MDR – Labelling Requirements

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The New EU Medical Device and IVD Regulations

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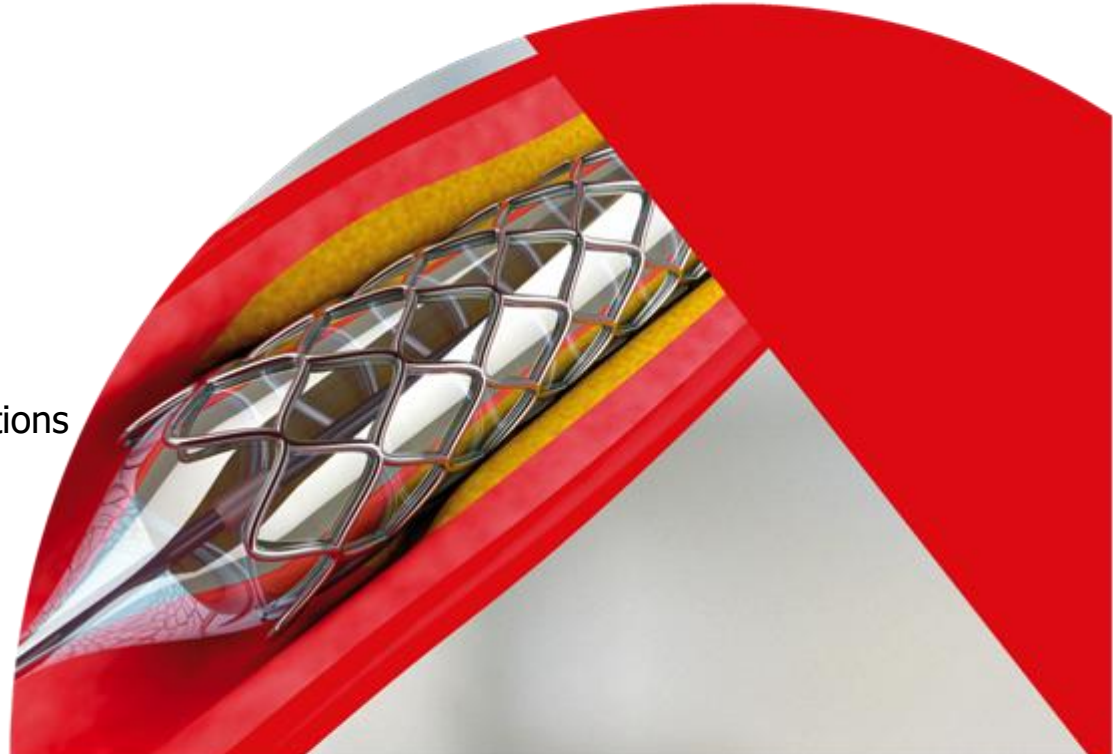

Information for Users (Labeling/IFU)

- 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.
- [a] New requirements for legibility & clarity - 'can be understood by 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 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
23.1b	13.1	11, 12	-
23.1c	-	-	-
23.1d	13.1	-	-
23.1e	-	-	-
23.1f	-	-	-
23.1g	-	-	-
23.1h	13.2	-	EN 980:2008 ISO 15223:2016 IEC 60417 IEC 60878

MDD / AIMDD / MDR

Information for Users (Labeling/IFU)

- General requirements (23.1)
- 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.
- IFU may be provided electronically in accordance with existing Regulation 207/2012
- Specific requirement to disclose residual risks in form of warnings etc.
- 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
23.1b	13.1	11, 12	-
23.1c	-	-	-
23.1d	13.1	-	-
23.1e	-	-	-
23.1f	-	-	-
23.1g	-	-	-
23.1h	13.2	-	EN 980:2008 ISO 15223:2016 IEC 60417 IEC 60878

Information for Users (Labeling/IFU)

- Labeling requirements (23.2)
- 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
- Indication if carcinogenic/mutagenic/toxic (CMR) substances
- UDI carrier according to Article 24, Annex V
- Indication if the device is a reprocessed single use device
- "Indication that the device is a medical device."
- Identification of absorbed or locally dispersed elements
- Many of these requirements do not yet have harmonised symbols

Reference Number			
SPR	MDD	AIMDD	Other
23.2a	13.3b	14.2, part 1	-
23.2b	13.3b	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	13.3 (l)	-	-
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)

- Sterile package requirements (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
- "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)
- "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)
- "an instruction to check the Instructions For Use for what to do if the sterile packaging is damaged etc."

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)

- IFU Requirements (SPR 23.4)
- New: "a specification of clinical benefits to be expected; where applicable, together with links to the summary of safety and clinical performance according to article 32."
- Explicit clarification about disclosing any residual risks in IFU (reiterated from 23.1)
- Any requirements for special facilities to be listed
- Information on preventative maintenance, cleaning, disinfection, etc.
  - State methods of eliminating risks to installing & servicing persons.
- 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, 2	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	-
23.4 m	13.6h	-	-
23.4n	13.6h	-	-

SPR 23.4 Continues on next slide…

Information for Users (Labeling/IFU)

- IFU Requirements (23.4)
- 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
- Single-use statement requirement is more detailed – says manufacturers must consider this specifically ("in a specific section") in the RM documentation and then feed this into the IFU!
- More detailed requirements for information on radiation, magnetic fields, etc.
- Requirements to identify any incompatibility or safety issues with medicinal or biological tissue aspects
- 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 (23.4)
- New requirement for implantables – include qualitative & quantitative information on materials and substances
- More detailed requirements on disposal instructions
- For use by lay persons – when user should consult a healthcare professional
- Information required for devices without a medical purpose (absence of benefit, related risks)
- Notice regarding requirements for vigilance reporting
- "Implant Card": Information to be supplied to patient with an implanted device (new requirement – Article 18)

Reference Number			
SPR	MDD	AIMDD	Other
23.4u	-	-	-
23.4v	13.6n		-
23.4w	-	-	-
23.4x	-	-	-
23.4y	13.6q	15, part 14	-
23.4z	-	-	-
23.4aa	-	-	-
23.4ab	-	-	-

Questions

Thank You!

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