

# Table of Contents

## MEDICAL DEVICE REGULATION (MDR)

published on May 5 2017 at

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

|                   |                                                                                                                                                                       |           |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>PREFACE</b>    | <b>“THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,...<br/>...HAVE ADOPTED THIS REGULATION:”</b>                                                       | <b>1</b>  |
| <b>CHAPTER I</b>  | <b>SCOPE and<br/>DEFINITIONS</b>                                                                                                                                      | <b>13</b> |
| Article 1         | Subject matter and scope                                                                                                                                              | 13        |
| Article 2         | Definitions                                                                                                                                                           | 15        |
| Article 3         | Amendment of certain definitions                                                                                                                                      | 20        |
| Article 4         | Regulatory status of products                                                                                                                                         | 20        |
| <b>CHAPTER II</b> | <b>MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES,<br/>OBLIGATIONS OF ECONOMIC OPERATORS,<br/>REPROCESSING,<br/>CE MARKING,<br/>FREE MOVEMENT</b> | <b>21</b> |
| Article 5         | Placing on the market and putting into service                                                                                                                        | 21        |
| Article 6         | Distance sales                                                                                                                                                        | 22        |
| Article 7         | Claims                                                                                                                                                                | 22        |
| Article 8         | Use of harmonised standards                                                                                                                                           | 22        |
| Article 9         | Common specifications                                                                                                                                                 | 23        |
| Article 10        | General obligations of manufacturers                                                                                                                                  | 23        |
| Article 11        | Authorised representative                                                                                                                                             | 25        |
| Article 12        | Change of authorised representative                                                                                                                                   | 26        |
| Article 13        | General obligations of importers                                                                                                                                      | 26        |
| Article 14        | General obligations of distributors                                                                                                                                   | 27        |
| Article 15        | Person responsible for regulatory compliance                                                                                                                          | 28        |
| Article 16        | Cases in which obligations of manufacturers apply to importers, distributors or other persons                                                                         | 29        |
| Article 17        | Single-use devices and their reprocessing                                                                                                                             | 30        |

|                    |                                                                                                                                                                                                    |           |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Article 18         | Implant card and information to be supplied to the patient with an implanted device                                                                                                                | 31        |
| Article 19         | EU declaration of conformity                                                                                                                                                                       | 32        |
| Article 20         | CE marking of conformity                                                                                                                                                                           | 32        |
| Article 21         | Devices for special purposes                                                                                                                                                                       | 33        |
| 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,<br/>REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS,<br/>SUMMARY OF SAFETY AND CLINICAL PERFORMANCE,<br/>EUROPEAN DATABASE ON MEDICAL DEVICES</b> | <b>34</b> |
| Article 25         | Identification within the supply chain                                                                                                                                                             | 34        |
| Article 26         | Medical devices nomenclature                                                                                                                                                                       | 34        |
| Article 27         | Unique Device Identification [UDI] system                                                                                                                                                          | 35        |
| Article 28         | UDI database                                                                                                                                                                                       | 36        |
| Article 29         | Registration of devices                                                                                                                                                                            | 37        |
| Article 30         | Electronic system for registration of economic operators                                                                                                                                           | 37        |
| Article 31         | Registration of manufacturers, authorised representatives and importers                                                                                                                            | 37        |
| Article 32         | Summary of safety and clinical performance                                                                                                                                                         | 38        |
| Article 33         | European database on medical devices                                                                                                                                                               | 38        |
| Article 34         | Functionality of Eudamed                                                                                                                                                                           | 40        |
| <b>CHAPTER IV</b>  | <b>NOTIFIED BODIES</b>                                                                                                                                                                             | <b>40</b> |
| Article 35         | Authorities responsible for notified bodies                                                                                                                                                        | 40        |
| Article 36         | Requirements relating to notified bodies                                                                                                                                                           | 41        |
| Article 37         | Subsidiaries and subcontracting                                                                                                                                                                    | 41        |
| Article 38         | Application by conformity assessment bodies for designation                                                                                                                                        | 41        |
| Article 39         | Assessment of the application                                                                                                                                                                      | 42        |
| Article 40         | Nomination of experts for joint assessment of applications for notification                                                                                                                        | 43        |
| Article 41         | Language requirements                                                                                                                                                                              | 43        |
| Article 42         | Designation and notification procedure                                                                                                                                                             | 43        |
| Article 43         | Identification number and list of notified bodies                                                                                                                                                  | 44        |
| Article 44         | Monitoring and re-assessment of notified bodies                                                                                                                                                    | 45        |
| Article 45         | Review of notified body assessment of technical documentation and clinical evaluation documentation                                                                                                | 46        |
| Article 46         | Changes to designations and notifications                                                                                                                                                          | 46        |
| Article 47         | Challenge to the competence of notified bodies                                                                                                                                                     | 48        |
| Article 48         | Peer review and exchange of experience between authorities responsible for notified bodies                                                                                                         | 48        |
| Article 49         | Coordination of notified bodies                                                                                                                                                                    | 49        |
| Article 50         | List of standard fees                                                                                                                                                                              | 49        |
| <b>CHAPTER V</b>   | <b>CLASSIFICATION and<br/>CONFORMITY ASSESSMENT</b>                                                                                                                                                | <b>49</b> |
| <b>Section 1</b>   | <b>CLASSIFICATION</b>                                                                                                                                                                              | <b>49</b> |
| Article 51         | Classification of devices                                                                                                                                                                          | 49        |
| <b>Section 2</b>   | <b>CONFORMITY ASSESSMENT</b>                                                                                                                                                                       | <b>50</b> |
| Article 52         | Conformity assessment procedures                                                                                                                                                                   | 50        |

|                    |                                                                                                                              |           |
|--------------------|------------------------------------------------------------------------------------------------------------------------------|-----------|
| Article 53         | Involvement of notified bodies in conformity assessment procedures                                                           | 52        |
| Article 54         | Clinical evaluation consultation procedure for certain class III and class IIb devices                                       | 52        |
| Article 55         | Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices                                  | 53        |
| Article 56         | Certificates of conformity                                                                                                   | 53        |
| Article 57         | Electronic system on notified bodies and on certificates of conformity                                                       | 54        |
| Article 58         | Voluntary change of notified body                                                                                            | 54        |
| Article 59         | Derogation from the conformity assessment procedures                                                                         | 55        |
| Article 60         | Certificate of free sale                                                                                                     | 55        |
| <b>CHAPTER VI</b>  | <b>CLINICAL EVALUATION and<br/>CLINICAL INVESTIGATIONS</b>                                                                   | <b>55</b> |
| Article 61         | Clinical evaluation                                                                                                          | 55        |
| Article 62         | General requirements regarding clinical investigations conducted to demonstrate conformity of devices                        | 57        |
| Article 63         | Informed consent                                                                                                             | 59        |
| Article 64         | Clinical investigations on incapacitated subjects                                                                            | 60        |
| Article 65         | Clinical investigations on minors                                                                                            | 60        |
| Article 66         | Clinical investigations on pregnant or breastfeeding women                                                                   | 61        |
| Article 67         | Additional national measures                                                                                                 | 61        |
| Article 68         | Clinical investigations in emergency situations                                                                              | 61        |
| Article 69         | Damage compensation                                                                                                          | 62        |
| Article 70         | Application for clinical investigations                                                                                      | 62        |
| Article 71         | Assessment by Member States                                                                                                  | 63        |
| Article 72         | Conduct of a clinical investigation                                                                                          | 64        |
| Article 73         | Electronic system on clinical investigations                                                                                 | 65        |
| Article 74         | Clinical investigations regarding devices bearing the CE marking                                                             | 66        |
| Article 75         | Substantial modifications to clinical investigations                                                                         | 66        |
| Article 76         | Corrective measures to be taken by Member States and information exchange between Member States                              | 66        |
| Article 77         | Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination | 67        |
| Article 78         | Coordinated assessment procedure for clinical investigations                                                                 | 68        |
| Article 79         | Review of coordinated assessment procedure                                                                                   | 69        |
| Article 80         | Recording and reporting of adverse events that occur during clinical investigations                                          | 69        |
| Article 81         | Implementing acts                                                                                                            | 70        |
| Article 82         | Requirements regarding other clinical investigations                                                                         | 71        |
| <b>CHAPTER VII</b> | <b>POST-MARKET SURVEILLANCE,<br/>VIGILANCE and<br/>MARKET SURVEILLANCE</b>                                                   | <b>71</b> |
| <b>Section 1</b>   | <b>POST-MARKET SURVEILLANCE</b>                                                                                              | <b>71</b> |
| Article 83         | Post-market surveillance system of the manufacturer                                                                          | 71        |
| Article 84         | Post-market surveillance plan                                                                                                | 72        |
| Article 85         | Post-market surveillance report                                                                                              | 72        |
| Article 86         | Periodic safety update report [PSUR]                                                                                         | 72        |
| <b>Section 2</b>   | <b>VIGILANCE</b>                                                                                                             | <b>73</b> |
| Article 87         | Reporting of serious incidents and field safety corrective actions                                                           | 73        |
| Article 88         | Trend reporting                                                                                                              | 74        |
| Article 89         | Analysis of serious incidents and field safety corrective actions                                                            | 74        |

|                     |                                                                                                                                                      |           |
|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Article 90          | Analysis of vigilance data                                                                                                                           | 76        |
| Article 91          | Implementing acts                                                                                                                                    | 76        |
| Article 92          | Electronic system on vigilance and on post-market surveillance                                                                                       | 77        |
| <b>Section 3</b>    | <b>MARKET SURVEILLANCE</b>                                                                                                                           | <b>78</b> |
| Article 93          | Market surveillance activities                                                                                                                       | 78        |
| Article 94          | Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance                                                           | 79        |
| Article 95          | Procedure for dealing with devices presenting an unacceptable risk to health and safety                                                              | 79        |
| Article 96          | Procedure for evaluating national measures at Union level                                                                                            | 80        |
| Article 97          | Other non-compliance                                                                                                                                 | 80        |
| Article 98          | Preventive health protection measures                                                                                                                | 80        |
| Article 99          | Good administrative practice                                                                                                                         | 81        |
| Article 100         | Electronic system on market surveillance                                                                                                             | 81        |
| <b>CHAPTER VIII</b> | <b>COOPERATION BETWEEN MEMBER STATES,<br/>MEDICAL DEVICE COORDINATION GROUP,<br/>EXPERT LABORATORIES,<br/>EXPERT PANELS and<br/>DEVICE REGISTERS</b> | <b>82</b> |
| Article 101         | Competent authorities                                                                                                                                | 82        |
| Article 102         | Cooperation                                                                                                                                          | 82        |
| Article 103         | Medical Device Coordination Group [MDCG]                                                                                                             | 82        |
| Article 104         | Support by the Commission                                                                                                                            | 83        |
| Article 105         | Tasks of the MDCG                                                                                                                                    | 83        |
| Article 106         | Provision of scientific, technical and clinical opinions and advice                                                                                  | 84        |
| Article 107         | Conflict of interests                                                                                                                                | 86        |
| Article 108         | Device registers and data banks                                                                                                                      | 86        |
| <b>CHAPTER IX</b>   | <b>CONFIDENTIALITY,<br/>DATA PROTECTION,<br/>FUNDING and<br/>PENALTIES</b>                                                                           | <b>86</b> |
| Article 109         | Confidentiality                                                                                                                                      | 86        |
| Article 110         | Data protection                                                                                                                                      | 87        |
| Article 111         | Levying of fees                                                                                                                                      | 87        |
| Article 112         | Funding of activities related to designation and monitoring of notified bodies                                                                       | 87        |
| Article 113         | Penalties                                                                                                                                            | 87        |
| <b>CHAPTER X</b>    | <b>FINAL PROVISIONS</b>                                                                                                                              | <b>87</b> |
| Article 114         | Committee procedure                                                                                                                                  | 87        |
| Article 115         | Exercise of the delegation                                                                                                                           | 88        |
| Article 116         | Separate delegated acts for different delegated powers                                                                                               | 88        |
| Article 117         | Amendment to Directive 2001/83/EC [ <i>medicinal products</i> ]                                                                                      | 88        |
| Article 118         | Amendments to Regulation (EC) No 178/2002 [ <i>food</i> ]                                                                                            | 89        |
| Article 119         | Amendments to Regulation (EC) No 1223/2009 [ <i>cosmetic products</i> ]                                                                              | 89        |
| Article 120         | Transitional provisions                                                                                                                              | 89        |
| Article 121         | Evaluation                                                                                                                                           | 90        |
| Article 122         | Repeal                                                                                                                                               | 90        |
| Article 123         | Entry into force and date of application                                                                                                             | 91        |

|                    |                                                                                                                                                                                                                |            |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <b>ANNEXES</b>     | <b>Table of contents</b>                                                                                                                                                                                       | <b>93</b>  |
| <b>ANNEX I</b>     | <b>GENERAL SAFETY AND PERFORMANCE REQUIREMENTS</b>                                                                                                                                                             | <b>94</b>  |
| <b>Chapter I</b>   | <b>GENERAL REQUIREMENTS (from 1. to 9.)</b>                                                                                                                                                                    | <b>94</b>  |
| <b>Chapter II</b>  | <b>REQUIREMENTS REGARDING DESIGN AND MANUFACTURE</b>                                                                                                                                                           | <b>95</b>  |
| 10.                | Chemical, physical and biological properties                                                                                                                                                                   | 95         |
| 11.                | Infection and microbial contamination                                                                                                                                                                          | 97         |
| 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 | 98         |
| 13.                | Devices incorporating materials of biological origin                                                                                                                                                           | 98         |
| 14.                | Construction of devices and interaction with their environment                                                                                                                                                 | 99         |
| 15.                | Devices with a diagnostic or measuring function                                                                                                                                                                | 99         |
| 16.                | Protection against radiation                                                                                                                                                                                   | 100        |
| 17.                | Electronic programmable systems – Devices that incorporate electronic programmable systems and software that are devices in themselves                                                                         | 100        |
| 18.                | Active devices and devices connected to them                                                                                                                                                                   | 101        |
| 19.                | Particular requirements for active implantable devices                                                                                                                                                         | 101        |
| 20.                | Protection against mechanical and thermal risks                                                                                                                                                                | 102        |
| 21.                | Protection against the risks posed to the patient or user by devices supplying energy or substances                                                                                                            | 102        |
| 22.                | Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons                                                                                                      | 102        |
| <b>Chapter III</b> | <b>REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE</b>                                                                                                                                         | <b>103</b> |
| 23.                | Label and instructions for use                                                                                                                                                                                 | 103        |
| 23.1.              | <i>General requirements regarding the information supplied by the manufacturer</i>                                                                                                                             | 103        |
| 23.2.              | <i>Information on the label</i>                                                                                                                                                                                | 104        |
| 23.3.              | Information on the packaging which maintains the sterile condition of a device ('sterile packaging')                                                                                                           | 104        |
| 23.4.              | <i>Information in the instructions for use</i>                                                                                                                                                                 | 105        |
| <b>ANNEX II</b>    | <b>TECHNICAL DOCUMENTATION</b>                                                                                                                                                                                 | <b>108</b> |
| 1.                 | Device description and specification, including variants and accessories                                                                                                                                       | 108        |
| 1.1.               | <i>Device description and specification</i>                                                                                                                                                                    | 108        |
| 1.2.               | <i>Reference to previous and similar generations of the device</i>                                                                                                                                             | 108        |
| 2.                 | Information to be supplied by the manufacturer                                                                                                                                                                 | 108        |
| 3.                 | Design and manufacturing information                                                                                                                                                                           | 109        |
| 4.                 | General safety and performance requirements                                                                                                                                                                    | 109        |
| 5.                 | Benefit-risk analysis and risk management                                                                                                                                                                      | 109        |
| 6.                 | Product verification and validation                                                                                                                                                                            | 109        |
| 6.1.               | <i>Pre-clinical and clinical data</i>                                                                                                                                                                          | 109        |
| 6.2.               | <i>Additional information required in specific cases</i>                                                                                                                                                       | 110        |
| <b>ANNEX III</b>   | <b>TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE</b>                                                                                                                                                     | <b>112</b> |
| 1.1.               | The post-market surveillance plan drawn up in accordance with Article 84                                                                                                                                       | 112        |
| 1.2.               | The PSUR [ <i>periodic safety update report</i> ] referred to in Article 86 and the post-market surveillance report referred to in Article 85                                                                  | 112        |

|                  |                                                                                                                                                                                                                                                                                                              |            |
|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <b>ANNEX IV</b>  | <b>EU DECLARATION OF CONFORMITY</b>                                                                                                                                                                                                                                                                          | <b>113</b> |
| <b>ANNEX V</b>   | <b>CE MARKING OF CONFORMITY</b>                                                                                                                                                                                                                                                                              | <b>114</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>115</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>115</b> |
| 1.               | Information relating to the economic operator                                                                                                                                                                                                                                                                | 115        |
| 2.               | Information relating to the device                                                                                                                                                                                                                                                                           |            |
| <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>116</b> |
| <b>PART C</b>    | <b>THE UDI SYSTEM</b>                                                                                                                                                                                                                                                                                        | <b>117</b> |
| 1.               | Definitions                                                                                                                                                                                                                                                                                                  | 117        |
| 2.               | General requirements                                                                                                                                                                                                                                                                                         | 118        |
| 3.               | The UDI                                                                                                                                                                                                                                                                                                      | 118        |
| 4.               | UDI carrier                                                                                                                                                                                                                                                                                                  | 119        |
| 5.               | General principles of the UDI database                                                                                                                                                                                                                                                                       | 120        |
| 6.               | Rules for specific device types                                                                                                                                                                                                                                                                              | 120        |
| 6.1.             | <i>Implantable devices</i>                                                                                                                                                                                                                                                                                   | 120        |
| 6.2.             | <i>Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing between uses</i>                                                                                                                                                                                                         | 120        |
| 6.3.             | <i>Systems and procedure packs as referred to in Article 22</i>                                                                                                                                                                                                                                              | 121        |
| 6.4.             | <i>Configurable devices</i>                                                                                                                                                                                                                                                                                  | 121        |
| 6.5.             | <i>Device software</i>                                                                                                                                                                                                                                                                                       | 121        |
| <b>ANNEX VII</b> | <b>REQUIREMENTS TO BE MET BY NOTIFIED BODIES</b>                                                                                                                                                                                                                                                             | <b>123</b> |
| <b>1.</b>        | <b>ORGANISATIONAL AND GENERAL REQUIREMENTS</b>                                                                                                                                                                                                                                                               | <b>123</b> |
| 1.1.             | Legal status and organisational structure                                                                                                                                                                                                                                                                    | 123        |
| 1.2.             | Independence and impartiality                                                                                                                                                                                                                                                                                | 123        |
| 1.3.             | Confidentiality                                                                                                                                                                                                                                                                                              | 124        |
| 1.4.             | Liability                                                                                                                                                                                                                                                                                                    | 125        |
| 1.5.             | Financial requirements                                                                                                                                                                                                                                                                                       | 125        |
| 1.6.             | Participation in coordination activities                                                                                                                                                                                                                                                                     | 125        |
| <b>2.</b>        | <b>QUALITY MANAGEMENT REQUIREMENTS</b>                                                                                                                                                                                                                                                                       | <b>125</b> |
| <b>3.</b>        | <b>RESOURCE REQUIREMENTS</b>                                                                                                                                                                                                                                                                                 | <b>126</b> |
| 3.1.             | General                                                                                                                                                                                                                                                                                                      | 126        |
| 3.2.             | Qualification criteria in relation to personnel                                                                                                                                                                                                                                                              | 126        |
| 3.3.             | Documentation of qualification, training and authorisation of personnel                                                                                                                                                                                                                                      | 129        |
| 3.4.             | Subcontractors and external experts                                                                                                                                                                                                                                                                          | 129        |
| 3.5.             | Monitoring of competences, training and exchange of experience                                                                                                                                                                                                                                               | 130        |
| <b>4.</b>        | <b>PROCESS REQUIREMENTS</b>                                                                                                                                                                                                                                                                                  | <b>130</b> |
| 4.1.             | General                                                                                                                                                                                                                                                                                                      | 130        |
| 4.2.             | Notified body quotations and pre-application activities                                                                                                                                                                                                                                                      | 130        |
| 4.3.             | Application review and contract                                                                                                                                                                                                                                                                              | 130        |
| 4.4.             | Allocation of resources                                                                                                                                                                                                                                                                                      | 131        |

|                    |                                                           |            |
|--------------------|-----------------------------------------------------------|------------|
| 4.5.               | Conformity assessment activities                          | 131        |
| 4.5.1.             | <i>General</i>                                            | 131        |
| 4.5.2.             | <i>Quality management system auditing</i>                 | 132        |
| 4.5.3.             | <i>Product verification</i>                               | 133        |
| 4.5.4.             | <i>Pre-clinical evaluation assessment</i>                 | 134        |
| 4.5.5.             | <i>Clinical evaluation assessment</i>                     | 134        |
| 4.5.6.             | <i>Specific procedures</i>                                | 135        |
| 4.6.               | Reporting                                                 | 135        |
| 4.7.               | Final review                                              | 136        |
| 4.8.               | Decisions and certifications                              | 136        |
| 4.9.               | Changes and modifications                                 | 137        |
| 4.10.              | Surveillance activities and post-certification monitoring | 137        |
| 4.11.              | Re-certification                                          | 138        |
| <b>ANNEX VIII</b>  | <b>CLASSIFICATION RULES</b>                               | <b>140</b> |
| <b>Chapter I</b>   | <b>DEFINITIONS SPECIFIC TO CLASSIFICATION RULES</b>       | <b>140</b> |
| 1.                 | Duration of use                                           | 140        |
| 2.                 | Invasive and active devices                               | 140        |
| <b>Chapter II</b>  | <b>IMPLEMENTING RULES (from 3.1. to 3.7.)</b>             | <b>140</b> |
| <b>Chapter III</b> | <b>CLASSIFICATION RULES</b>                               | <b>141</b> |
| 4.                 | Non-invasive devices                                      | 141        |
| 4.1.               | <i>Rule 1</i>                                             | 141        |
| 4.2.               | <i>Rule 2</i>                                             | 141        |
| 4.3.               | <i>Rule 3</i>                                             | 141        |
| 4.4.               | <i>Rule 4</i>                                             | 141        |
| 5.                 | Invasive devices                                          | 142        |
| 5.1.               | <i>Rule 5</i>                                             | 142        |
| 5.2.               | <i>Rule 6</i>                                             | 142        |
| 5.3.               | <i>Rule 7</i>                                             | 142        |
| 5.4.               | <i>Rule 8</i>                                             | 143        |
| 6.                 | Active devices                                            | 143        |
| 6.1.               | <i>Rule 9</i>                                             | 143        |
| 6.2.               | <i>Rule 10</i>                                            | 143        |
| 6.3.               | <i>Rule 11</i>                                            | 144        |
| 6.4.               | <i>Rule 12</i>                                            | 144        |
| 6.5.               | <i>Rule 13</i>                                            | 144        |
| 7.                 | Special rules                                             | 144        |
| 7.1.               | <i>Rule 14</i>                                            | 144        |
| 7.2.               | <i>Rule 15</i>                                            | 144        |
| 7.3.               | <i>Rule 16</i>                                            | 144        |
| 7.4.               | <i>Rule 17</i>                                            | 144        |
| 7.5.               | <i>Rule 18</i>                                            | 145        |
| 7.6.               | <i>Rule 19</i>                                            | 145        |
| 7.7.               | <i>Rule 20</i>                                            | 145        |
| 7.8.               | <i>Rule 21</i>                                            | 145        |
| 7.9.               | <i>Rule 22</i>                                            | 145        |

|                    |                                                                                                                                                                                                                                                      |            |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <b>ANNEX IX</b>    | <b>CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION</b>                                                                                                                                       | <b>146</b> |
| <b>Chapter I</b>   | <b>QUALITY MANAGEMENT SYSTEM</b>                                                                                                                                                                                                                     | <b>146</b> |
| 1.                 | (no title)                                                                                                                                                                                                                                           | 146        |
| 2.                 | Quality management system assessment                                                                                                                                                                                                                 | 146        |
| 3.                 | Surveillance assessment applicable to class IIa, class IIb and class III devices                                                                                                                                                                     | 148        |
| <b>Chapter II</b>  | <b>ASSESSMENT OF THE TECHNICAL DOCUMENTATION</b>                                                                                                                                                                                                     | <b>149</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)                                                                                       | 149        |
| 5.                 | Specific additional procedures                                                                                                                                                                                                                       | 150        |
| 5.1                | <i>Assessment procedure for certain class III and class IIb devices</i>                                                                                                                                                                              | 150        |
| 5.2.               | <i>Procedure in the case of devices incorporating a medicinal substance</i>                                                                                                                                                                          | 151        |
| 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>                                                       | 152        |
| 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>                                                                                 | 153        |
| 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) | 153        |
| <b>Chapter III</b> | <b>ADMINISTRATIVE PROVISIONS (from 7. to 8.)</b>                                                                                                                                                                                                     | <b>154</b> |
| <b>ANNEX X</b>     | <b>CONFORMITY ASSESSMENT BASED ON TYPE EXAMINATION</b>                                                                                                                                                                                               | <b>155</b> |
| 1.                 | (no title)                                                                                                                                                                                                                                           | 155        |
| 2.                 | Application                                                                                                                                                                                                                                          | 155        |
| 3.                 | Assessment                                                                                                                                                                                                                                           | 155        |
| 4.                 | Certificate                                                                                                                                                                                                                                          | 156        |
| 5.                 | Changes to the type                                                                                                                                                                                                                                  | 156        |
| 6.                 | Specific additional procedures                                                                                                                                                                                                                       | 156        |
| 7.                 | Administrative provisions                                                                                                                                                                                                                            | 156        |
| <b>ANNEX XI</b>    | <b>CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION</b>                                                                                                                                                                                | <b>157</b> |
| 1. to 3.           | (no title)                                                                                                                                                                                                                                           | 157        |
| <b>PART A</b>      | <b>PRODUCTION QUALITY ASSURANCE</b>                                                                                                                                                                                                                  | <b>157</b> |
| 4. to 5.           | (no title)                                                                                                                                                                                                                                           | 157        |
| 6.                 | Quality management system                                                                                                                                                                                                                            | 157        |
| 7.                 | Surveillance                                                                                                                                                                                                                                         | 158        |
| 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)    | 158        |
| 9.                 | Administrative provisions                                                                                                                                                                                                                            | 158        |
| 10.                | Application to class IIa devices                                                                                                                                                                                                                     | 158        |
| <b>PART B</b>      | <b>PRODUCT VERIFICATION</b>                                                                                                                                                                                                                          | <b>159</b> |
| 11. to 14.         | (no title)                                                                                                                                                                                                                                           | 159        |
| 15.                | Verification by examination and testing of every product                                                                                                                                                                                             | 159        |
| 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)    | 160        |
| 17.                | Administrative provisions                                                                                                                                                                                                                            | 160        |
| 18.                | Application to class IIa devices                                                                                                                                                                                                                     | 160        |

|                    |                                                                                                                                                                                        |            |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <b>ANNEX XII</b>   | <b>CERTIFICATES ISSUED BY A NOTIFIED BODY</b>                                                                                                                                          | <b>161</b> |
| <b>Chapter I</b>   | <b>GENERAL REQUIREMENTS</b>                                                                                                                                                            | <b>161</b> |
| <b>Chapter II</b>  | <b>MINIMUM CONTENT OF THE CERTIFICATES</b>                                                                                                                                             | <b>161</b> |
| <b>ANNEX XIII</b>  | <b>PROCEDURE FOR CUSTOM-MADE DEVICES</b>                                                                                                                                               | <b>163</b> |
| <b>ANNEX XIV</b>   | <b>CLINICAL EVALUATION and<br/>POST-MARKET CLINICAL FOLLOW-UP</b>                                                                                                                      | <b>164</b> |
| <b>PART A</b>      | <b>CLINICAL EVALUATION</b>                                                                                                                                                             | <b>164</b> |
| <b>PART B</b>      | <b>POST-MARKET CLINICAL FOLLOW-UP [PMCF]</b>                                                                                                                                           | <b>165</b> |
| <b>ANNEX XV</b>    | <b>CLINICAL INVESTIGATIONS</b>                                                                                                                                                         | <b>167</b> |
| <b>Chapter I</b>   | <b>GENERAL REQUIREMENTS</b>                                                                                                                                                            | <b>167</b> |
| 1.                 | Ethical principles                                                                                                                                                                     | 167        |
| 2.                 | Methods                                                                                                                                                                                | 167        |
| <b>Chapter II</b>  | <b>DOCUMENTATION REGARDING THE APPLICATION FOR CLINICAL INVESTIGATION</b>                                                                                                              | <b>167</b> |
| 1.                 | Application form                                                                                                                                                                       | 167        |
| 2.                 | Investigator's Brochure [IB]                                                                                                                                                           | 168        |
| 3.                 | Clinical Investigation Plan [CIP]                                                                                                                                                      | 169        |
| 4.                 | Other information                                                                                                                                                                      | 171        |
| <b>Chapter III</b> | <b>OTHER OBLIGATIONS OF THE SPONSOR</b>                                                                                                                                                | <b>171</b> |
| <b>ANNEX XVI</b>   | <b>LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE<br/>REFERRED TO IN ARTICLE 1(2)</b>                                                                                  | <b>173</b> |
| <b>ANNEX XVII</b>  | <b>CORRELATION TABLE</b> <i>[between Council Directive 90/385/EEC for active implantable<br/>medical devices, Council Directive 93/42/EEC for medical devices and this Regulation]</i> | <b>174</b> |