# CONTENTS

## CHAPTER 1
Welcome

## CHAPTER 2
Background to the MDR

## CHAPTER 3
How to use this guidebook

## CHAPTER 4
Compliance guide

## CHAPTER 5
Device Classification
- Classification Rules
- Non-Invasive Devices
- Invasive Devices
- Active Devices
- Special Rules
- Device which are not Medical Devices

## CHAPTER 6
Clinical Evaluation

## CHAPTER 7
Conformity Assessment Route & Annexes

## CHAPTER 8
QMS Tables
- ISO 13485 to MDR requirements table
- MDR ARTICLE TO ISO 13485 CLAUSE table
- MDR Annex TO ISO 13485 CLAUSE table

## CHAPTER 9
Timelines
- Timelines from the MDR
- Visual Timeline
Article 31: Registration of Economic Operators 155
Article 32: Summary of safety and clinical performance 157
Article 33: European database on medical devices 159
Article 34: Functionality of Eudamed 161
Article 35: Authorities responsible for notified bodies 162
Article 36: Requirements relating to notified bodies 164
Article 37: Subsidiaries and subcontracting 165
Article 38: Application by CABs for designation 166
Article 39: Assessment of the application 167
Article 40: Assessment of applications for notification 169
Article 41: Language requirements 171
Article 42: Designation and notification procedure 173
Article 43: Identification number and list of notified bodies 174
Article 44: Monitoring and re-assessment of notified bodies 175
Article 45: Review of notified body assessment 176
Article 46: Changes to designations and notifications 177
Article 47: Challenge to the competence of notified bodies 178
Article 48: Exchange of experience between authorities 179
Article 49: Coordination of notified bodies 180
Article 50: List of standard fees 181
Article 51: Classification of devices 182
Article 52: Conformity assessment procedures 184
Article 53: Notified bodies in conformity assessment 186
Article 54: Clinical evaluation consultation procedure 187
Article 55: Mechanism for scrutiny of conformity assessments 189
Article 56: Certificates of conformity 190
Article 57: System on NBs and certificates of conformity 191
Article 58: Voluntary change of notified body 192
Article 59: Derogation from conformity assessment 193
Article 60: Certificate of free sale 194
Article 61: Clinical evaluation 195
Article 62: Requirements regarding clinical investigations 197
Article 63: Informed consent 200
Article 64: Clinical investigations on incapacitated subjects 201
Article 65: Clinical investigations on minors 202
Article 66: Investigations on pregnant/breastfeeding women 203
Article 67: Additional national measures 204
Article 68: Clinical investigations in emergency situations 205
Article 69: Damage compensation 207
Article 70: Application for clinical investigations 208
Article 71: Assessment by Member States 210
Article 72: Conduct of a clinical investigation 211
Article 73: Electronic system on clinical investigations 212
Article 74: Clinical investigations with CE marked devices 213
Article 75: Substantial modifications to clinical investigations 214
Article 76: Information exchange between Member States 215
Article 77: Information at the end of a clinical investigation 216
Article 78: Assessment procedure for clinical investigations 217
Article 79: Review of coordinated assessment procedure 218
Article 80: Adverse events during clinical investigations 219
Article 81: Implementing acts 220
Article 82: Requirements of other clinical investigations 221
Article 83: Post-market surveillance system of manufacturer 222
Article 84: Post-market surveillance plan 224
Article 85: Post-market surveillance report 225
Article 86: Periodic safety update report 226
Article 87: Incidents and field safety corrective actions 228
Article 88: Trend reporting 229
Article 89: Analysis of incidents & field safety corrective actions 230
Article 90: Analysis of vigilance data 231
Article 91: Implementing acts 232
Article 92: System on vigilance and post-market surveillance 233
<table>
<thead>
<tr>
<th>Article</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>93</td>
<td>Market surveillance activities</td>
<td>234</td>
</tr>
<tr>
<td>94</td>
<td>Devices with unacceptable risk or noncompliance</td>
<td>235</td>
</tr>
<tr>
<td>95</td>
<td>Dealing with devices presenting unacceptable risk</td>
<td>236</td>
</tr>
<tr>
<td>96</td>
<td>Evaluating national measures at Union level</td>
<td>237</td>
</tr>
<tr>
<td>97</td>
<td>Other non-compliance</td>
<td>238</td>
</tr>
<tr>
<td>98</td>
<td>Preventive health protection measures</td>
<td>239</td>
</tr>
<tr>
<td>99</td>
<td>Good administrative practice</td>
<td>240</td>
</tr>
<tr>
<td>100</td>
<td>Electronic system on market surveillance</td>
<td>241</td>
</tr>
<tr>
<td>101</td>
<td>Competent authorities</td>
<td>242</td>
</tr>
<tr>
<td>102</td>
<td>Cooperation</td>
<td>244</td>
</tr>
<tr>
<td>103</td>
<td>Medical Device Coordination Group</td>
<td>245</td>
</tr>
<tr>
<td>104</td>
<td>Support by the Commission</td>
<td>246</td>
</tr>
<tr>
<td>105</td>
<td>Tasks of the MDCG</td>
<td>247</td>
</tr>
<tr>
<td>106</td>
<td>Provision of opinions and advice</td>
<td>249</td>
</tr>
<tr>
<td>107</td>
<td>Conflict of interests</td>
<td>250</td>
</tr>
<tr>
<td>108</td>
<td>Device registers and databanks</td>
<td>251</td>
</tr>
<tr>
<td>109</td>
<td>Confidentiality</td>
<td>252</td>
</tr>
<tr>
<td>110</td>
<td>Data protection</td>
<td>254</td>
</tr>
<tr>
<td>111</td>
<td>Levying of fees</td>
<td>255</td>
</tr>
<tr>
<td>112</td>
<td>Funding of activities related to notified bodies</td>
<td>256</td>
</tr>
<tr>
<td>113</td>
<td>Penalties</td>
<td>257</td>
</tr>
<tr>
<td>114</td>
<td>Committee procedure</td>
<td>258</td>
</tr>
<tr>
<td>115</td>
<td>Exercise of the delegation</td>
<td>259</td>
</tr>
<tr>
<td>116</td>
<td>Separate delegated acts for delegated powers</td>
<td>260</td>
</tr>
<tr>
<td>117</td>
<td>Amendment to Directive 2001/83/EC</td>
<td>261</td>
</tr>
<tr>
<td>118</td>
<td>Amendment to Regulation (EC) No 178/2002</td>
<td>262</td>
</tr>
<tr>
<td>119</td>
<td>Amendment to Regulation (EC) No 1223/2009</td>
<td>263</td>
</tr>
<tr>
<td>120</td>
<td>Transitional provisions</td>
<td>264</td>
</tr>
<tr>
<td>121</td>
<td>Evaluation</td>
<td>265</td>
</tr>
<tr>
<td>122</td>
<td>Repeal</td>
<td>266</td>
</tr>
<tr>
<td>123</td>
<td>Entry into force and date of application</td>
<td>267</td>
</tr>
</tbody>
</table>
Contents

CHAPTER 11 269
MDR Overview - Annexes

ANNEX I - General Safety & Performance Requirements 270
ANNEX II - Technical Documentation 324
ANNEX III - Post-Market Surveillance 327

A quick PMS Checklist: 329
ANNEX IV - Declaration Of Conformity 330
ANNEX V - CE Marking of Conformity 332
ANNEX VI - UDI 334
ANNEX VII - Requirements to be met by Notified Bodies 338
ANNEX VIII - Classification Rules 341
ANNEX IX - Conformity Assessment based on a QMS 346
ANNEX X - Conformity Assessment - Type Examination 349
ANNEX XI - Conformity Assessment - Product Verification 351
ANNEX XII - Certificates issued by a Notified Body 354
ANNEX XIII - Procedure for Custom-Made Devices 356
ANNEX XIV - Clinical Evaluation and PMCF 358
ANNEX XV - Clinical Investigations 360
ANNEX XVI - Products without a Medical Purpose 362
ANNEX XVII - Correlation Table 363

CHAPTER 12 365
Indexes & Look Ups 365

Acronyms 365

List of regulations and Directives 367

Delegating Acts 369
Implementing Acts 370

CHAPTER 13 375
People 375