

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 II

MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT

Article 21

Devices for special purposes

- 1 Member States shall not create obstacles to:
 - a investigational devices being supplied to an investigator for the purpose of a clinical investigation if they meet the conditions laid down in Articles 62 to 80 and Article 82, in the implementing acts adopted pursuant to Article 81 and in Annex XV;
 - b custom-made devices being made available on the market if Article 52(8) and Annex XIII have been complied with.

The devices referred to in the first subparagraph shall not bear the CE marking, with the exception of the devices referred to in Article 74.

- 2 Custom-made devices shall be accompanied by the statement referred to in Section 1 of Annex XIII, which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been made available in their territory.

- 3 At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create obstacles to the showing of devices which do not comply with this Regulation, provided a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with this Regulation.