

Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance)

CHAPTER 2

MARKETING AUTHORISATION REQUIREMENTS

Article 6

Issues specific to medical devices

- 1 A medical device which forms part of a combined advanced therapy medicinal product shall meet the essential requirements laid down in Annex I to Directive 93/42/EEC.
- 2 An active implantable medical device which forms part of a combined advanced therapy medicinal product shall meet the essential requirements laid down in Annex 1 to Directive 90/385/EEC.

Status:

Point in time view as at 31/01/2020.

Changes to legislation:

There are outstanding changes not yet made to Regulation (EC) No 1394/2007 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.