

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) (revoked)

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##### CHAPTER I

##### GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by their manufacturer and...
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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...
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  - 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 way...
  - 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
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  - 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 way...
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  - 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...
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  - 19.2. Devices intended for self-testing or near-patient testing shall be designed...
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## CHAPTER III

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

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  - 1.1. Device description and specification
  - 1.2. Reference to previous and similar generations of the device
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3. DESIGN AND MANUFACTURING INFORMATION
  - 3.1. Design information
  - 3.2. Manufacturing information

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CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE...

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#### THE UDI SYSTEM

1. Definitions
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- 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...

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council. (See end of Document for details)

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- 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

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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
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Verification by examination and testing of every product batch

- 4.5.4. Performance evaluation assessment
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- 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
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### 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
  - 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 B and C devices, the...
  - 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 assess the technical documentation 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...

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### 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

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2. CLINICAL PERFORMANCE STUDIES
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  - 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...

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#### OTHER OBLIGATIONS OF THE SPONSOR

## ANNEX XV

### CORRELATION TABLE

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council.