

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 I

SCOPE AND DEFINITIONS

Article 4

Regulatory status of products

1 Without prejudice to Article 2(2) of Directive 2001/83/EC, upon a duly substantiated request of a Member State, the Commission shall, after consulting the Medical Device Coordination Group established under Article 103 of this Regulation ('MDCG'), by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3) of this Regulation.

2 The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

3 The Commission shall ensure that Member States share expertise in the fields of medical devices, *in vitro* diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products, in order to determine the appropriate regulatory status of a product, or category or group of products.

4 When deliberating on the possible regulatory status as a device of products involving medicinal products, human tissues and cells, biocides or food products, the Commission shall ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA), as relevant.

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Point in time view as at 31/01/2020. This version of this provision has been superseded.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) 2017/745 of the European Parliament and of the Council, Article 4.