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)

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1. Devices shall achieve the performance intended by their manufacturer and...

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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...

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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...
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- 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...
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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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  - 6.1.1. Specimen type
  - 6.1.2. Analytical performance characteristics
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    - 6.1.2.2. Analytical sensitivity
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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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   - Unit of Use DI
   - Configurable device
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   - 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...
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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...

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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...

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   - 5.1. Assessment of the technical documentation of class B, C and...
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1. EU type-examination is the procedure whereby a notified body ascertains...

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   - 5.1. The applicant shall inform the notified body which issued the...
   - 5.2. Changes to the approved device including limitations of its intended...
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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.

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5. Verification of manufactured class D devices
   - 5.1. In the case of class D devices, the manufacturer shall...
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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...

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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.