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

Article 2

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

(a) 'instructions for use' means information provided by the manufacturer to inform the user of the device of its safe and proper use, of its expected performances and of any precautions to be taken as outlined in the relevant parts of point 15 of Annex 1 to Directive 90/385/EEC and of point 13 of Annex I to Directive 93/42/EEC;

(b) 'instructions for use in electronic form' means instructions for use displayed in electronic form by the device, contained in portable electronic storage media supplied by the manufacturer together with the device, or instructions for use available through a website;

(c) 'professional users' means persons using the medical device in the course of their work and in the framework of a professional healthcare activity;

(d) 'fixed installed medical devices' means devices and their accessories which are intended to be installed, fastened or otherwise secured at a specific location in a healthcare facility so that they cannot be moved from this location or detached without using tools or apparatus, and which are not specifically intended to be used within a mobile healthcare facility.