BSI Transitions
Medical Devices Regulation

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.

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	-	-
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 800001
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.

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