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)

Section 2

Conformity assessment

CHAPTER VI

CLINICAL EVIDENCE, PERFORMANCE EVALUATION AND PERFORMANCE STUDIES

CHAPTER IX

CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES

CHAPTER X

FINAL PROVISIONS

ANNEXES

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...

ANNEX VII

REQUIREMENTS TO BE MET BY NOTIFIED BODIES

ANNEX VIII

CLASSIFICATION RULES

ANNEX IX

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

CHAPTER I

QUALITY MANAGEMENT SYSTEM

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

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...

CHAPTER II

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.