

## REGULATIONS

### 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

#### Article 2

#### Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
  - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
  - providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
  - products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.
- (2) 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);
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## Adapted from MHRA draft guidance on the health institution exemption

### In-house manufacturing

Manufacturing or modifying a device by a health institution could include:

- the putting together of a medical device from raw materials or component parts, or
- the complete rebuilding of an existing medical device, or
- making a new medical device from used devices, or
- fully refurbishing a medical device, or
- developing software that meets the definition of a medical device, or
- using a product for a medical purpose that is not CE marked as a medical device, or
- putting together combinations of medical devices and other equipment, or
- significant deviations from the instructions for use that alter the function, performance or purpose of a medical device, or
- using an existing medical device for a different purpose from that intended by the manufacturer, or
- modifying a medical device for a new purpose, function or performance;

and where this action is not explicit in a manufacturer's intended purpose or instructions for use.

If such activity is undertaken, then Article 5.5 must be applied.

## CHAPTER II

**MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT***Article 5***Placing on the market and putting into service**

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.
3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.
4. Devices that are manufactured and used within health institutions shall be considered as having been put into service.
5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:
  - (a) the devices are not transferred to another legal entity,
  - (b) manufacture and use of the devices occur under appropriate quality management systems,
  - (c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,
  - (d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;
  - (e) the health institution draws up a declaration which it shall make publicly available, including:
    - (i) the name and address of the manufacturing health institution;
    - (ii) the details necessary to identify the devices;
    - (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,
  - (f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;
  - (g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and
  - (h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.

6. In order to ensure the uniform application of Annex I, the Commission may 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 114(3).