

# Table of Contents

## MEDICAL DEVICE REGULATION (MDR)

Consolidated version (pdf) dated on 24 April 2020:

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02017R0745-20200424&from=EN>

### REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017 on

**Medical Devices,**

amending

**Directive 2001/83/EC [medicinal products],**

**Regulation (EC) No 178/2002 [food] and**

**Regulation (EC) No 1223/2009 [cosmetic products]**

and repealing Council Directives

**90/385/EEC [active implantable medical devices] and**

**93/42/EEC [medical devices]**

For recitals (i.e. the “preface” or “reasoning” for the regulation) see the original MDR (pdf):

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN>

Find the MDR language versions, document information, electronic table of contents, etc. from:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745>

<b>CHAPTER I</b>	<b>SCOPE and DEFINITIONS</b>	<b>2</b>
Article 1	Subject matter and scope	2
Article 2	Definitions	5
Article 3	Amendment of certain definitions	13
Article 4	Regulatory status of products	13
<b>CHAPTER II</b>	<b>MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT</b>	<b>14</b>
Article 5	Placing on the market and putting into service	14
Article 6	Distance sales	15
Article 7	Claims	16
Article 8	Use of harmonised standards	16
Article 9	Common specifications	17
Article 10	General obligations of manufacturers	17
Article 11	Authorised representative	21
Article 12	Change of authorised representative	22

Article 13	General obligations of importers	23
Article 14	General obligations of distributors	24
Article 15	Person responsible for regulatory compliance	25
Article 16	Cases in which obligations of manufacturers apply to importers, distributors or other persons	27
Article 17	Single-use devices and their reprocessing	28
Article 18	Implant card and information to be supplied to the patient with an implanted device	30
Article 19	EU declaration of conformity	31
Article 20	CE marking of conformity	32
Article 21	Devices for special purposes	32
Article 22	Systems and procedure packs	33
Article 23	Parts and components	34
Article 24	Free movement	34
<b>CHAPTER III</b>	<b>IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES</b>	<b>35</b>
Article 25	Identification within the supply chain	35
Article 26	Medical devices nomenclature	35
Article 27	Unique Device Identification [UDI] system	35
Article 28	UDI database	38
Article 29	Registration of devices	38
Article 30	Electronic system for registration of economic operators	39
Article 31	Registration of manufacturers, authorised representatives and importers	40
Article 32	Summary of safety and clinical performance	40
Article 33	European database on medical devices	41
Article 34	Functionality of Eudamed	43
<b>CHAPTER IV</b>	<b>NOTIFIED BODIES</b>	<b>44</b>
Article 35	Authorities responsible for notified bodies	44
Article 36	Requirements relating to notified bodies	45
Article 37	Subsidiaries and subcontracting	45
Article 38	Application by conformity assessment bodies for designation	46
Article 39	Assessment of the application	46
Article 40	Nomination of experts for joint assessment of applications for notification	48
Article 41	Language requirements	48
Article 42	Designation and notification procedure	49
Article 43	Identification number and list of notified bodies	50
Article 44	Monitoring and re-assessment of notified bodies	51
Article 45	Review of notified body assessment of technical documentation and clinical evaluation documentation	52
Article 46	Changes to designations and notifications	53
Article 47	Challenge to the competence of notified bodies	56
Article 48	Peer review and exchange of experience between authorities responsible for notified bodies	56
Article 49	Coordination of notified bodies	57
Article 50	List of standard fees	58

<b>CHAPTER V</b>	<b>CLASSIFICATION and CONFORMITY ASSESSMENT</b>	<b>58</b>
<b>Section 1</b>	<b>CLASSIFICATION</b>	<b>58</b>
Article 51	Classification of devices	58
<b>Section 2</b>	<b>CONFORMITY ASSESSMENT</b>	<b>59</b>
Article 52	Conformity assessment procedures	59
Article 53	Involvement of notified bodies in conformity assessment procedures	62
Article 54	Clinical evaluation consultation procedure for certain class III and class IIb devices	62
Article 55	Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices	63
Article 56	Certificates of conformity	64
Article 57	Electronic system on notified bodies and on certificates of conformity	64
Article 58	Voluntary change of notified body	65
Article 59	Derogation from the conformity assessment procedures	66
Article 60	Certificate of free sale	66
<b>CHAPTER VI</b>	<b>CLINICAL EVALUATION and CLINICAL INVESTIGATIONS</b>	<b>67</b>
Article 61	Clinical evaluation	67
Article 62	General requirements regarding clinical investigations conducted to demonstrate conformity of devices	70
Article 63	Informed consent	72
Article 64	Clinical investigations on incapacitated subjects	74
Article 65	Clinical investigations on minors	74
Article 66	Clinical investigations on pregnant or breastfeeding women	75
Article 67	Additional national measures	76
Article 68	Clinical investigations in emergency situations	76
Article 69	Damage compensation	77
Article 70	Application for clinical investigations	77
Article 71	Assessment by Member States	79
Article 72	Conduct of a clinical investigation	80
Article 73	Electronic system on clinical investigations	81
Article 74	Clinical investigations regarding devices bearing the CE marking	82
Article 75	Substantial modifications to clinical investigations	82
Article 76	Corrective measures to be taken by Member States and information exchange between Member States	83
Article 77	Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination	83
Article 78	Coordinated assessment procedure for clinical investigations	84
Article 79	Review of coordinated assessment procedure	87
Article 80	Recording and reporting of adverse events that occur during clinical investigations	87
Article 81	Implementing acts	89
Article 82	Requirements regarding other clinical investigations	89
<b>CHAPTER VII</b>	<b>POST-MARKET SURVEILLANCE, VIGILANCE and MARKET SURVEILLANCE</b>	<b>90</b>
<b>Section 1</b>	<b>POST-MARKET SURVEILLANCE</b>	<b>90</b>

Article 83	Post-market surveillance system of the manufacturer	90
Article 84	Post-market surveillance plan	91
Article 85	Post-market surveillance report	91
Article 86	Periodic safety update report [PSUR]	91
<b>Section 2</b>	<b>VIGILANCE</b>	<b>92</b>
Article 87	Reporting of serious incidents and field safety corrective actions	92
Article 88	Trend reporting	94
Article 89	Analysis of serious incidents and field safety corrective actions	94
Article 90	Analysis of vigilance data	97
Article 91	Implementing acts	97
Article 92	Electronic system on vigilance and on post-market surveillance	98
<b>Section 3</b>	<b>MARKET SURVEILLANCE</b>	<b>100</b>
Article 93	Market surveillance activities	100
Article 94	Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance	101
Article 95	Procedure for dealing with devices presenting an unacceptable risk to health and safety	102
Article 96	Procedure for evaluating national measures at Union level	103
Article 97	Other non-compliance	103
Article 98	Preventive health protection measures	104
Article 99	Good administrative practice	105
Article 100	Electronic system on market surveillance	105
<b>CHAPTER VIII</b>	<b>COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EXPERT LABORATORIES, EXPERT PANELS and DEVICE REGISTERS</b>	<b>106</b>
Article 101	Competent authorities	106
Article 102	Cooperation	106
Article 103	Medical Device Coordination Group [MDCG]	106
Article 104	Support by the Commission	107
Article 105	Tasks of the MDCG	108
Article 106	Provision of scientific, technical and clinical opinions and advice	108
Article 107	Conflict of interests	112
Article 108	Device registers and data banks	112
<b>CHAPTER IX</b>	<b>CONFIDENTIALITY, DATA PROTECTION, FUNDING and PENALTIES</b>	<b>112</b>
Article 109	Confidentiality	112
Article 110	Data protection	113
Article 111	Levying of fees	113
Article 112	Funding of activities related to designation and monitoring of notified bodies	113
Article 113	Penalties	113
<b>CHAPTER X</b>	<b>FINAL PROVISIONS</b>	<b>114</b>
Article 114	Committee procedure	114

Article 115	Exercise of the delegation	114
Article 116	Separate delegated acts for different delegated powers	115
Article 117	Amendment to Directive 2001/83/EC [ <i>medicinal products</i> ]	115
Article 118	Amendments to Regulation (EC) No 178/2002 [ <i>food</i> ]	116
Article 119	Amendments to Regulation (EC) No 1223/2009 [ <i>cosmetic products</i> ]	116
Article 120	Transitional provisions	116
Article 121	Evaluation	118
Article 122	Repeal	118
Article 123	Entry into force and date of application	119

---

<b>ANNEXES</b>	<b>Table of contents</b>	<b>122</b>
----------------	--------------------------	------------

<b>ANNEX I</b>	<b>GENERAL SAFETY AND PERFORMANCE REQUIREMENTS</b>	<b>123</b>
----------------	--	------------

<b>Chapter I</b>	<b>GENERAL REQUIREMENTS (from 1. to 9.)</b>	<b>123</b>
------------------	---	------------

<b>Chapter II</b>	<b>REQUIREMENTS REGARDING DESIGN AND MANUFACTURE</b>	<b>124</b>
-------------------	--	------------

10.	Chemical, physical and biological properties	124
-----	--	-----

11.	Infection and microbial contamination	127
-----	---------------------------------------	-----

12.	Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combination of substances that are absorbed by or locally dispersed in the human body	128
-----	--	-----

13.	Devices incorporating materials of biological origin	128
-----	--	-----

14.	Construction of devices and interaction with their environment	129
-----	--	-----

15.	Devices with a diagnostic or measuring function	130
-----	---	-----

16.	Protection against radiation	131
-----	------------------------------	-----

17.	Electronic programmable systems – Devices that incorporate electronic programmable systems and software that are devices in themselves	132
-----	--	-----

18.	Active devices and devices connected to them	132
-----	--	-----

19.	Particular requirements for active implantable devices	133
-----	--	-----

20.	Protection against mechanical and thermal risks	134
-----	---	-----

21.	Protection against the risks posed to the patient or user by devices supplying energy or substances	134
-----	---	-----

22.	Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	135
-----	---	-----

<b>Chapter III</b>	<b>REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE</b>	<b>135</b>
--------------------	--	------------

23.	Label and instructions for use	135
-----	--------------------------------	-----

23.1.	<i>General requirements regarding the information supplied by the manufacturer</i>	135
-------	--	-----

23.2.	<i>Information on the label</i>	136
-------	---------------------------------	-----

23.3.	Information on the packaging which maintains the sterile condition of a device ('sterile packaging')	137
-------	--	-----

23.4.	<i>Information in the instructions for use</i>	138
-------	--	-----

<b>ANNEX II</b>	<b>TECHNICAL DOCUMENTATION</b>	<b>142</b>
-----------------	--------------------------------	------------

1.	Device description and specification, including variants and accessories	142
----	--	-----

1.1.	<i>Device description and specification</i>	142
------	---	-----

1.2.	<i>Reference to previous and similar generations of the device</i>	143
------	--	-----

2.	Information to be supplied by the manufacturer	143
----	--	-----

3.	Design and manufacturing information	143
4.	General safety and performance requirements	143
5.	Benefit-risk analysis and risk management	144
6.	Product verification and validation	144
6.1.	<i>Pre-clinical and clinical data</i>	144
6.2.	<i>Additional information required in specific cases</i>	145
<b>ANNEX III</b>	<b>TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE</b>	<b>147</b>
1.	The post-market surveillance plan drawn up in accordance with Article 84	147
2.	The PSUR [ <i>periodic safety update report</i> ] referred to in Article 86 and the post-market surveillance report referred to in Article 85	148
<b>ANNEX IV</b>	<b>EU DECLARATION OF CONFORMITY</b>	<b>149</b>
<b>ANNEX V</b>	<b>CE MARKING OF CONFORMITY</b>	<b>150</b>
<b>ANNEX VI</b>	<b>INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI [<i>UDI device identifier</i>] IN ACCORDANCE WITH ARTICLES 28 AND 29, and THE UDI SYSTEM</b>	<b>151</b>
<b>PART A</b>	<b>INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31</b>	<b>151</b>
1.	Information relating to the economic operator	151
2.	Information relating to the device	151
<b>PART B</b>	<b>CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI [<i>UDI device identifier</i>] IN ACCORDANCE WITH ARTICLES 28 AND 29</b>	<b>152</b>
<b>PART C</b>	<b>THE UDI SYSTEM</b>	<b>153</b>
1.	Definitions	153
2.	General requirements	155
3.	The UDI	155
4.	UDI carrier	156
5.	General principles of the UDI database	157
6.	Rules for specific device types	158
6.1.	<i>Implantable devices</i>	158
6.2.	<i>Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing between uses</i>	158
6.3.	<i>Systems and procedure packs as referred to in Article 22</i>	158
6.4.	<i>Configurable devices</i>	159
6.5.	<i>Device software</i>	159
<b>ANNEX VII</b>	<b>REQUIREMENTS TO BE MET BY NOTIFIED BODIES</b>	<b>161</b>
<b>1.</b>	<b>ORGANISATIONAL AND GENERAL REQUIREMENTS</b>	<b>161</b>
1.1.	Legal status and organisational structure	161
1.2.	Independence and impartiality	162
1.3.	Confidentiality	163
1.4.	Liability	163
1.5.	Financial requirements	164

1.6.	Participation in coordination activities	164
<b>2.</b>	<b>QUALITY MANAGEMENT REQUIREMENTS</b>	<b>164</b>
<b>3.</b>	<b>RESOURCE REQUIREMENTS</b>	<b>165</b>
3.1.	General	165
3.2.	Qualification criteria in relation to personnel	166
3.3.	Documentation of qualification, training and authorisation of personnel	169
3.4.	Subcontractors and external experts	169
3.5.	Monitoring of competences, training and exchange of experience	170
<b>4.</b>	<b>PROCESS REQUIREMENTS</b>	<b>171</b>
4.1.	General	171
4.2.	Notified body quotations and pre-application activities	171
4.3.	Application review and contract	172
4.4.	Allocation of resources	172
4.5.	Conformity assessment activities	172
4.5.1.	<i>General</i>	172
4.5.2.	<i>Quality management system auditing</i>	173
4.5.3.	<i>Product verification</i>	175
4.5.4.	<i>Pre-clinical evaluation assessment</i>	176
4.5.5.	<i>Clinical evaluation assessment</i>	177
4.5.6.	<i>Specific procedures</i>	178
4.6.	Reporting	178
4.7.	Final review	178
4.8.	Decisions and certifications	179
4.9.	Changes and modifications	179
4.10.	Surveillance activities and post-certification monitoring	180
4.11.	Re-certification	182
<b>ANNEX VIII</b>	<b>CLASSIFICATION RULES</b>	<b>183</b>
<b>Chapter I</b>	<b>DEFINITIONS SPECIFIC TO CLASSIFICATION RULES</b>	<b>183</b>
1.	Duration of use	183
2.	Invasive and active devices	183
<b>Chapter II</b>	<b>IMPLEMENTING RULES (from 3.1. to 3.7.)</b>	<b>184</b>
<b>Chapter III</b>	<b>CLASSIFICATION RULES</b>	<b>184</b>
4.	Non-invasive devices	184
4.1.	<i>Rule 1</i>	184
4.2.	<i>Rule 2</i>	184
4.3.	<i>Rule 3</i>	185
4.4.	<i>Rule 4</i>	185
5.	Invasive devices	185
5.1.	<i>Rule 5</i>	185
5.2.	<i>Rule 6</i>	186
5.3.	<i>Rule 7</i>	186
5.4.	<i>Rule 8</i>	186
6.	Active devices	187
6.1.	<i>Rule 9</i>	187
6.2.	<i>Rule 10</i>	187

6.3.	Rule 11	188
6.4.	Rule 12	188
6.5.	Rule 13	188
7.	Special rules	188
7.1.	Rule 14	188
7.2.	Rule 15	189
7.3.	Rule 16	189
7.4.	Rule 17	189
7.5.	Rule 18	189
7.6.	Rule 19	189
7.7.	Rule 20	189
7.8.	Rule 21	189
7.9.	Rule 22	190
<b>ANNEX IX</b>	<b>CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION</b>	<b>191</b>
<b>Chapter I</b>	<b>QUALITY MANAGEMENT SYSTEM</b>	<b>191</b>
1.	(no title)	191
2.	Quality management system assessment	191
3.	Surveillance assessment applicable to class IIa, class IIb and class III devices	194
<b>Chapter II</b>	<b>ASSESSMENT OF THE TECHNICAL DOCUMENTATION</b>	<b>195</b>
4.	Assessment of the technical documentation applicable to class III devices and to the class IIb devices referred to in the second subparagraph of Article 52(4)	195
5.	Specific additional procedures	197
5.1	<i>Assessment procedure for certain class III and class IIb devices</i>	197
5.2.	<i>Procedure in the case of devices incorporating a medicinal substance</i>	199
5.3.	<i>Procedure in the case of devices manufactured utilising, or incorporating, tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable</i>	200
5.4.	<i>Procedure in the case of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body</i>	201
6.	Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma as referred to in Article 1(8)	201
<b>Chapter III</b>	<b>ADMINISTRATIVE PROVISIONS (from 7. to 8.)</b>	<b>202</b>
<b>ANNEX X</b>	<b>CONFORMITY ASSESSMENT BASED ON TYPE EXAMINATION</b>	<b>203</b>
1.	(no title)	203
2.	Application	203
3.	Assessment	203
4.	Certificate	204
5.	Changes to the type	204
6.	Specific additional procedures	205
7.	Administrative provisions	205
<b>ANNEX XI</b>	<b>CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION</b>	<b>206</b>
1. to 3.	(no title)	206
<b>PART A</b>	<b>PRODUCTION QUALITY ASSURANCE</b>	<b>206</b>
4. to 5.	(no title)	206



6.	Quality management system	206
7.	Surveillance	207
8.	Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8)	207
9.	Administrative provisions	207
10.	Application to class IIa devices	208
<b>PART B</b>	<b>PRODUCT VERIFICATION</b>	<b>208</b>
11. to 14.	(no title)	208
15.	Verification by examination and testing of every product	209
16.	Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8)	209
17.	Administrative provisions	210
18.	Application to class IIa devices	210
<b>ANNEX XII</b>	<b>CERTIFICATES ISSUED BY A NOTIFIED BODY</b>	<b>211</b>
<b>Chapter I</b>	<b>GENERAL REQUIREMENTS</b>	<b>211</b>
<b>Chapter II</b>	<b>MINIMUM CONTENT OF THE CERTIFICATES</b>	<b>211</b>
<b>ANNEX XIII</b>	<b>PROCEDURE FOR CUSTOM-MADE DEVICES</b>	<b>213</b>
<b>ANNEX XIV</b>	<b>CLINICAL EVALUATION and POST-MARKET CLINICAL FOLLOW-UP</b>	<b>214</b>
<b>PART A</b>	<b>CLINICAL EVALUATION</b>	<b>214</b>
<b>PART B</b>	<b>POST-MARKET CLINICAL FOLLOW-UP [PMCF]</b>	<b>215</b>
<b>ANNEX XV</b>	<b>CLINICAL INVESTIGATIONS</b>	<b>217</b>
<b>Chapter I</b>	<b>GENERAL REQUIREMENTS</b>	<b>217</b>
1.	Ethical principles	217
2.	Methods	217
<b>Chapter II</b>	<b>DOCUMENTATION REGARDING THE APPLICATION FOR CLINICAL INVESTIGATION</b>	<b>218</b>
1.	Application form	218
2.	Investigator's Brochure [IB]	219
3.	Clinical Investigation Plan [CIP]	220
4.	Other information	222
<b>Chapter III</b>	<b>OTHER OBLIGATIONS OF THE SPONSOR</b>	<b>223</b>
<b>ANNEX XVI</b>	<b>LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)</b>	<b>225</b>
<b>ANNEX XVII</b>	<b>CORRELATION TABLE</b> [between Council Directive 90/385/EEC for active implantable medical devices, Council Directive 93/42/EEC for medical devices and this Regulation]	<b>226</b>