

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)

CHAPTER V

CLASSIFICATION AND CONFORMITY ASSESSMENT

SECTION I

Classification

Article 51

Classification of devices

1 Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

2 Any dispute between the manufacturer and the notified body concerned, arising from the application of Annex VIII, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in the last indent of point (b) of the second paragraph of Section 2.2 of Annex IX has its registered place of business. Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

3 At the request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:

- a application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;
- b that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII.

4 The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.

Status: Point in time view as at 05/04/2017. This version of this provision has been superseded.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council, Article 51. (See end of Document for details)

5 In order to ensure the uniform application of Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

6 The implementing acts referred to in paragraphs 3, 4 and 5 of this Article shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Status:

Point in time view as at 05/04/2017. This version of this provision has been superseded.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council, Article 51.