# CONTENTS

## CHAPTER 1
Welcome

## CHAPTER 2
Background to the IVDR

## CHAPTER 3
How to use this guidebook

## CHAPTER 4
Compliance guide

## CHAPTER 5
Device Classification
Classification Rules

## CHAPTER 6
Performance Evaluation
Performance Evaluation and Clinical Evidence table
Performance Evaluation report checklist

## CHAPTER 7
Conformity Assessment Route & Annexes
Table 1: Routes to conformity
Table 2: Annex requirement table
Table 3: Requirements for Annex IX Section 5
Table 4: Quality Management System reference table

## CHAPTER 8
QMS Tables
ISO 13485 to IVDR requirements table
IVDR Article TO ISO 13485 clause table
IVDR Annex TO ISO 13485 clause table

## CHAPTER 9
Timelines
Visual Timeline
Table Timeline
CHAPTER 10

IVDR Overview - Articles

Article 1: Subject Matter and Scope

Article 2: Definitions

Article 3: Regulatory status of products

Article 4: Genetic Information, Counselling and Informed Consent

Article 5: Placing on the market & putting into service

Article 6: Distance Sales

Article 7: Claims

Article 8: Use of harmonised standards

Article 9: Common specifications

Article 10: General obligations of manufacturers

Article 11: Authorised representative

Article 12: Change of authorised representative

Article 13: General obligations of importers

Article 14: General obligations of distributors

Article 15: Person responsible for regulatory compliance

Article 16: When Manufacturer obligations apply to others

Article 17: EU Declaration of conformity

Article 18: CE marking of conformity

Article 19: Devices for special purposes

Article 20: Parts and components

Article 21: Free movement

Article 22: Identification within the supply chain

Article 23: In Vitro Diagnostic Devices nomenclature

Article 24: Unique Device Identification system

Article 25: UDI database

Article 26: Registration of devices

Article 27: Eudamed registration

Article 28: Registration of Economic Operators
Article 29: Summary of safety and performance 130
Article 30: European database on In Vitro Diagnostic Devices 133
Article 31: Authorities responsible for notified bodies 135
Article 32: Requirements relating to notified bodies 136
Article 33: Subsidiaries and subcontracting 137
Article 34: Designation of notified bodies 138
Article 35: Assessment of the application 139
Article 36: Nomination of experts 141
Article 37: Language requirements 142
Article 38: Designation and notification procedure 143
Article 39: Number and list of notified bodies 144
Article 40: Monitoring and re-assessment of notified bodies 145
Article 41: Review of notified body assessment 146
Article 42: Changes to designations and notifications 147
Article 43: Challenge to the competence of notified bodies 149
Article 44: Exchange between authorities 150
Article 45: Coordination of notified bodies 151
Article 46: List of standard fees 152
Article 47: Classification of devices 153
Article 48: Conformity assessment procedures 154
Article 49: Conformity assessment 155
Article 50: Scrutiny of Class D devices 156
Article 51: Certificates of conformity 157
Article 52: Electronic system on NBs and certificates 158
Article 53: Voluntary change of notified body 160
Article 54: Derogation from conformity assessment 161
Article 55: Certificate of free sale 162
Article 56: Performance evaluation and clinical evidence 163
Article 57: Performance studies 166
Article 58: Requirements for certain studies 167
Contents

Article 59: Informed consent 169
Article 60: Performance studies on incapacitated subjects 170
Article 61: Performance studies on minors 171
Article 62: Studies on pregnant & nursing women 172
Article 63: Additional national measures 173
Article 64: Performance studies in emergency situations 174
Article 65: Damage compensation 175
Article 66: Application for performance studies 176
Article 67: Assessment by Member States 177
Article 68: Conduct a performance study 178
Article 69: Electronic system on performance studies 179
Article 70: Studies regarding CE marked devices 180
Article 71: Modifications to performance studies 181
Article 72: Corrective measures by Member States 182
Article 73: Information to be provided 183
Article 74: Coordinated assessment for studies 184
Article 75: Review of coordinated assessment 185
Article 76: Reporting adverse events during studies 186
Article 77: Implementing acts 187
Article 78: Post-market surveillance system 188
Article 79: Post-market surveillance plan 189
Article 80: Post-market surveillance report 190
Article 81: Periodic safety update report 191
Article 82: Serious incidents and FSCA 193
Article 83: Trend reporting 195
Article 84: Analysis of incidents & FSCA 196
Article 85: Analysis of vigilance data 198
Article 86: Implementing acts 199
Article 87: Electronic system on PMS 200
Article 88: Market surveillance activities 201
Article 89: Devices presenting an unacceptable risk  
Article 90: Dealing with devices presenting risk  
Article 91: Evaluating measures at Union level  
Article 92: Other non-compliance  
Article 93: Preventive health protection measures  
Article 94: Good administrative practice  
Article 95: Electronic system on market surveillance  
Article 96: Competent authorities  
Article 97: Cooperation  
Article 98: In Vitro Diagnostic Device Coordination Group  
Article 99: Tasks of the MDCG  
Article 100: The EU reference laboratories  
Article 101: Device registers and databanks  
Article 102: Confidentiality  
Article 103: Data protection  
Article 104: Levying of fees  
Article 105: Funding of notified bodies  
Article 106: Penalties  
Article 107: Committee procedure  
Article 108: Exercise of the delegation  
Article 109: Delegated acts for delegated powers  
Article 110: Transitional provisions  
Article 111: Evaluation  
Article 112: Repeal  
Article 113: Entry into force and date of application  

CHAPTER 11  
IVDR Overview - Annexes  
ANNEX I - General Safety & Performance Requirements  
ANNEX II - Technical Documentation  
ANNEX III - Technical Documentation on PMS
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>A typical PMS Checklist</td>
<td>313</td>
</tr>
<tr>
<td>ANNEX IV - EU Declaration Of Conformity</td>
<td>314</td>
</tr>
<tr>
<td>ANNEX V - CE Marking of Conformity</td>
<td>316</td>
</tr>
<tr>
<td>ANNEX VI - UDI</td>
<td>318</td>
</tr>
<tr>
<td>ANNEX VII - Requirements to be met by Notified Bodies</td>
<td>321</td>
</tr>
<tr>
<td>ANNEX VIII - Classification Rules</td>
<td>324</td>
</tr>
<tr>
<td>ANNEX IX - Conformity Assessment based on a QMS</td>
<td>326</td>
</tr>
<tr>
<td>ANNEX X - Conformity Assessment based on Type-Examination</td>
<td>329</td>
</tr>
<tr>
<td>ANNEX XI - Production Quality Assurance</td>
<td>331</td>
</tr>
<tr>
<td>ANNEX XII - Certificates issued by a Notified Body</td>
<td>333</td>
</tr>
<tr>
<td>ANNEX XIII - Performance Evaluation</td>
<td>335</td>
</tr>
<tr>
<td>ANNEX XIV - Interventional Performance Studies</td>
<td>338</td>
</tr>
<tr>
<td>ANNEX XV - Correlation Table</td>
<td>342</td>
</tr>
</tbody>
</table>

### CHAPTER 12

- Indexes & Look Ups                                                   | 343  |
- Acronyms                                                             | 343  |
- List of regulations and directives                                  | 346  |
- Delegating Acts                                                      | 348  |
- Implementing Acts                                                    | 350  |

### CHAPTER 13

- People                                                                | 355  |

### CHAPTER 14

- MDCG Guidance                                                        | 365  |