



The label should contain the following particulars which may appear on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

- a) The information required on the label should be provided in a label on the device itself. If this is not practicable or appropriate (for example, for small-size devices, contact lenses, bone cement, software, etc.), some or all the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.
- b) The label should contain the brand or trade name of the medical device or IVD medical device.
- c) The details strictly necessary for a user to identify the device and its use, e.g. ‘cardiac ablation catheter 10 French / 20 cms’ or ‘pediatric thermometer’ or ‘tongue depressor’, and a product catalogue code.
- d) The name and address of the manufacturer in a format that is recognisable and allows the location of the manufacturer to be established.
- e) For imported medical devices, the name and postal address of either the authorised representative, or importer or distributor established within the importing country/jurisdiction (**if applicable**). This information may be added by the authorised representative, importer or distributor, rather than be provided by the manufacturer, in which case, the additional label should not obscure any of the manufacturer's labels.
- f) If the device is IVD, the label must contain an indication that the device is for in vitro diagnostic use (IVD).
- g) Where appropriate, an indication that the device contains or incorporates a medicinal or biological substance, e.g. heparin coated catheter.
- h) The label should include the batch code, batch number, lot code, lot number, serial number, control number, or version number of the medical device or IVD medical device, as appropriate preceded by the word LOT or SERIAL NUMBER or an equivalent symbol.
- i) An unambiguous indication of the date until when the medical device may be used safely, expressed at least as the year and month (e.g. on reagents or consumables), where this is relevant.

- j) For instruments, where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable.
- k) Where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package.
- l) An indication of any special storage and/or handling condition that applies.
- m) If the medical device is supplied as sterile, an indication of its sterile state and, where appropriate, the sterilization method.
- n) Warnings or precautions to be taken that need to be brought to the immediate attention of the professional user, the lay person or other person (e.g. 'CAUTION – LASER' or 'CONTAINS POTENTIALLY INFECTIOUS MATERIAL'). This information may be kept to a minimum in which case more detailed information will appear in the instructions for use.
- o) If the medical device is intended for single use an indication of that fact
- p) If the device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is custom made), an indication of that fact.
- q) IVD medical device kits include individual reagents and articles that may be made available as separate IVD medical devices. In this situation, these IVD medical devices should comply with the label content requirements.

**General Secretariat
National Medicines and Poisons Board**