Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (Text with EEA relevance)

Article 3

1 Subject to the conditions set out in paragraph 2, manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to any of the following devices:

a active implantable medical devices and their accessories covered by Directive 90/385/EEC intended to be used exclusively for the implantation or programming of a defined active implantable medical device;

b implantable medical devices and their accessories covered by Directive 93/42/EEC intended to be used exclusively for the implantation of a defined implantable medical device;

c fixed installed medical devices covered by Directive 93/42/EEC;

d medical devices and their accessories covered by Directives 90/385/EEC and 93/42/EEC fitted with a built-in system visually displaying the instructions for use;

e stand-alone software covered by Directive 93/42/EEC.

2 Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions:

a the devices and accessories are intended for exclusive use by professional users;

b the use by other persons is not reasonably foreseeable.