

Regulation (EU) 2017/746 of the European Parliament and of the Council of
5 April 2017 on in vitro diagnostic medical devices and repealing Directive
98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance)

CHAPTER I

INTRODUCTORY PROVISIONS

Section 1

Scope and definitions

- Article 1 Subject matter and scope
Article 2 Definitions

Section 2

Regulatory status of products and counselling

- Article 3 Regulatory status of products
Article 4 Genetic information, counselling and informed consent

CHAPTER II

MAKING AVAILABLE ON THE MARKET AND PUTTING
INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC
OPERATORS, CE MARKING, FREE MOVEMENT

- Article 5 Placing on the market and 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 Cases in which obligations of manufacturers apply to importers,
distributors or other persons
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

CHAPTER III

IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES

Article 22	Identification within the supply chain
Article 23	Medical devices nomenclature
Article 24	Unique Device Identification system
Article 25	UDI database
Article 26	Registration of devices
Article 27	Electronic system for registration of economic operators
Article 28	Registration of manufacturers, authorised representatives and importers
Article 29	Summary of safety and performance
Article 30	European database on medical devices

CHAPTER IV

NOTIFIED BODIES

Article 31	Authorities responsible for notified bodies
Article 32	Requirements relating to notified bodies
Article 33	Subsidiaries and subcontracting
Article 34	Application by conformity assessment bodies for designation
Article 35	Assessment of the application
Article 36	Nomination of experts for joint assessment of applications for notification
Article 37	Language requirements
Article 38	Designation and notification procedure
Article 39	Identification number and list of notified bodies
Article 40	Monitoring and re-assessment of notified bodies
Article 41	Review of notified body assessment of technical documentation and performance evaluation documentation
Article 42	Changes to designations and notifications
Article 43	Challenge to the competence of notified bodies
Article 44	Peer review and exchange of experience between authorities responsible for notified bodies
Article 45	Coordination of notified bodies
Article 46	List of standard fees

CHAPTER V

CLASSIFICATION AND CONFORMITY ASSESSMENT

Section 1

Classification

Article 47	Classification of devices
------------	---------------------------

Section 2

Conformity assessment

Article 48	Conformity assessment procedures
Article 49	Involvement of notified bodies in conformity assessment procedures
Article 50	Mechanism for scrutiny of conformity assessments of class D devices
Article 51	Certificates of conformity
Article 52	Electronic system on notified bodies and on certificates of conformity
Article 53	Voluntary change of notified body
Article 54	Derogation from the conformity assessment procedures
Article 55	Certificate of free sale

CHAPTER VI

CLINICAL EVIDENCE, PERFORMANCE EVALUATION AND PERFORMANCE STUDIES

Article 56	Performance evaluation and clinical evidence
Article 57	General requirements regarding performance studies
Article 58	Additional requirements for certain performance studies
Article 59	Informed consent
Article 60	Performance studies on incapacitated subjects
Article 61	Performance studies on minors
Article 62	Performance studies on pregnant or breastfeeding women
Article 63	Additional national measures
Article 64	Performance studies in emergency situations
Article 65	Damage compensation
Article 66	Application for performance studies
Article 67	Assessment by Member States
Article 68	Conduct of a performance study
Article 69	Electronic system on performance studies
Article 70	Performance studies regarding devices bearing the CE marking
Article 71	Substantial modifications to performance studies
Article 72	Corrective measures to be taken by Member States and information exchange between Member States on performance studies
Article 73	Information from the sponsor at the end of a performance study or in the event of a temporary halt or early termination
Article 74	Coordinated assessment procedure for performance studies
Article 75	Review of the coordinated assessment procedure
Article 76	Recording and reporting of adverse events that occur during performance studies
Article 77	Implementing acts

CHAPTER VII

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

Section 1

Post-market surveillance

Article 78	Post-market surveillance system of the manufacturer
Article 79	Post-market surveillance plan
Article 80	Post-market surveillance report
Article 81	Periodic safety update report

Section 2

Vigilance

Article 82	Reporting of serious incidents and field safety corrective actions
Article 83	Trend reporting
Article 84	Analysis of serious incidents and field safety corrective actions
Article 85	Analysis of vigilance data
Article 86	Implementing acts
Article 87	Electronic system on vigilance and post-market surveillance

Section 3

Market surveillance

Article 88	Market surveillance activities
Article 89	Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance
Article 90	Procedure for dealing with devices presenting an unacceptable risk to health and safety
Article 91	Procedure for evaluating national 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

CHAPTER VIII

COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EU REFERENCE LABORATORIES AND DEVICE REGISTERS

Article 96	Competent authorities
Article 97	Cooperation
Article 98	Medical Device Coordination Group
Article 99	Tasks of the MDCG
Article 100	The European Union reference laboratories
Article 101	Device registers and databanks

CHAPTER IX

CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES

Article 102	Confidentiality
Article 103	Data protection
Article 104	Levying of fees
Article 105	Funding of activities related to designation and monitoring of notified bodies
Article 106	Penalties

CHAPTER X

FINAL PROVISIONS

Article 107	Committee procedure
Article 108	Exercise of the delegation
Article 109	Separate delegated acts for different delegated powers
Article 110	Transitional provisions
Article 111	Evaluation
Article 112	Repeal
Article 113	Entry into force and date of application
	Signature

ANNEXES

I	General safety and performance requirements
II	Technical documentation
III	Technical documentation on post-market surveillance
IV	EU declaration of conformity
V	CE marking of conformity
VI	Information to be submitted upon the registration of devices and...
VII	Requirements to be met by notified bodies
VIII	Classification rules
IX	Conformity assessment based on a quality management system and on...
X	Conformity assessment based on type examination
XI	Conformity assessment based on production quality assurance
XII	Certificates issued by a notified body

- XIII Performance evaluation, performance studies and post-market performance follow-up
- XIV Interventional clinical performance studies and certain other performance studies
- XV Correlation table

ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

CHAPTER I

GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by their manufacturer and...
2. The requirement in this Annex to reduce risks as far...
3. Manufacturers shall establish, implement, document and maintain a risk management...
4. Risk control measures adopted by manufacturers for the design and...
5. In eliminating or reducing risks related to use error, the...
6. The characteristics and performance of a device shall not be...
7. Devices shall be designed, manufactured and packaged in such a...
8. All known and foreseeable risks, and any undesirable effects shall...

CHAPTER II

REQUIREMENTS REGARDING PERFORMANCE, DESIGN AND MANUFACTURE

9. Performance characteristics
 - 9.1. Devices shall be designed and manufactured in such a way...
 - 9.2. The performance characteristics of the device shall be maintained during...
 - 9.3. Where the performance of devices depends on the use of...
 - 9.4. The characteristics and performances of the device shall be specifically...
10. Chemical, physical and biological properties
 - 10.1. Devices shall be designed and manufactured in such a way...
 - 10.2. Devices shall be designed, manufactured and packaged in such a...
 - 10.3. Devices shall be designed and manufactured in such a way...
 - 10.4. Devices shall be designed and manufactured in such a way...
11. Infection and microbial contamination
 - 11.1. Devices and their manufacturing processes shall be designed in such...
 - 11.2. Devices labelled either as sterile or as having a specific...
 - 11.3. Devices labelled as sterile shall be processed, manufactured, packaged and,...
 - 11.4. Devices intended to be sterilised shall be manufactured and packaged...
 - 11.5. Packaging systems for non-sterile devices shall maintain the integrity and...

- 11.6. The labelling of the device shall distinguish between identical or...
12. Devices incorporating materials of biological origin
13. Construction of devices and interaction with their environment
 - 13.1. If the device is intended for use in combination with...
 - 13.2. Devices shall be designed and manufactured in such a way...
 - 13.3. Devices shall be designed and manufactured in such a way...
 - 13.4. Devices shall be designed and manufactured in such a way...
 - 13.5. Devices that are intended to be operated together with other...
 - 13.6. Devices shall be designed and manufactured in such a way...
 - 13.7. The measuring, monitoring or display scale (including colour change and...
14. Devices with a measuring function
 - 14.1. Devices having a primary analytical measuring function shall be designed...
 - 14.2. The measurements made by devices with a measuring function shall...
15. Protection against radiation
 - 15.1. Devices shall be designed, manufactured and packaged in such a...
 - 15.2. When devices are intended to emit hazardous, or potentially hazardous,...
 - 15.3. The operating instructions for devices emitting hazardous or potentially hazardous...
16. Electronic programmable systems — devices that incorporate electronic programmable systems...
 - 16.1. Devices that incorporate electronic programmable systems, including software, or software...
 - 16.2. For devices that incorporate software or for software that are...
 - 16.3. Software referred to in this Section that is intended to...
 - 16.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks...
17. Devices connected to or equipped with an energy source
 - 17.1. For devices connected to or equipped with an energy source,...
 - 17.2. Devices where the safety of the patient depends on an...
 - 17.3. Devices shall be designed and manufactured in such a way...
 - 17.4. Devices shall be designed and manufactured in such a way...
 - 17.5. Devices shall be designed and manufactured in such a way...
18. Protection against mechanical and thermal risks
 - 18.1. Devices shall be designed and manufactured in such a way...
 - 18.2. Devices shall be sufficiently stable under the foreseen operating conditions....
 - 18.3. Where there are risks due to the presence of moving...
 - 18.4. Devices shall be designed and manufactured in such a way...
 - 18.5. Devices shall be designed and manufactured in such a way...
 - 18.6. Terminals and connectors to the electricity, gas or hydraulic and...
 - 18.7. Errors likely to be made when fitting or refitting certain...
 - 18.8. Accessible parts of devices (excluding the parts or areas intended...
19. Protection against the risks posed by devices intended for self-testing...
 - 19.1. Devices intended for self-testing or near-patient testing shall be designed...
 - 19.2. Devices intended for self-testing or near-patient testing shall be designed...

- 19.3. Devices intended for self-testing and near-patient testing shall, where feasible,...

CHAPTER III

REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE

20. Label and instructions for use
- 20.1. General requirements regarding the information supplied by the manufacturer
 - 20.2. Information on the label
 - 20.3. Information on the packaging which maintains the sterile condition of...
 - 20.4. Information in the instructions for use
 - 20.4.1. The instructions for use shall contain all of the following...
 - 20.4.2. In addition, the instructions for use for devices intended for...

ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary thereof to...

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES
 - 1.1. Device description and specification
 - 1.2. Reference to previous and similar generations of the device
2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER
3. DESIGN AND MANUFACTURING INFORMATION
 - 3.1. Design information
 - 3.2. Manufacturing information
4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT
6. PRODUCT VERIFICATION AND VALIDATION
 - 6.1. Information on analytical performance of the device
 - 6.1.1. Specimen type
 - 6.1.2. Analytical performance characteristics
 - 6.1.2.1. Accuracy of measurement
 - 6.1.2.2. Analytical sensitivity
 - 6.1.2.3. Analytical specificity
 - 6.1.2.4. Metrological traceability of calibrator and control material values
 - 6.1.2.5. Measuring range of the assay
 - 6.1.2.6. Definition of assay cut-off
 - 6.1.3. The analytical performance report referred to in Annex XIII.
 - 6.2. Information on clinical performance and clinical evidence. Performance Evaluation Report...
 - 6.3. Stability (excluding specimen stability)

- 6.3.1. Claimed shelf-life
- 6.3.2. In-use stability
- 6.3.3. Shipping stability
- 6.4. Software verification and validation
- 6.5. Additional information required in specific cases

ANNEX III

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

The technical documentation on post-market surveillance to be drawn up...

1. The post-market surveillance plan drawn up in accordance with Article...
2. The PSUR referred to in Article 81 and the post-market...

ANNEX IV

EU DECLARATION OF CONFORMITY

The EU declaration of conformity shall contain the following information:...

Name, registered trade name or registered trade mark and, if...

ANNEX V

CE MARKING OF CONFORMITY

1. The CE marking shall consist of the initials 'CE' taking...
2. If the CE marking is reduced or enlarged the proportions...
3. The various components of the CE marking shall have substantially...

ANNEX VI

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 26(3) AND 28, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26 AND THE UDI SYSTEM

PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 26(3) AND 28

1. Information relating to the economic operator
2. Information relating to the device

PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26

PART C

THE UDI SYSTEM

1. Definitions
 - Automatic identification and data capture ('AIDC')
 - Basic UDI-DI
 - Unit of Use DI
 - Configurable device
 - Configuration
 - UDI-DI
 - Human Readable Interpretation (HRI)
 - Packaging levels
 - Production Identifier (UDI-PI)
 - Radio Frequency Identification ('RFID')
 - Shipping containers
 - Unique Device Identifier ('UDI')
 - UDI carrier
2. General requirements
 - 2.1. The affixing of the UDI is an additional requirement —...
 - 2.2. The manufacturer shall assign and maintain unique UDIs for its...
 - 2.3. Only the manufacturer may place the UDI on the device...
 - 2.4. Only coding standards provided by issuing entities designated by the...
3. The UDI
 - 3.1. A UDI shall be assigned to the device itself or...
 - 3.2. Shipping containers shall be exempted from the requirement in Section...
 - 3.3. The UDI shall contain two parts: a UDI-DI and a...
 - 3.4. The UDI-DI shall be unique at each level of device...
 - 3.5. If a lot number, serial number, software identification or expiry...
 - 3.6. Each component that is considered to be a device and...
 - 3.7. Kits shall be assigned and bear their own UDI.
 - 3.8. The manufacturer shall assign the UDI to a device following...
 - 3.9. A new UDI-DI shall be required whenever there is a...
 - 3.10. Manufacturers that repackage or relabel devices with their own label...
4. UDI carrier
 - 4.1. The UDI carrier (AIDC and HRI representation of the UDI)...
 - 4.2. In the event of there being significant space constraints on...
 - 4.3. For single use class A and class B devices packaged...
 - 4.4. For devices exclusively intended for retail point of sale, the...
 - 4.5. When AIDC carriers other than the UDI carrier are part...
 - 4.6. If linear bar codes are used, the UDI-DI and UDI-PI...
 - 4.7. If there are significant constraints limiting the use of both...
 - 4.8. The HRI format shall follow the rules of the UDI...
 - 4.9. If the manufacturer is using RFID technology, a linear or...
 - 4.10. Devices that are reusable shall bear a UDI carrier on...
 - 4.11. The UDI carrier shall be readable during normal use and...

- 4.12. If the UDI carrier is readily readable or scannable through...
- 4.13. In the case of single finished devices made up of...
- 4.14. The UDI carrier shall be placed in a manner such...
- 4.15. Bar code carriers that include both a UDI-DI and a...
- 5. General principles of the UDI database
 - 5.1. The UDI database shall support the use of all core...
 - 5.2. Manufacturers shall be responsible for the initial submission and updates...
 - 5.3. Appropriate methods/procedures for validation of the data provided shall be...
 - 5.4. Manufacturers shall periodically verify the correctness of all of the...
 - 5.5. The presence of the device UDI-DI in the UDI database...
 - 5.6. The database shall allow for the linking of all the...
 - 5.7. The data for new UDI-DIs shall be available at the...
 - 5.8. Manufacturers shall update the relevant UDI database record within 30...
 - 5.9. Internationally accepted standards for data submission and updates shall, wherever...
 - 5.10. The user interface of the UDI database shall be available...
 - 5.11. Data relating to devices that are no longer available on...
- 6. Rules for specific device types
 - 6.1. Reusable devices that are part of kits and that require...
 - 6.1.1. The UDI of such devices shall be placed on the...
 - 6.1.2. The UDI-PI characteristics such as the lot or serial number...
 - 6.2. Device software
 - 6.2.1. UDI assignment Criteria
 - 6.2.2. A new UDI-DI shall be required whenever there is a...
 - 6.2.3. Minor software revisions shall require a new UDI-PI and not...
 - 6.2.4. UDI placement criteria for software

ANNEX VII

REQUIREMENTS TO BE MET BY NOTIFIED BODIES

- 1. ORGANISATIONAL AND GENERAL REQUIREMENTS
 - 1.1. Legal status and organisational structure
 - 1.1.1. Each notified body shall be established under the national law...
 - 1.1.2. If the notified body is a legal entity that is...
 - 1.1.3. If a notified body wholly or partly owns legal entities...
 - 1.1.4. The organisational structure, allocation of responsibilities, reporting lines and operation...
 - 1.1.5. The notified body shall clearly document its organisational structure and...
 - 1.1.6. The notified body shall identify the persons in top-level management...
 - 1.2. Independence and impartiality
 - 1.2.1. The notified body shall be a third-party body that is...
 - 1.2.2. The notified body shall be organised and operated so as...
 - 1.2.3. The notified body, its top-level management and the personnel responsible...
 - 1.2.4. Involvement in consultancy services in the field of devices prior...
 - 1.2.5. The impartiality of notified bodies, of their top-level management and...
 - 1.2.6. If a notified body is owned by a public entity...

- 1.2.7. The notified body shall ensure and document that the activities...
 - 1.2.8. The notified body shall operate in accordance with a set...
 - 1.2.9. The requirements laid down in this Section shall in no...
 - 1.3. Confidentiality
 - 1.3.1. The notified body shall have documented procedures in place ensuring...
 - 1.3.2. The personnel of a notified body shall observe professional secrecy...
 - 1.4. Liability
 - 1.4.1. The notified body shall take out appropriate liability insurance for...
 - 1.4.2. The scope and overall financial value of the liability insurance...
 - 1.5. Financial requirements
 - 1.6. Participation in coordination activities
 - 1.6.1. The notified body shall participate in, or ensure that its...
 - 1.6.2. The notified body shall take into consideration guidance and best...
- 2. QUALITY MANAGEMENT REQUIREMENTS
 - 2.1. The notified body shall establish, document, implement, maintain and operate...
 - 2.2. The quality management system of the notified body shall address...
 - 2.3. The top-level management of the notified body shall ensure that...
 - 2.4. The notified body shall require all personnel to formally commit...
- 3. RESOURCE REQUIREMENTS
 - 3.1. General
 - 3.1.1. Notified bodies shall be capable of carrying out all the...
 - 3.1.2. The notified body shall ensure that personnel involved in conformity...
 - 3.1.3. The notified body shall clearly document the extent and limits...
 - 3.2. Qualification criteria in relation to personnel
 - 3.2.1. The notified body shall establish and document qualification criteria and...
 - 3.2.2. The qualification criteria referred to in Section 3.2.1 shall refer...
 - 3.2.3. The personnel responsible for establishing qualification criteria and for authorising...
 - 3.2.4. The notified body shall have permanent availability of personnel with...
 - 3.2.5. The personnel responsible for carrying out product-related reviews, (product reviewers),...
 - 3.2.6. The personnel responsible for carrying out audits of the manufacturer's...
 - 3.2.7. The personnel with overall responsibility for final reviews and decision-making...
 - 3.3. Documentation of qualification, training and authorisation of personnel
 - 3.3.1. The notified body shall have a procedure in place to...
 - 3.3.2. For all of its personnel referred to in Sections 3.2.3...
 - 3.4. Subcontractors and external experts
 - 3.4.1. Notified bodies may, without prejudice to Section 3.2, subcontract certain...
 - 3.4.2. Where a notified body subcontracts certain conformity assessment activities either...
 - 3.4.3. Where subcontractors or external experts are used in the context...
 - 3.5. Monitoring of competences, training and exchange of experience
 - 3.5.1. The notified body shall establish procedures for the initial evaluation...
 - 3.5.2. Notified bodies shall review at regular intervals, the competence of...
- 4. PROCESS REQUIREMENTS

- 4.1. General
- 4.2. Notified body quotations and pre-application activities
- 4.3. Application review and contract
- 4.4. Allocation of resources
- 4.5. Conformity assessment activities
 - 4.5.1. General
 - 4.5.2. Quality management system auditing
 - 4.5.3. Product verification
 - Assessment of the technical documentation
 - Type-examinations
 - Verification by examination and testing of every product batch
 - 4.5.4. Performance evaluation assessment
 - 4.5.5. Specific Procedures
- 4.6. Reporting
- 4.7. Final review
- 4.8. Decisions and certifications
- 4.9. Changes and modifications
- 4.10. Surveillance activities and post-certification monitoring
- 4.11. Re-certification

ANNEX VIII

CLASSIFICATION RULES

- 1. IMPLEMENTING RULES
 - 1.1. Application of the classification rules shall be governed by the...
 - 1.2. If the device in question is intended to be used...
 - 1.3. Accessories for an in vitro diagnostic medical device shall be...
 - 1.4. Software, which drives a device or influences the use of...
 - 1.5. Calibrators intended to be used with a device shall be...
 - 1.6. Control materials with quantitative or qualitative assigned values intended for...
 - 1.7. The manufacturer shall take into consideration all classification and implementation...
 - 1.8. Where a manufacturer states multiple intended purposes for a device,...
 - 1.9. If several classification rules apply to the same device, the...
 - 1.10. Each of the classification rules shall apply to first line...
- 2. CLASSIFICATION RULES
 - 2.1. Rule 1
 - 2.2. Rule 2
 - 2.3. Rule 3
 - 2.4. Rule 4
 - 2.5. Rule 5
 - 2.6. Rule 6
 - 2.7. Rule 7

ANNEX IX

CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

CHAPTER I

QUALITY MANAGEMENT SYSTEM

1. The manufacturer shall establish, document and implement a quality management...
2. Quality management system assessment
 - 2.1. The manufacturer shall lodge an application for assessment of its...
 - 2.2. Implementation of the quality management system shall ensure compliance with...
 - 2.3. Audit
 - 2.4. The manufacturer in question shall inform the notified body which...
3. Surveillance assessment applicable to class C and class D devices...
 - 3.1. The aim of surveillance is to ensure that the manufacturer...
 - 3.2. The manufacturer shall give authorisation to the notified body to...
 - 3.3. Notified bodies shall periodically, at least once every 12 months,...
 - 3.4. The notified body shall randomly perform at least once every...
 - 3.5. In the case of class C devices, the surveillance assessment...
 - 3.6. Notified bodies shall ensure that the composition of the assessment...
 - 3.7. If the notified body finds a divergence between the sample...

CHAPTER II

ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4. Assessment of the technical documentation of class B, C and...
 - 4.1. In addition to the obligation laid down in Section 2,...
 - 4.2. The application shall describe the design, manufacture and performance of...
 - 4.3. The notified body shall examine the application by using staff,...
 - 4.4. The notified body shall review the clinical evidence presented by...
 - 4.5. The notified body shall, in circumstances in which the clinical...
 - 4.6. The notified body shall verify that the clinical evidence and...
 - 4.7. Based on its assessment of the clinical evidence, the notified...
 - 4.8. The notified body shall clearly document the outcome of its...
 - 4.9. Before issuing an EU technical documentation assessment certificate, the notified...
 - 4.10. The notified body shall provide the manufacturer with a report...
 - 4.11. Changes to the approved device shall require approval from the...
 - 4.12. To verify conformity of manufactured class D devices, the manufacturer...
 - 4.13. The manufacturer may place the devices on the market, unless...
5. Assessment of the technical documentation of specific types of devices...
 - 5.1. Assessment of the technical documentation of class B, C and...
 - 5.2. Assessment of the technical documentation of companion diagnostics

CHAPTER III

ADMINISTRATIVE PROVISIONS

6. The manufacturer or, where the manufacturer does not have a...
7. Each Member State shall require that the documentation referred to...

ANNEX X

CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

1. EU type-examination is the procedure whereby a notified body ascertains...
2. Application
3. Assessment
4. Certificate
5. Changes to the type
 - 5.1. The applicant shall inform the notified body which issued the...
 - 5.2. Changes to the approved device including limitations of its intended...
 - 5.3. Changes to the intended purpose and conditions of use of...
 - 5.4. Where the changes could affect the performance claimed by the...
 - 5.5. Where the changes affect the performance or the intended use...
6. Administrative provisions

ANNEX XI

CONFORMITY ASSESSMENT BASED ON PRODUCTION QUALITY ASSURANCE

1. The manufacturer shall ensure that the quality management system approved...
2. When the manufacturer fulfils the obligations laid down in Section...
3. Quality management system
 - 3.1. The manufacturer shall lodge an application for assessment of its...
 - 3.2. Implementation of the quality management system shall be such as...
 - 3.3. The first and second paragraphs of Section 2.3 of Annex...
 - 3.4. Section 2.4 of Annex IX shall apply.
4. Surveillance
5. Verification of manufactured class D devices
 - 5.1. In the case of class D devices, the manufacturer shall...
 - 5.2. The manufacturer may place the devices on the market, unless...
6. Administrative provisions

ANNEX XII
CERTIFICATES ISSUED BY A NOTIFIED BODY

CHAPTER I

GENERAL REQUIREMENTS

CHAPTER II

MINIMUM CONTENT OF THE CERTIFICATES

ANNEX XIII

PERFORMANCE EVALUATION, PERFORMANCE STUDIES
AND POST-MARKET PERFORMANCE FOLLOW-UP

PART A

PERFORMANCE EVALUATION AND PERFORMANCE STUDIES

1. PERFORMANCE EVALUATION
 - 1.1. Performance evaluation plan
 - 1.2. Demonstration of the scientific validity and the analytical and clinical...
 - 1.2.1. Demonstration of the scientific validity
 - 1.2.2. Demonstration of the analytical performance
 - 1.2.3. Demonstration of the clinical performance
 - 1.3. Clinical evidence and performance evaluation report
 - 1.3.1. The manufacturer shall assess all relevant scientific validity, analytical and...
 - 1.3.2. Performance evaluation report
 - 1.3.3. The clinical evidence and its assessment in the performance evaluation...
2. CLINICAL PERFORMANCE STUDIES
 - 2.1. Purpose of clinical performance studies
 - 2.2. Ethical considerations for clinical performance studies
 - 2.3. Methods for clinical performance studies
 - 2.3.1. Clinical performance study design type
 - 2.3.2. Clinical performance study plan
 - 2.3.3. Clinical performance study report
3. OTHER PERFORMANCE STUDIES

PART B

POST-MARKET PERFORMANCE FOLLOW-UP

4. PMPF shall be understood to be a continuous process that...
5. PMPF shall be performed pursuant to a documented method laid...
 - 5.1. The PMPF plan shall specify the methods and procedures for...
 - 5.2. The PMPF plan shall include at least:

6. The manufacturer shall analyse the findings of the PMPF and...
7. The conclusions of the PMPF evaluation report shall be taken...
8. If PMPF is not deemed appropriate for a specific device...

ANNEX XIV

INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND CERTAIN OTHER PERFORMANCE STUDIES

CHAPTER I

DOCUMENTATION REGARDING THE APPLICATION FOR INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND OTHER PERFORMANCE STUDIES INVOLVING RISKS FOR THE SUBJECTS OF THE STUDIES

CHAPTER II

OTHER OBLIGATIONS OF THE SPONSOR

ANNEX XV

CORRELATION TABLE

- (1) Opinion of 14 February 2013 ([OJ C 133, 9.5.2013, p. 52](#)).
- (2) Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 7 March 2017 (not yet published in the Official Journal).
- (3) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices ([OJ L 331, 7.12.1998, p. 1](#)).
- (4) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility ([OJ L 96, 29.3.2014, p. 79](#)).
- (5) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom ([OJ L 13, 17.1.2014, p. 1](#)).
- (6) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services ([OJ L 241, 17.9.2015, p. 1](#)).
- (7) Regulation (EU) No 1025/2012 of 25 October 2012 of the European Parliament and of the Council on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([OJ L 316, 14.11.2012, p. 12](#)).
- (8) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ([OJ L 218, 13.8.2008, p. 30](#)).
- (9) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC ([OJ L 218, 13.8.2008, p. 82](#)).
- (10) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products ([OJ L 210, 7.8.1985, p. 29](#)).
- (11) Judgment of 28 July 2011 in *Orifarm and Paranova*, joined cases C-400/09 and C-207/10, ECLI:EU:C:2011:519.
- (12) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (see page 1 of this Official Journal).
- (13) Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices ([OJ L 102, 23.4.2010, p. 45](#)).
- (14) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ([OJ L 281, 23.11.1995, p. 31](#)).
- (15) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ([OJ L 8, 12.1.2001, p. 1](#)).
- (16) Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the protection of animals used for scientific purposes ([OJ L 276, 20.10.2010, p. 33](#)).
- (17) [OJ L 123, 12.5.2016, p. 1](#).
- (18) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13](#)).
- (19) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ([OJ L 189, 20.7.1990, p. 17](#))

- (20) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1)
- (21) OJ C 358, 7.12.2013, p. 10.