



Medical Devices Regulation (MDR)

Mapping Guide



Low priority



Medium priority



High priority

A guide to help you to map the MDR Safety and Performance Requirements (SPRs) to the Essential Requirements for Medical Device Directive (MDD), Active Implantable Medical Device Directive (AIMD). The document also lists other relevant information which can help you in planning your transition to the MDR.

| SPR | Reference Number | | |
|------|------------------|--------|---|
| | MDD | AIMDD | Other |
| 1 | 1, 2, 3 | 1, 2,6 | - |
| 2 | 2 | 8 | - |
| 3 | - | - | EN ISO 14971 |
| 4 | 2 | 6 | - |
| 5 | 1 | - | - |
| 6 | 4 | 3 | - |
| 7 | 5 | 4 | EN ISO 11607-2 |
| 8 | 6 | 5 | - |
| 9 | - | - | MDR Annex XVI |
| 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 | - | - | MDR Annex VIII Rule 19 |
| 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 | - | - |

| Reference Number | | | |
|------------------|------------|-----------|---|
| SPR | MDD | AIMDD | Other |
| 11.8 | 8.7 | - | - |
| 12.1 | 7.4 | 10 | Directive 2001/83/EC; MDR: Annex IX, Ch. II, Sec. 5.2, MDR Annex VIII Rule 14 |
| 12.2 | - | - | Directive 2001/83/EC |
| 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 | - | - | - |
| 14.1 | 9.1 | 9 | - |
| 14.2a | 9.2 | 8 | - |
| 14.2b | 9.2 | 8 | EN 60601-1+A1 EN 60601-1-2 |
| 14.2c | 7.3 | - | - |
| 14.2d | - | - | EN 60601-1+A1 ISO 80001 |
| 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 | - | - | - |
| 15 | 10.1, 10.3 | - | Directive 80/181/EEC |
| 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 | - | - |
| 17.1 | 12.1 | - | - |
| 17.2 | 12.2 | 9, part 7 | - |
| 17.3 | - | - | - |
| 17.4 | - | - | EN 60601-1+A1 |
| 18.1 | 12.1 | - | - |

| Reference Number | | | |
|------------------|-------------|--------------------|---|
| SPR | MDD | AIMDD | Other |
| 18.2 | 12.2 | - | EN 60601-1+A1 |
| 18.3 | 12.3 | - | - |
| 18.4 | 12.4 | - | - |
| 18.5 | 12.5 | - | - |
| 18.6 | - | - | EN 60601-1+A1 EN 60601-1-2 |
| 18.7 | 12.6 | - | - |
| 18.8 | - | - | - |
| 19.1 | - | 8 | - |
| 19.2 | - | 9 | - |
| 19.3 | - | 11 | - |
| 19.4 | - | 12 | MDR, Article 31 |
| 20 | 12.7 | - | EN ISO 14708 EN 45502 |
| 20.5 | - | - | - |
| 21.1 | 12.8.1 | 9 | - |
| 21.2 | 12.8.2 | - | - |
| 21.3 | 12.9 | - | - |
| 22 | - | - | EN 62366 EN 60601-1-11 |
| 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 | - | - | EU Reg 207/2012 |
| 23.1g | - | - | - |
| 23.1h | 13.2 | - | EN 980:2008 ISO 15223:2016 IEC 60417 IEC 60878 |
| 23.2a | 13.3c | 14.2, part 2 | - |
| 23.2b | 13.3b, 13.4 | 14.2, part 2 and 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 | - | - | - |

| Reference Number | | | |
|------------------|--------------|--------------|-------------|
| SPR | MDD | AIMDD | Other |
| 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 | - | - |
| 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 | - | - |
| 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, | - | - |
| 23.4l | 13.6g | 15, part 8 | - |
| 23.4m | 13.6h | - | - |
| 23.4n | 13.6h | - | - |
| 23.4o | - | 15, part 9 | - |
| 23.4p | 13.6h | - | - |

| Reference Number | | | |
|------------------|-------------------------|------------------------|---------------------------------------|
| SPR | MDD | AIMDD | Other |
| 23.4q | 13.6c | - | - |
| 23.4r | 13.6j | - | - |
| 23.4s | 13.6k - m | 15, part 2 | - |
| 23.4t | - | - | - |
| 23.4u | - | - | - |
| 23.4v | 13.6n | - | - |
| 23.4w | - | - | - |
| 23.4x | - | - | - |
| 23.4y | 13.6q | 15, part 1-4 | - |
| 23.4z | - | - | - |
| 23.4aa | - | - | - |
| 23.4ab | - | - | - |
| Absent | 6a | 5a | MDR Annex XIV |
| Absent | 7.4 - consultation text | 10 - consultation text | MDR Annex IX, Chapter II, Section 5.2 |

Please note: This document is a guide to help you to map 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 table 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.

Find out more about how BSI can support your transition by visiting our website [bsigroup.com/es-ES/Productos-Sanitarios/](https://www.bsigroup.com/es-ES/Productos-Sanitarios/) or call: **+34 91 400 86 20**



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