REF. 6701

Medical Devices

Own Brand Labelling

Conformance

CE MARKING AND PRODUCT SAFETY

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Introduction - Procedure for Own Brand Labelling

1. OBL and OEM

1.1. In this document, we refer to you as the OBL (Own Brand Labeller) and to the original manufacturer of the product that you want to rebrand as the OEM (Original Equipment Manufacturer).

1.2. The Medical Device Directive 93/42/EEC (MDD) does not use these terms and refers only to Manufacturers.

1.3. OBL and OEM, however, are the most common terms used in the medical devices market and by Notified Bodies (NoBos).

1.4. As an OBL you will rely mostly on the OEM's CE marking process, but you bear full responsibility for the product; under the law, you are the manufacturer. For this reason you require full visibility of what the OEM has done to complete the CE marking process.

2. Applicability of the Conformance OBL Package

2.1. If you have followed our guidance '0_Am I an OBL?', available (for free) on our online shop, and have then purchased this package, you have already determined that you are an OBL.

2.2. If you have not done this check yet, follow the guidance. If you do not fit the OBL situation, talk to us for further advice.

2.3. As the OBL, all of the legal duties that the MDD imposes on the Manufacturer apply to you. The Authorities (the MHRA, in the UK) require you to be able to demonstrate compliance of your device with the MDD.

3. Guidance

3.1. Several official guidance documents are available on the Internet, free of charge at this web-address:

https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

3.1.1. MEDDEV;

Classification Criteria

Generic device group		Applicable	Description
art 1 Definitions, scope Indent 2. (m)	means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics		

Single use device		Applicable	Description
art 1 Definitions, scope Indent 2. (g)	single use device' means a device intended to be used once only for a single patient.		

Administration of medicinal products		Applicable	Description
art 1 Definitions, scope Indent 3	where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, that device shall be governed by the MDD, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product		
art 1 Definitions, scope Indent 3	If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Directive 2001/83/EC. The relevant essential requirements of Annex I to this Directive shall apply as far as safety and performance-related device features are concerned.		