

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 VI

**CLINICAL EVIDENCE, PERFORMANCE  
EVALUATION AND PERFORMANCE STUDIES**

*Article 56*

**Performance evaluation and clinical evidence**

1 Confirmation of conformity with relevant general safety and performance requirements set out in Annex I, in particular those concerning the performance characteristics referred to in Chapter I and Section 9 of Annex I, under the normal conditions of the intended use of the device, and the evaluation of the interference(s) and cross-reaction(s) and of the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I, shall be based on scientific validity, analytical and clinical performance data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

To that end, manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XIII.

2 The clinical evidence shall support the intended purpose of the device as stated by the manufacturer and be based on a continuous process of performance evaluation, following a performance evaluation plan.

3 A performance evaluation shall follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with this Article and with Part A of Annex XIII:

- a scientific validity;
- b analytical performance;
- c clinical performance.

The data and conclusions drawn from the assessment of those elements shall constitute the clinical evidence for the device. The clinical evidence shall be such as to scientifically demonstrate, by reference to the state of the art in medicine, that the intended clinical benefit(s) will be achieved and that the device is safe. The clinical evidence derived from the performance evaluation shall provide scientifically valid assurance, that the relevant general safety and performance requirements set out in Annex I, are fulfilled, under normal conditions of use.

4 Clinical performance studies in accordance with Section 2 of Part A of Annex XIII shall be carried out unless it is duly justified to rely on other sources of clinical performance data.

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*Status: Point in time view as at 31/01/2020. This version of this provision has been superseded.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, Article 56. (See end of Document for details)*

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5 The scientific validity data, the analytical performance data and the clinical performance data, their assessment and the clinical evidence derived therefrom, shall be documented in the performance evaluation report referred to in Section 1.3.2 of Part A of Annex XIII. The performance evaluation report shall be part of the technical documentation, referred to in Annex II, relating to the device concerned.

6 The performance evaluation and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's PMPF plan in accordance with Part B of Annex XIII and the post-market surveillance plan referred to in Article 79.

The performance evaluation report for class C and D devices shall be updated when necessary, but at least annually, with the data referred to in the first subparagraph. The summary of safety and performance referred to in Article 29(1) shall be updated as soon as possible, where necessary.

7 Where necessary to ensure the uniform application of Annex XIII, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

**Status:**

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**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, Article 56.