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Medical Device Regulation mapping guide

A guide to map your transition from MDD and AIMDD to the MDR

Mapping to the MDR from MDD and AIMD

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

Key: Low priority Medium priority High priority

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

Reference number			
SPR	**MDD**	**AIMDD**	**Other**
11.6	8.5	-	-
11.7	8.6	-	-
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 EN 60601-1-2
14.2c	7.3	-	-
14.2d	-	-	EN 60601-1 EN IEC 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

Reference number			
SPR	**MDD**	**AIMDD**	**Other**
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
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 60601-1-2
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 parts EN 45502 parts
20.5	-	-	-
21.1	12.8.1	9	-
21.2	12.8.2	-	-
21.3	12.9	-	-
22	-	-	EN 62366-1 EN 60601-1-11
23.1a	-	-	EN 62366-1 EN 60601-1-6
23.1b	13.1	11, 12	-
23.1c	-	-	-
23.1d	13.1	-	-
23.1e	-	-	-
23.1f	-	-	-

Reference number			
SPR	**MDD**	**AIMDD**	**Other**
23.1g	-	-	-
23.1h	13.2	-	EN ISO 15223-1 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	-	-	-
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	-

Reference number			
SPR	**MDD**	**AIMDD**	**Other**
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	-	-
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 mapping the Essential Requirements of MDD and AIMDD to the MDR GSPRs. This is not an exhaustive list and, whilst BSI believes that it accurately reflects the regulatory environment at the time of publication, be aware of the complexity and the ever-changing nature of the regulatory framework. Therefore, this table is not to be considered as providing any legal advice and is not to be used as substitute for reading the regulations or consulting a qualified expert.

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