INTERPRETATIVE DOCUMENT

of the Commission's Services

INTERPRETATION OF THE MEDICAL DEVICE DIRECTIVES IN RELATION TO MEDICAL DEVICE OWN BRAND LABELLERS

(1) An own brand labeller (OBL)[1] purchases a finished (or component parts of a) medical device from the Original Equipment Manufacturer (OEM), which he then places on the market under his own name or trade mark (brand label).

(2) This own brand labeller may not be the person who actually designs, manufactures, packages or labels the device.

(3) The question that has been raised is: who is, in this instance, the legal manufacturer?

(4) It appears that this economic operator, the own brand labeller, meets the definition of manufacturer as set out in the medical devices Directives, which reads (emphasis added):

(5) "the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party."[2] In addition to this, it is also justified that the own brand labeller has the regulatory responsibility as a manufacturer due to the fact that a brand is a symbolic representation of all the information connected to the product. It serves to create associations and expectations around it, and it is the most reliable visible evidence of who has regulatory responsibility from the time where the products are sold until their end-of-life. Furthermore, in some instances, it is not easy to identify the actual assembler or the original equipment

[1] Also referred to as private labeller.

[2] Article 1 (2) (i) Directive 90/385/EEC as last amended by Directive 2007/47/EC, Article 1 (2) (f) Directive 93/42/EEC as last amended by Directive 2007/47/EC and Article 1 (2) (f) Directive 98/79/EC on in vitro diagnostic medical devices as last amended by Directive Regulation (EC) No 1882/2003

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: BREY 14/110. Telephone: direct line (32-2) 295 91 10; Fax (32-2) 296 64 67
E-mail: Sharon.frank@ec.europa.eu

manufacturer. Therefore, from a consumer and patient safety perspective, own brand labellers should bear the regulatory responsibility of a manufacturer.

(6) Moreover, a number of third countries (e.g. Canada and the United States of America) consider that own brand labellers are manufacturers. In addition, when looking to documentation from notified bodies, it seems that a number of notified bodies (in Denmark and France, for example) consider that own brand labellers are manufacturers within the meaning of the medical devices Directives. Some Member States provide the same information on their website (e.g. Ireland and the United Kingdom).

***