPR 10.4

- Longer and more specific than either of directives
- “Devices shall be designed and manufactured in such a way as to reduce ~~[... the risks posed by substances leaking from the device]~~ as far as possible the risks posed by substances or particles, including wear debris, degradation products, processing residues, that may be released from the device”
- Guidelines on carcinogenic, mutagenic, or toxic to reproduction (CMR) or endocrine disrupting substances
 - Concentration restrictions (0.1% w/w) specifically defined – specific justifications required above this limit
- Guidelines on phthalates – mandated updates by “relevant Scientific Committee” (this is a requirement for Commission update, and not a requirement on manufacturers – unusual/unique)
- Labelling [requirements] to identify these substances

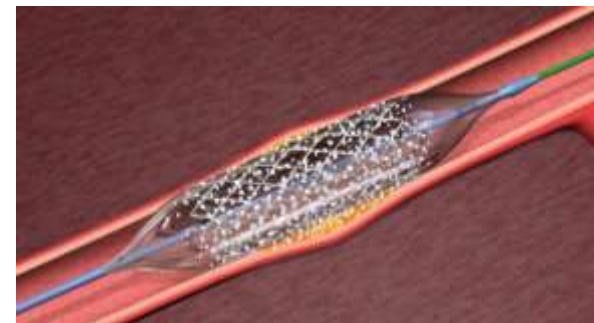
Reference Number			
SPR	MDD	AIMDD	Other
10.4	7.5	-	Regulation 1272/2008, Regulation 1907/2006, Regulation 528/2012



Medicinal Substances / Substances Absorbed or Dispersed – SPR 12

- **Scope has expanded:**
 1. Devices incorporating medicinal substance(s) (same as MDD/AIMDD);
 2. Devices containing substance(s) absorbed or locally dispersed (new)
- **Gone:** “Liable to act,” but definitions still state substance must have an action “ancillary” to the device.
- Details regarding consultation have moved out of ERs/SPRs into Annex IX, Chapter II, Section 5.2 and not repeated in SPR 12.1
- For device type #2 above, notified body will have to verify absorption, distribution, metabolism, excretion, interactions, etc.
 - Per Annex IX, consultation will be needed if devices or metabolic products are absorbed in order to achieve their intended purpose.

Reference Number			
SPR	MDD	AIMDD	Other
12.1	7.4	10	- MDR: Annex IX, Chapter II, Sec. 5.2 - Directive 2001/83/EC - MDR Annex VIII Rule 14
12.2	-	-	Directive 2001/83/EC
Absent	7.4 - consult. text	10 - consult. text	MDR Annex IX, Chapter II, Sec. 5.2



Human / Animal / Biological Tissue Requirements – SPR 13

- **New: SPR 13.1 - devices manufactured utilising tissues or cells, or their derivatives, of human origin which are non-viable or rendered non-viable**
 - Expands scope: previously only human blood derivatives were in scope of MDD
- Most changes to animal tissue requirements (SPR 13.2) are clarifications ensuring consistency with 22442-2 and Regulation 722/2012
 - Animal tissue requirements are new to AIMD ERs
- **New: SPR 13.3 - other non-viable biological substances (aside from human and animal) – this is a 'catch-all' and could include derivatives of any other living organism i.e. bacteria, plant, etc.**

Reference Number			
SPR	MDD	AIMDD	Other
13.1	7.4	10	Directive 2004/23/EC Directive 2002/98/EC
13.2	8.2	-	EN ISO 22442-2 EU Reg 722/2012
13.3	-	-	-



Construction of devices and interaction with their environment – SPR 14

- More explicit clarifications of existing requirements
- Increased emphasis on minimizing IT environment, software, cybersecurity risks
- Connections handled by users shall be designed to avoid misconnection (for example, non-compatible connector standards ISO 80369 series)
- Design for safe calibration and maintenance
- Design for use in combination
- Design & manufacture for safe disposal
- Some ties to new IFU requirements

Reference Number			
SPR	MDD	AIMDD	Other
14.1	9.1	9	-
14.2a	9.2	8	-
14.2b	9.2	8	EN 60606-1
14.2c	7.3	-	-
14.2d	-	-	EN 60601-1 ISO 80001 IEC 82304-1
14.2e	7.6	-	-
14.2f	9.2	-	-
14.2g	9.2	8	-
14.3	9.3	-	-
14.4	-	-	-
14.5	14.1	9.1	-
14.6	10.2	-	-
14.7	-	-	-

Devices with a diagnostic or measuring function – SPR 15

- Minor changes only
- **Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability within appropriate limits of accuracy for their intended purpose, based on appropriate scientific and technical methods."**
- The measurements made by devices with a measuring function ~~must be~~ **shall be** expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.
- **provide sufficient accuracy, precision and stability for their intended purpose**
 - New vs. AIMD **ER 8**
- **MDD ER 10.2** (ergonomic principles) has moved into Construction and Environmental Properties (SPR 14)

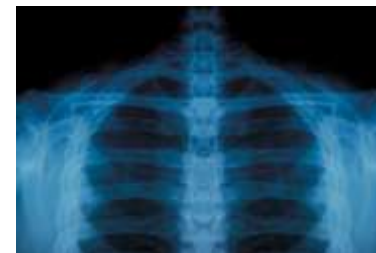
Reference Number			
SPR	MDD	AIMDD	Other
15	10.1, 10.3	-	Directive 80/181/EEC



Protection against radiation – SPR 16

- Requirements largely similar
- Protecting the patient and user
- *"Information regarding the acceptance testing, the performance testing and the acceptance criteria, the maintenance procedure shall also be specified."*
- Both intended and unintended radiation: exposure of patients, users, and other persons to be reduced as far as possible
 - *"Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected."*
- **Ionising radiation: New reference to 2013/59/EURATOM directive (superseding an older reference in AIMDD)**
 - This directive has specific requirements for maximum radiation limits for varying subjects and circumstances, and other requirements
- Ionising radiation: *"and, if possible, monitored during treatment."*

Reference Number			
SPR	MDD	AIMDD	Other
16.1a	11.1	-	-
16.1b	11.4	-	-
16.2a	11.2.1	-	-
16.2b	11.2.2	-	-
16.3	11.3	-	-
16.4a	11.5.1	8	2013/59/Euratom
16.4b	-	-	-
16.4c	11.5.2	-	-
16.4d	11.5.3	-	-



Electronic Programmable Systems – SPR 17

- Information security and cybersecurity – increased emphasis including data protection
- More explicit requirements from EN 60601-1
- For devices that incorporate ~~medical~~ software or for software that are devices in themselves, the software shall be ~~validated~~ **developed and manufactured** according to the state of the art taking into account the principles of development life cycle, risk management, **including information security, verification and validation.**
 - Addressing more of the product life cycle (vs. 'validated' only)
- SPR 17.4: Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.**
- SPR 17.3 New: Considerations for mobile computing platforms – size, contrast ratio, light, noise, etc.**

Reference Number			
SPR	MDD	AIMDD	Other
17.1	12.1	-	-
17.2	12.2	9, part 7	-
17.3	-	-	-
17.4	-	-	EN 60601-1+A1



Active devices and devices connected to them – SPR 18

- Many identical requirements to Directives
- Where safety depends on an internal power supply - Indication or indication for low power supply (currently in EN 60601)
- SPR 18.5 “Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic fields-electromagnetic interference”
- New requirement (SPR 18.6) - Devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.
- New requirement (SPR 18.8) - Devices shall be designed and manufactured in such a way as to avoid unauthorized access to the device as far as possible that would hamper the device to run as intended.
 - Recurring emphasis on cybersecurity

Reference Number			
SPR	MDD	AIMDD	Other
18.1	12.1	-	-
18.2	12.2	-	EN 60601
18.3	12.3	-	-
18.4	12.4	-	-
18.5	12.5	-	-
18.6	-	-	EN 60601-1 EN 60601-2
18.7	12.6	-	-
18.8	-	-	-



Particular requirements for active implantable devices – SPR 19

- No major changes or additions have been noted in SPR 19 in comparison to the current requirements in the AIMDD ERs.
- Other aspects of AIMDD ER 8 and 9 have not been removed, but are now represented in other SPRs as part of the merging of the two Directives (see SPR 10.1, 14.1, 14.2, 16.4, 17).
- No new definitions

Reference Number			
SPR	MDD	AIMDD	Other
19.1	-	8	-
19.2	-	9	-
19.3	-	11	-
19.4	-	12	MDR, Article 31



Protection against mechanical and thermal risks – SPR 20

- Many identical requirements
- Some more explicit, or clarifications on EN 60601-1
- New requirement (SPR 20.5) – *"Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk."*

Reference Number			
SPR	MDD	AIMDD	Other
20	12.7	-	-
20.5	-	-	-

Protection against the risks posed to the patient or user by supplied energy or substances – SPR 21

- Many identical requirements in this section
- Minor rewording only for MDD
- Most text new vs. AIMDD
- “flow-rate” → “delivered amount”;
“guarantee” → “assure”
- “Prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.”

SPR	Reference Number		
	MDD	AIMDD	Other
21.1	12.8.1	9	-
21.2	12.8.2	-	-
21.3	12.9	-	-



New requirement – Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons - SPR 22

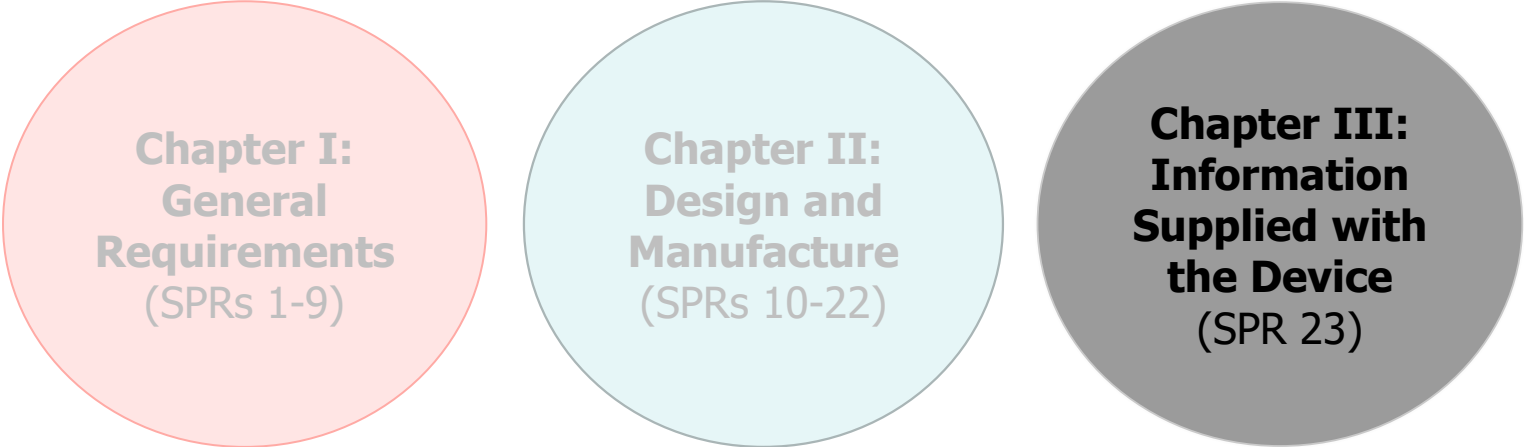
- New specific requirements which must be verified
- New definition/concept of “Lay person” user
- Requirements align with current expectations, but now explicitly in Regulation
- *22.1: Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.*
- *22.2: Devices for use by lay persons shall be designed and manufactured in such a way as to*
 - *ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information, and*
 - *reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and*
 - *reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.*
- *22.3: Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person*
 - *can verify that, at the time of use, the device will perform as intended by the manufacturer, and*
 - *if applicable, is warned if the device has failed to provide a valid result.*

Reference Number			
SPR	MDD	AIMDD	Other
22	-	-	-



“lay person” users come up again in specific labeling requirements (SPR 23)

Annex I, Chapter III: Information Supplied



**Chapter I:
General
Requirements**
(SPRs 1-9)

**Chapter II:
Design and
Manufacture**
(SPRs 10-22)

**Chapter III:
Information
Supplied with
the Device**
(SPR 23)

Information for Users (Labeling/IFU) – SPR 23

- General requirements (23.1)
- Performance information to be in labelling
- Increased focus on clarity and on intended users
- Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate.
 - If the manufacturer has a website the [relevant safety and performance] information shall be available and up to date
- (a) New requirements for legibility & clarity – IFU to be *"written in terms readily understood by the intended user"*
- (e) New: *"Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge"*
- Generally similar to AIMDD ER 14, 15 but new definitions "professional or lay, or other person" and [a]-[b]

Reference Number			
SPR	MDD	AIMDD	Other
23.1a	-	-	EN 62366-1 EN TR 62366-2 EN 60601-1-6
23.1b	13.1	11, 12	-
23.1c	-	-	-
23.1d	13.1	-	-
23.1e	-	-	-
23.1f	-	-	Regulation 207/2012
23.1g	-	-	-
23.1h	13.2	-	-

Information for Users (Labeling/IFU) – SPR 23

- General requirements (**SPR 23.1**)
- (c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification (RFID) or bar codes.
- (f) IFU may be provided electronically in accordance with existing Regulation 207/2012
- (g) Specific requirement to disclose residual risks in form of warnings etc. (SPR 23.1(g))
- *"Any symbol or identification colour used shall conform to the harmonised standards or CS."*

Reference Number			
SPR	MDD	AIMDD	Other
23.1a	-	-	EN 62366-1 EN TR 62366-2 EN 60601-1-6
23.1b	13.1	11, 12	-
23.1c	-	-	-
23.1d	13.1	-	-
23.1e	-	-	-
23.1f	-	-	Regulation 207/2012
23.1g	-	-	-
23.1h	13.2	-	-

Information for Users (Labeling/IFU) – SPR 23

- Labeling requirements (SPR 23.2)
- (e) Label must have indication if the device incorporates:
 - Medicinal substance
 - Human blood/plasma derivative
 - Tissues/cells/derivatives of human origin
 - Tissues/cells/derivatives of animal origin
- (f) Indication if carcinogenic/mutagenic/toxic (CMR) substances as per SPR 10.4.5
- (h) UDI carrier according to Article 24, Annex V
- (o) Indication if the device is a reprocessed single use device
- (q) “Indication that the device is a medical device.”
- (r) Identification of absorbed or locally dispersed elements
- Many of these requirements do not have harmonised symbols currently

SPR	Reference Number		
	MDD	AIMDD	Other
23.2a	13.3c	14.2, part 2	-
23.2b	13.3b, 13.4	14.2, part 2-3	-
23.2c	13.3a	14.2, part 1	-
23.2d	13.3a	-	-
23.2e	13.3n	14.2, part 11	-
23.2f	7.5		-
23.2g	13.3d	11-	-
23.2h	-	-	-
23.2i	13.3e	14.2, part 9	-
23.2j	13.3l	-	-
23.2k	13.3i	-	-
23.2l	13.3c, 13.3m	-	-
23.2m	13.3k	-	-
23.2n	13.3f	-	-
23.2o	-	-	-
23.2p	13.3g	14.2, part 6	-
23.2q	13.3h	14.2, part 5	-
23.2r	-	-	-
23.2s	13.3d	-	-

Information for Users (Labeling/IFU) – SPR 23

- Sterile package requirements (**SPR 23.3**)
 - AIMDD already distinguishes sterile pack from trade pack / sales pack; this distinction is new to MDD devices
 - Mostly a sub-set of existing labelling requirements
- (a) *"an indication permitting the sterile packaging to be recognized as such,"* – i.e. disclaimers, sterile symbol, instructions for inspecting seal integrity (**ER 14.1 indent 2**)
- (i) *"an indication of the time limit for using or implanting the device safely,"* – best equates to the 'use by date' (**ER 14.1 last indent**)
- (j) *"an instruction to check the Instructions For Use for what to do if the sterile packaging is damaged or unintentionally opened before use."*

Reference Number			
SPR	MDD	AIMDD	Other
23.3a	13.3c	14.1, part 2	-
23.3b	-	14.1, part 7	-
23.3c	13.3m	14.1, part 1	-
23.3d	13.3a	14.1, part 3	-
23.3e	13.3b	14.1, part 4	-
23.3f	13.3h	14.1, part 5	-
23.3g	13.3g	14.1, part 6	-
23.3h	13.3l	14.1, part 8	-
23.3i	13.3e	14.1, part 9	-
23.3j	13.3i	-	-

Information for Users (Labeling/IFU) – SPR 23

- IFU Requirements (**SPR 23.4**)
- (c-d) New: a specification of clinical benefits to be expected; where applicable, and links to the summary of safety and clinical performance according to article 32.”
- (g) Explicit clarification about disclosing any residual risks in IFU (reiterated from 23.1)
- (j) Any requirements for special facilities to be listed
- (k) Information on preventative maintenance, cleaning, disinfection, etc.
 - State methods of eliminating risks to installing & servicing persons.
- (n) Reusable devices – Information to identify when the device should no longer be reused / max. number reuses
 - clarification ‘appropriate to the Member State’

Reference Number			
SPR	MDD	AIMDD	Other
23.4a	13.6a	15, part 2	-
23.4b	13.4	15, part 2	-
23.4c	-	-	MDR Art. 32
23.4d	-	-	MDR Art. 32
23.4e	13.6b	15, part 3	-
23.4f	-	15, part 2	-
23.4g	13.6e	15, part 2	-
23.4h	13.6d, p	-	-
23.4i	13.6i	-	-
23.4j	13.3j, 13.6a	15, part 5	-
23.4k	13.6d, p	-	-
23.4l	13.6g	15, part 8	-
23.4m	13.6h	-	-
23.4n	13.6h	-	-

SPR 23.4 Continues on next slide...

(a)

Super Balloon[®]

Drug Coated Coronary Dilatation Catheter

(c)



Acme Device

0086 First Street

OutofthisWorld, Anywhere 00086

USA

866.YYY.ZZZZ

www.acme-device.com

(d)

EC REP

EU Representative, Inc.

XX la Boulevard

Country ZZZZZ

EU

+XX - PHONE

PN-XXX-YY-A

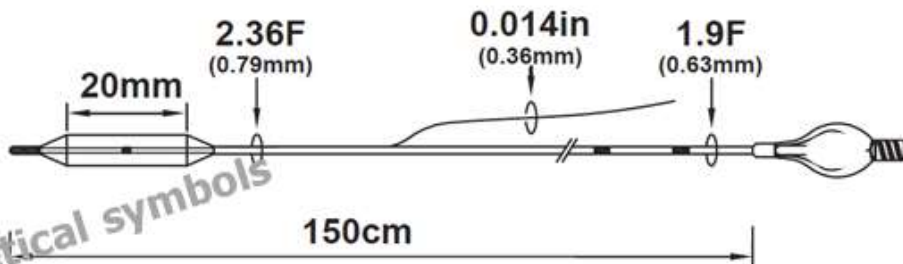
(b)

Rapid Exchange, 150cm, 1.5 mm diameter, 0.014 Guidewire compatible guidewire



1.5mm

0.056in
(1.42mm)



Sample only – Hypothetical symbols

(i)

REF 2015-150RX-XYZ



2020-11

(g)

LOT XXXXXXXXXX

(m)



Do not inflate above rated burst pressure

(e)

(e)

(q)



(21.1 c)



(k)



(n)

STERILE

(l)



(h)



Information for Users (Labeling/IFU) – SPR 23

- IFU Requirements (**SPR 23.4**)
- (o) Reconditioning - “An indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.” [AIMDD ER 15]
 - Responsibility of reprocessor to comply with SPRs; explicit clarification for MDD; Existing in AIMDD within ER 15
- (p) Single-use statement requirement is more detailed – manufacturers must consider this specifically (“in a specific section”) in the RM documentation and then feed this into the IFU
- (r-s) More detailed requirements for information on radiation, magnetic fields, etc.
- (s) Requirements to identify any incompatibility or safety issues with medicinal or biological tissue aspects
- (t) Warnings/precautions about anything absorbed or locally dispersed including possible interactions, risks of overdose etc.

Reference Number			
SPR	MDD	AIMDD	Other
23.4o	-	15, part 9	-
23.4p	13.6h	-	-
23.4q	13.6c	-	-
23.4r	13.6j	-	-
23.4s	13.6k - m	15, part 2	-
23.4t	-	-	-

SPR 23.4 Continues on next slide...

Information for Users (Labeling/IFU)

- IFU Requirements (**SPR 23.4**)
- (u) New requirement for implantables – include qualitative & quantitative information on materials and substances
- (v) More detailed requirements on disposal instructions
- (w) Devices for use by lay persons – when user should consult a healthcare professional
- (x) Information required for devices without a medical purpose (absence of benefit, related risks)
- (z) Notice regarding requirements for vigilance reporting
- (aa) “Implant Card”: Information to be supplied to patient with an implanted device (new requirement – Article 18)
- (ab) minimum requirements for electronic programmable systems – hardware, networks, security, etc.

Reference Number			
SPR	MDD	AIMDD	Other
23.4u	-	-	-
23.4v	13.6n	-	-
23.4w	-	-	-
23.4x	-	-	-
23.4y	13.6q	-	-
23.4z	-	-	-
23.4aa	-	-	-
23.4ab	-	-	-

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Documenting Compliance

Annex II

4. General safety and performance requirements

Documentation shall contain

- Information to demonstrate conformity to general safety and performance requirements (GSPR or SPRs) that are applicable (Annex I) taking into account its intended purpose and shall include... methods used to demonstrate conformity (justification, validation and verification). Demonstration of conformation shall include:
 - SPRs that apply... explanation of why any SPR does not apply;
 - Method(s) used to demonstrate conformity...
 - Harmonised standards, CS or other solutions applied and
 - The precise identity of the controlled documents offering evidence of conformity... Harmonised Standard, CS or method(s) [including] a cross-reference to the location of such evidence within the full technical documentation...

Clearly have to show/demonstrate how each SPR is met/satisfied.

Annex II 4. General safety and performance requirements

- Documentation shall contain information to demonstrate conformity to general safety and performance requirements (GSPR or SPRs) that are applicable (Annex I) taking into account its intended purpose and shall include methods used to demonstrate conformity (justification, validation and verification).
- Demonstration of conformation shall include:

SPR	Applicability	Standard or CS	Demonstration/ testing (justification, validation and verification)	Location (Precise identity)
X				
Y				
Z				

Have to clearly show/demonstrate how each SPR is met/satisfied.



Conclusions and More Resources

Conclusions and Final Thoughts: Essential Requirements vs. Safety & Performance Requirements

- Similar structure and flow
- Many expanded requirements, some new requirements
- Many requirements align with state of the art harmonized standards
- Manufacturers should begin to get familiar with these
 - Focus on areas of highest impact for your organization
 - As with the ERs, all requirements may not apply to all devices



Where can I find full details of the changes?

bsigroup.com/MDR-revision

bsigroup.com/IVDR-revision

Webinars: bsigroup.com/webinars

Whitepapers: bsigroup.com/whitepapers

Please ask if you want any extra information from BSI.



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Extra Materials

Common Specifications

- The Medical Devices Regulation has provided for 'CS' in Article 9. These are defined in Article 2 as a set of technical and/or clinical requirements other than standard that provide a means of complying with the legal obligations applicable to a device, process or system.
- Article 9 states that CS will be adopted where no harmonized standards exist—OR—where relevant harmonized standards are not sufficient—OR—where there is a need to address public health concerns. These CS will be developed by expert panels appointed by the Commission, in consultation with the Medical Device Coordination Group (MDCG, Article 103)
- Devices in conformity with CS shall be presumed to be in conformity with the relevant requirements of the MDR. The MDR states that manufacturers shall comply with applicable CS unless they can duly justify that their solutions ensure at least an equivalent level of safety and performance. Finally, manufacturers of the devices without a medical purpose as listed in Annex XVI are required to comply with any relevant CS for those products.
- Manufacturers should monitor the Commission website for developments. CS are likely to be published in the Official Journal of the European Union, as is currently done for the similar in vitro diagnostic 'Common Technical Specifications.'

Implant Card (Article 18)

Manufacturer of an implantable device shall provide the following with the device:

- information to allow identification of device, including:
 - Name, serial number, lot, UDI, model, name, address & website of Mfg.
- Warnings, precautions or measures to be taken by the patient or provider regarding:
 - Interference with external influences, medical examination, environment conditions
- Expected lifetime and any follow-up
- Any information to ensure safe use by the patient

Implant Card (Article 18)

Other considerations:

- shall be in the language(s) determined by the member state
- written so that it can be understood by the lay person
- updates to patient should be available on Mfg. website
- member states shall require healthcare institutions to provide rapid access to this information
 - The implant card shall bear the identity of the patient
- certain implants are exempted, including:
 - Sutures, dental implants, wedges, wires, plates, screws, pins, clips and connectors

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Potential Symbols

Standards and Harmonisation

- ISO 15223 very recently harmonised against existing Directives

- Nothing is harmonised against the MDR or IVDR

- In the absence of any standard, Notified Bodies assess conformity to the requirements of the legislation

UDI & Information available in an electronic format



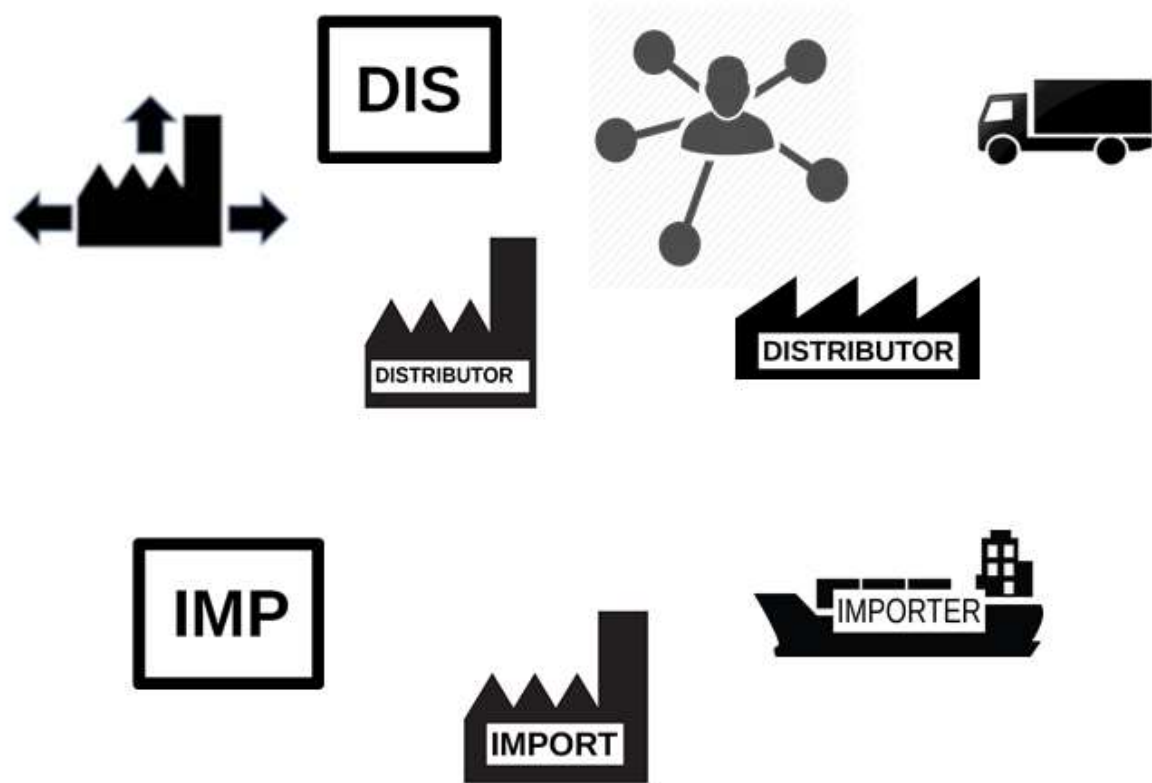
UDI Carrier

- MDR, Annex I, 23.2, h.
- IVDR, Annex I, 20.2, g.

RFID

- MDR, Annex I, 23.1, c.
- IVDR, Annex I, 20.1, c.

Distributor & Importer



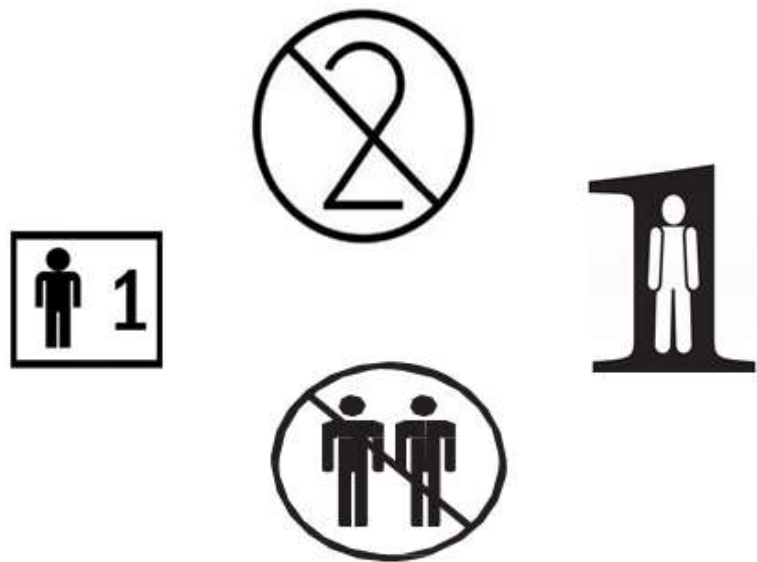
Distributor

- MDR, Article 14
- IVDR, Article 14

Importer

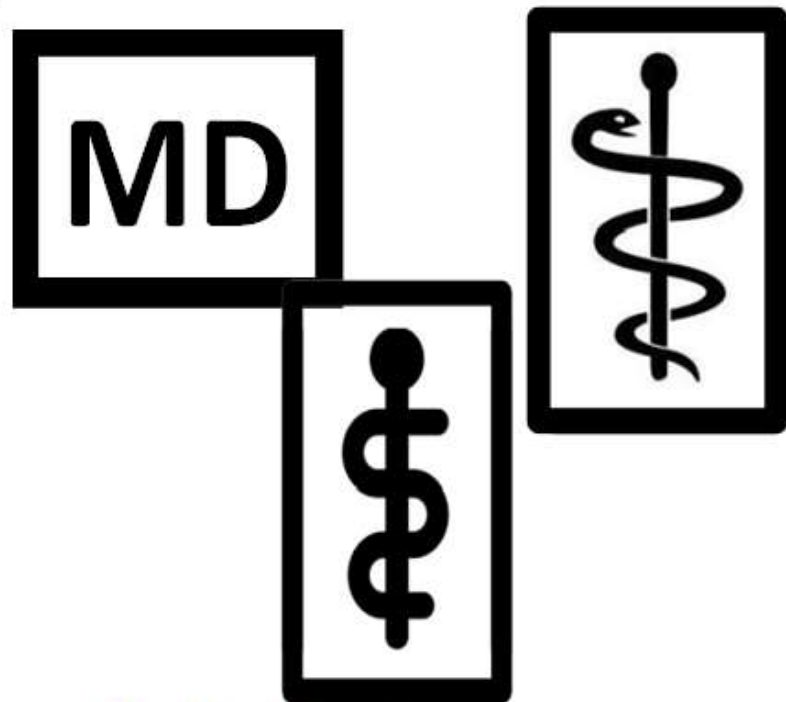
- MDR, Article 13.3
- IVDR, Article 13.3

Single Patient Use & Medical Device



Single Use

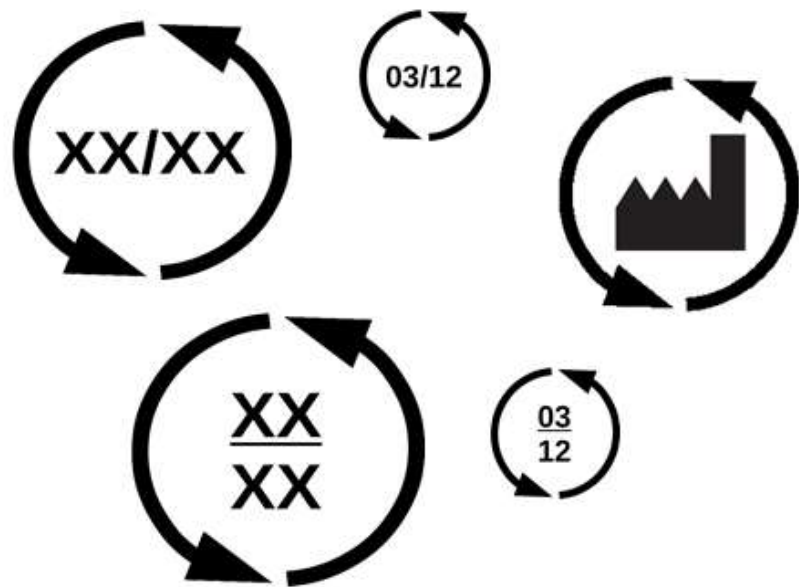
- MDR, Annex I, 23.2, n
- IVDR, Annex I, 20.2, p



Medical Device

- MDR, Annex I, 23.2, q
- IVDR, Annex I, 20.2, e

Reprocessing & Devices with no medical purpose



Reprocessing (number of cycles)

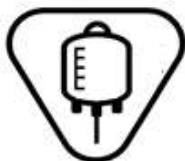
- MDR, Annex I, 23.2, o



Device with no medical purpose

- Annex XVI

Incorporates medicinal substances, blood derivatives, human tissues, animal tissues

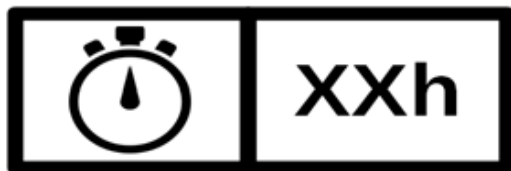


Rx, AT, etc.

- MDR, Annex I, 23.2, e.



Continuous Use, Hazardous Substances, Nano Materials +



Continuous Use

- MDR, Annex VIII



Carcinogenic, Mutagenic, Toxic to Reproduction

- MDR, Annex I, SPR 10.4.5
- MDR, Annex I, 23.2, f.



Nanomaterials

- MDR, Annex I, SPR 10.6

Sterility and what to do if packaging damaged



Sterile Packaging

- MDR, Annex I, 23.3, c.
- MDR, Annex I, 23.3, j.