EU Medical Device Directive (93/42/EEC) labelling requirements

The essential requirements of the Medical Device Directive (93/42/EEC) referred to as the MDD set out the detailed requirements for labelling of medical devices in Annex 1 paragraphs 8.7, 13.2 and 13.3 (a)-(n). These sections are reproduced below for your information.* or Click here for a link to the directive.

EN 980:2008, the European standard developed to help medical device manufacturers to comply with these essential requirements was due to be withdrawn from the list of harmonised standards in 2013 and to be superseded by ISO 15223-1:2012 but the latter has not been harmonised yet because the EU Commission saw issues with the Z annexes of the standard. EN 980:2008 remains harmonised currently (June 2015) but the list of harmonised standards can be checked by following the link here. The symbols and requirements of EN 980 have been incorporated into ISO 15223-1 but there are additional symbols in ISO 15223-1. The MDD allows the use of symbols from non-harmonized standards provided that the symbols and colours are described in the documentation supplied with the device (see MDD Annex I item 13.2). Therefore, as most manufacturers define all symbols, regardless of origin, this gap in a harmonized standard for symbols should not be an issue.

ISO 15223-1:2012 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied: General requirements

Please refer to Table ZA.1 in Annex ZA of the standard to check exactly which essential requirements of the MDD are covered.

The standard covers information that is considered by regulatory authorities to be essential for the safe and proper use of medical devices. The information can appear on the medical device itself, as part of the label, or provided with the medical device using internationally recognized symbols listed in Table 1 of the standard with precisely defined descriptions to transcend language barriers.

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* 8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.

13.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.

13.3. The label must bear the following particulars:

(a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;

(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;
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(c) where appropriate, the word ‘STERILE’;
(d) where appropriate, the batch code, preceded by the word ‘LOT’ or the serial number;
(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;
(f) where appropriate, an indication that the device is for single use. A manufacturer’s indication of single use must be consistent across the Community;
(g) if the device is custom-made, the words ‘custom-made device’;
(h) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;
(i) any special storage and/or handling conditions;
(j) any special operating instructions;
(k) any warnings and/or precautions to take;
(l) year of manufacture for active devices other than those covered by(e). This indication may be included in the batch or serial number;
(m) where applicable, method of sterilization;
(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.

N.B. Please refer to the SBA disclaimer concerning this information which is provided for education purposes only.