

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 (Text with EEA relevance)

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2. The requirement in this Annex to reduce risks as far as...
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 side-effects, shall...
9. For the devices referred to in Annex XVI, the general safety...

#### CHAPTER II

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  - 10.1. Devices shall be designed and manufactured in such a way...
  - 10.2. Devices shall be designed, manufactured and packaged in such a...
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- 10.4.5. Labelling
- 10.5. Devices shall be designed and manufactured in such a way...
- 10.6. 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. Where necessary devices shall be designed to facilitate their safe...
  - 11.3. Devices labelled as having a specific microbial state shall be...
  - 11.4. Devices delivered in a sterile state shall be designed, manufactured...
  - 11.5. Devices labelled as sterile shall be processed, manufactured, packaged and,...
  - 11.6. Devices intended to be sterilised shall be manufactured and packaged...
  - 11.7. Packaging systems for non-sterile devices shall maintain the integrity and...
  - 11.8. The labelling of the device shall distinguish between identical or...
- 12. Devices incorporating a substance considered to be a medicinal product...
  - 12.1. In the case of devices referred to in the first...
  - 12.2. Devices that are composed of substances or of combinations of...
- 13. Devices incorporating materials of biological origin
  - 13.1. For devices manufactured utilising derivatives of tissues or cells of...
  - 13.2. For devices manufactured utilising tissues or cells of animal origin,...
  - 13.3. For devices manufactured utilising non-viable biological substances other than those...
- 14. Construction of devices and interaction with their environment
  - 14.1. If the device is intended for use in combination with...
  - 14.2. Devices shall be designed and manufactured in such a way...
  - 14.3. Devices shall be designed and manufactured in such a way...
  - 14.4. Devices shall be designed and manufactured in such a way...
  - 14.5. Devices that are intended to be operated together with other...
  - 14.6. Any measurement, monitoring or display scale shall be designed and...
  - 14.7. Devices shall be designed and manufactured in such a way...
- 15. Devices with a diagnostic or measuring function
  - 15.1. Diagnostic devices and devices with a measuring function, shall be...
  - 15.2. The measurements made by devices with a measuring function shall...
- 16. Protection against radiation
  - 16.1. General
  - 16.2. Intended radiation
  - 16.3. Devices shall be designed and manufactured in such a way...
  - 16.4. Ionising radiation
- 17. Electronic programmable systems — devices that incorporate electronic programmable systems...
  - 17.1. Devices that incorporate electronic programmable systems, including software, or software...
  - 17.2. For devices that incorporate software or for software that are...
  - 17.3. Software referred to in this Section that is intended to be...
  - 17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks...

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18. Active devices and devices connected to them
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  - 18.2. Devices where the safety of the patient depends on an...
  - 18.3. Devices where the safety of the patient depends on an...
  - 18.4. Devices intended to monitor one or more clinical parameters of...
  - 18.5. Devices shall be designed and manufactured in such a way...
  - 18.6. Devices shall be designed and manufactured in such a way...
  - 18.7. Devices shall be designed and manufactured in such a way...
  - 18.8. Devices shall be designed and manufactured in such a way...
19. Particular requirements for active implantable devices
  - 19.1. Active implantable devices shall be designed and manufactured in such...
  - 19.2. Active implantable devices shall be designed and manufactured in such...
  - 19.3. Active implantable devices and, if appropriate, their component parts shall...
  - 19.4. Active implantable devices shall bear a code by which they...
20. Protection against mechanical and thermal risks
  - 20.1. Devices shall be designed and manufactured in such a way...
  - 20.2. Devices shall be designed and manufactured in such a way...
  - 20.3. Devices shall be designed and manufactured in such a way...
  - 20.4. Terminals and connectors to the electricity, gas or hydraulic and...
  - 20.5. Errors likely to be made when fitting or refitting certain...
  - 20.6. Accessible parts of devices (excluding the parts or areas intended...
21. Protection against the risks posed to the patient or user...
  - 21.1. Devices for supplying the patient with energy or substances shall...
  - 21.2. Devices shall be fitted with the means of preventing and/or...
  - 21.3. The function of the controls and indicators shall be clearly...
22. Protection against the risks posed by medical devices intended by...
  - 22.1. Devices for use by lay persons shall be designed and...
  - 22.2. Devices for use by lay persons shall be designed and...
  - 22.3. Devices for use by lay persons shall, where appropriate, include...

### CHAPTER III

#### REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE

23. Label and instructions for use
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  - 23.2. Information on the label
  - 23.3. Information on the packaging which maintains the sterile condition of...
  - 23.4. Information in the instructions for use

### ANNEX II

#### TECHNICAL DOCUMENTATION

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



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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
4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT
6. PRODUCT VERIFICATION AND VALIDATION
  - 6.1. Pre-clinical and clinical data
  - 6.2. Additional information required in specific cases

### ANNEX III

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- 1.1. The post-market surveillance plan drawn up in accordance with Article 84....
- 1.2. The PSUR referred to in Article 86 and the post-market surveillance...

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#### EU DECLARATION OF CONFORMITY

The EU declaration of conformity shall contain all of the...  
Name, registered trade name or registered trade mark and, if...

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#### 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...

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#### INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE

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DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH  
THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI SYSTEM

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INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES  
AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31

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 28 AND 29

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THE UDI SYSTEM

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  - Automatic identification and data capture ('AIDC')
  - Basic UDI-DI
  - Unit of Use DI
  - Configurable device
  - Configuration
  - UDI-DI
  - Human Readable Interpretation ('HRI')
  - Packaging levels
  - 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 3.1....
  - 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. Systems and procedure packs as referred to in Article 22 shall...
  - 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 and/or relabel devices, with their own label...
4. UDI carrier

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- 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 devices of classes I and IIa packaged and...
  - 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, in the...
  - 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 possible,...
    - 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. Implantable devices:
    - 6.2. Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing between uses...
      - 6.2.1. The UDI of such devices shall be placed on the...
      - 6.2.2. The UDI-PI characteristics such as the lot or serial number...
    - 6.3. Systems and procedure packs as referred to in Article 22
      - 6.3.1. The natural or legal person referred to in Article 22 shall...
      - 6.3.2. Device contents of system or procedure packs shall bear a...
      - 6.3.3. Placement of the UDI carrier on systems or procedure packs...
    - 6.4. Configurable devices:
      - 6.4.1. A UDI shall be assigned to the configurable device in...
      - 6.4.2. The configurable device UDI-DI shall be assigned to groups of...
      - 6.4.3. A configurable device UDI-PI shall be assigned to each individual...
      - 6.4.4. The carrier of the configurable device UDI shall be placed...
      - 6.4.5. Each component that is considered a device and is commercially...
    - 6.5. Device Software
      - 6.5.1. UDI assignment Criteria
      - 6.5.2. A new UDI-DI shall be required whenever there is a...
      - 6.5.3. Minor software revisions shall require a new UDI-PI and not...
      - 6.5.4. UDI placement criteria for software

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## 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 in no way preclude...
  - 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 to...

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- 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 clearly...
  - 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
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  - 4.3. Application review and contract
  - 4.4. Allocation of resources
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      - Type-examinations
      - Verification by examination and testing of every product
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    - 4.5.5. Clinical evaluation assessment
    - 4.5.6. 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

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## ANNEX VIII CLASSIFICATION RULES

### CHAPTER I

#### DEFINITIONS SPECIFIC TO CLASSIFICATION RULES

1. DURATION OF USE
  - 1.1. ‘Transient’ means normally intended for continuous use for less than...
  - 1.2. ‘Short term’ means normally intended for continuous use for between...
  - 1.3. ‘Long term’ means normally intended for continuous use for more...
2. INVASIVE AND ACTIVE DEVICES
  - 2.1. ‘Body orifice’ means any natural opening in the body, as...
  - 2.2. ‘Surgically invasive device’ means:
  - 2.3. ‘Reusable surgical instrument’ means an instrument intended for surgical use...
  - 2.4. ‘Active therapeutic device’ means any active device used, whether alone...
  - 2.5. ‘Active device intended for diagnosis and monitoring’ means any active...
  - 2.6. ‘Central circulatory system’ means the following blood vessels: arteriae pulmonales,...
  - 2.7. ‘Central nervous system’ means the brain, meninges and spinal cord....
  - 2.8. ‘Injured skin or mucous membrane’ means an area of skin...

### CHAPTER II

#### IMPLEMENTING RULES

- 3.1. Application of the classification rules shall be governed by the...
- 3.2. If the device in question is intended to be used...
- 3.3. Software, which drives a device or influences the use of...
- 3.4. If the device is not intended to be used solely...
- 3.5. If several rules, or if, within the same rule, several...
- 3.6. In calculating the duration referred to in Section 1, continuous use...
- 3.7. A device is considered to allow direct diagnosis when it...

### CHAPTER III

#### CLASSIFICATION RULES

4. NON-INVASIVE DEVICES
  - 4.1. Rule 1
  - 4.2. Rule 2
  - 4.3. Rule 3
  - 4.4. Rule 4
5. INVASIVE DEVICES

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council. (See end of Document for details)*

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- 5.1. Rule 5
- 5.2. Rule 6
- 5.3. Rule 7
- 5.4. Rule 8
  
- 6. ACTIVE DEVICES
  - 6.1. Rule 9
  - 6.2. Rule 10
  - 6.3. Rule 11
  - 6.4. Rule 12
  - 6.5. Rule 13
  
- 7. SPECIAL RULES
  - 7.1. Rule 14
  - 7.2. Rule 15
  - 7.3. Rule 16
  - 7.4. Rule 17
  - 7.5. Rule 18
  - 7.6. Rule 19
  - 7.7. Rule 20
  - 7.8. Rule 21
  - 7.9. Rule 22

## 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 IIa, class IIb and class...
  - 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 IIa and class IIb devices,...
  - 3.6. The notified body shall ensure that the composition of the...
  - 3.7. If the notified body finds a divergence between the sample...

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## CHAPTER II

### ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4. Assessment of the technical documentation applicable to class III devices...
  - 4.1. In addition to the obligations laid down in Section 2, the...
  - 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. The notified body shall provide the manufacturer with a report...
  - 4.10. Changes to the approved device shall require approval from the...
5. Specific additional procedures
  - 5.1. Assessment procedure for certain class III and class IIb devices...
  - 5.2. Procedure in the case of devices incorporating a medicinal substance...
  - 5.3. Procedure in the case of devices manufactured utilising, or incorporating, ...
    - 5.3.1. Tissues or cells of human origin or their derivatives
    - 5.3.2. Tissues or cells of animal origin or their derivatives
  - 5.4. Procedure in the case of devices that are composed of...
6. Batch verification in the case of devices incorporating, as an...

## CHAPTER III

### ADMINISTRATIVE PROVISIONS

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

## 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...
6. Specific additional procedures



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7. Administrative provisions

ANNEX XI

CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION

1. The objective of the conformity assessment based on product conformity...
2. Where an EU type-examination certificate has been issued in accordance...
3. By way of derogation from Sections 1 and 2 above,...

PART A

PRODUCTION QUALITY ASSURANCE

4. The manufacturer shall ensure that the quality management system approved...
5. When the manufacturer fulfils the obligations laid down in Section 4,...
6. Quality management system
  - 6.1. The manufacturer shall lodge an application for assessment of its...
  - 6.2. Implementation of the quality management system shall be such as...
  - 6.3. The first and second paragraph of Section 2.3 of Annex IX shall apply....
  - 6.4. Section 2.4 of Annex IX shall apply.
7. Surveillance
8. Batch verification in the case of devices incorporating, as an...
9. Administrative provisions
10. Application to class IIa devices
  - 10.1. By way of derogation from Section 5, by virtue of the...
  - 10.2. For class IIa devices the notified body shall assess, as...
  - 10.3. Where the assessment under Section 10.2. confirms that the class IIa...
  - 10.4. Samples additional to those taken for the initial conformity assessment...
  - 10.5. By way of derogation from Section 6, the manufacturer or its...

PART B

PRODUCT VERIFICATION

11. Product verification shall be understood to be the procedure whereby...
12. The manufacturer shall take all the measures necessary to ensure...
13. The manufacturer shall undertake to institute and keep up to...
14. The notified body shall carry out the appropriate examinations and...
15. Verification by examination and testing of every product
  - 15.1. Every device shall be examined individually and the appropriate physical...
  - 15.2. The notified body shall affix, or have affixed, its identification...

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16. Batch verification in the case of devices incorporating, as an...
17. Administrative provisions
18. Application to class IIa devices
  - 18.1. By way of derogation from Section 11, by virtue of the...
  - 18.2. The verification conducted by the notified body in accordance with...
  - 18.3. If the verification referred to in Section 18.2 confirms that the...
  - 18.4. By way of derogation from Section 17, the manufacturer or its...

## ANNEX XII

### CERTIFICATES ISSUED BY A NOTIFIED BODY

#### CHAPTER I

##### GENERAL REQUIREMENTS

1. Certificates shall be drawn up in one of the official...
2. Each certificate shall refer to only one conformity assessment procedure....
3. Certificates shall only be issued to one manufacturer. The name...
4. The scope of the certificates shall unambiguously identify the device...
5. The notified body shall be able to demonstrate on request,...
6. Certificates shall contain, if applicable, a note that, for the...
7. EU quality management system certificates and EU quality assurance certificates...
8. Where a certificate is supplemented, modified or re-issued, the new...

#### CHAPTER II

##### MINIMUM CONTENT OF THE CERTIFICATES

## ANNEX XIII

### PROCEDURE FOR CUSTOM-MADE DEVICES

1. For custom-made devices, the manufacturer or its authorised representative shall...
2. The manufacturer shall undertake to keep available for the competent...
3. The manufacturer shall take all the measures necessary to ensure...
4. The statement referred to in the introductory part of Section 1...
5. The manufacturer shall review and document experience gained in the...

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## ANNEX XIV

### CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

#### PART A

#### CLINICAL EVALUATION

1. To plan, continuously conduct and document a clinical evaluation, manufacturers...
2. The clinical evaluation shall be thorough and objective, and take...
3. A clinical evaluation may be based on clinical data relating...
4. The results of the clinical evaluation and the clinical evidence...

#### PART B

#### POST-MARKET CLINICAL FOLLOW-UP

5. PMCF shall be understood to be a continuous process that...
6. PMCF shall be performed pursuant to a documented method laid...
  - 6.1. The PMCF plan shall specify the methods and procedures for...
  - 6.2. The PMCF plan shall include at least:
7. The manufacturer shall analyse the findings of the PMCF and...
8. The conclusions of the PMCF evaluation report shall be taken...

## ANNEX XV

### CLINICAL INVESTIGATIONS

#### CHAPTER I

#### GENERAL REQUIREMENTS

1. Ethical principles
2. Methods
  - 2.1. Clinical investigations shall be performed on the basis of an...
  - 2.2. The procedures used to perform the clinical investigation shall be...
  - 2.3. The research methodologies used to perform the clinical investigation shall...
  - 2.4. Clinical investigations shall be performed in accordance with the clinical...
  - 2.5. All the appropriate technical and functional features of the device,...
  - 2.6. The endpoints of the clinical investigation shall address the intended...
  - 2.7. Investigators shall have access to the technical and clinical data...
  - 2.8. The clinical investigation report, signed by the investigator, shall contain...

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## CHAPTER II

### DOCUMENTATION REGARDING THE APPLICATION FOR CLINICAL INVESTIGATION

1. Application form
2. Investigator's Brochure
3. Clinical Investigation Plan
  - 3.1. General
    - 3.1.1. Single identification number of the clinical investigation, as referred to...
    - 3.1.2. Identification of the sponsor — name, address and contact details...
    - 3.1.3. Information on the principal investigator at each investigational site, the...
    - 3.1.4. A brief description of how the clinical investigation is financed...
    - 3.1.5. Overall synopsis of the clinical investigation, in an official Union...
  - 3.2. Identification and description of the device, including its intended purpose,...
  - 3.3. Risks and clinical benefits of the device to be examined,...
  - 3.4. Description of the relevance of the clinical investigation in the...
  - 3.5. Objectives and hypotheses of the clinical investigation.
  - 3.6. Design of the clinical investigation with evidence of its scientific...
    - 3.6.1. General information such as type of investigation with rationale for...
    - 3.6.2. Information on the investigational device, on any comparator and on...
    - 3.6.3. Information on subjects, selection criteria, size of investigation population, representativeness...
    - 3.6.4. Details of measures to be taken to minimise bias, such...
    - 3.6.5. Description of the clinical procedures and diagnostic methods relating to...
    - 3.6.6. Monitoring plan.
  - 3.7. Statistical considerations, with justification, including a power calculation for the...
  - 3.8. Data management.
  - 3.9. Information about any amendments to the CIP.
  - 3.10. Policy regarding follow-up and management of any deviations from the...
  - 3.11. Accountability regarding the device, in particular control of access to...
  - 3.12. Statement of compliance with the recognised ethical principles for medical...
  - 3.13. Description of the Informed consent process.
  - 3.14. Safety reporting, including definitions of adverse events and serious adverse...
  - 3.15. Criteria and procedures for follow-up of subjects following the end,...
  - 3.16. A description of the arrangements for taking care of the...
  - 3.17. Policy as regards the establishment of the clinical investigation report...
  - 3.18. List of the technical and functional features of the device,...
  - 3.19. Bibliography.
4. Other information
  - 4.1. A signed statement by the natural or legal person responsible...
  - 4.2. Where applicable according to national law, copy of the opinion...
  - 4.3. Proof of insurance cover or indemnification of subjects in case...
  - 4.4. Documents to be used to obtain informed consent, including the...
  - 4.5. Description of the arrangements to comply with the applicable rules...
  - 4.6. Full details of the available technical documentation, for example detailed...

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## CHAPTER III

### OTHER OBLIGATIONS OF THE SPONSOR

1. The sponsor shall undertake to keep available for the competent...
2. The Sponsor shall have an agreement in place to ensure...
3. The documentation mentioned in this Annex shall be kept for a...
4. The Sponsor shall appoint a monitor that is independent from...
5. The Sponsor shall complete the follow-up of investigation subjects.
6. The Sponsor shall provide evidence that the investigation is being...
7. The Sponsor shall prepare a clinical investigation report which includes...

## ANNEX XVI

### LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)

1. Contact lenses or other items intended to be introduced into...
2. Products intended to be totally or partially introduced into the...
3. Substances, combinations of substances, or items intended to be used...
4. Equipment intended to be used to reduce, remove or destroy...
5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet)...
6. Equipment intended for brain stimulation that apply electrical currents or...

## ANNEX XVII

### CORRELATION TABLE

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- (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) 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).
- (4) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).
- (5) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).
- (6) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).
- (7) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).
- (8) Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).
- (9) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).
- (10) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (OJ L 33, 8.2.2003, p. 30).
- (11) Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).
- (12) 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).
- (13) 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).
- (14) 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).
- (15) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 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).
- (16) 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).
- (17) 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).
- (18) 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).
- (19) 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).

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- (20) Judgment of 28 July 2011 in Orifarm and Paranova, joined cases C-400/09 and C-207/10, ECLI:EU:C:2011:519.
- (21) Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices (OJ L 102, 23.4.2010, p. 45).
- (22) 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).
- (23) 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).
- (24) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).
- (25) 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 (see page 176 of this Official Journal).
- (26) OJ L 123, 12.5.2016, p. 1.
- (27) 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).
- (28) Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).
- (29) Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.2012, p. 3).
- (30) Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43).
- (31) Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41).
- (32) Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8).
- (33) OJ C 358, 7.12.2013, p. 10.

**Status:**

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