Safety Notice
Medical Devices

IRISH MEDICINES BOARD

"Intended Purpose" of a Medical Device

Guidance for healthcare settings

Priority 3 – Advisory

IMB Safety Notice: SN2014(29) **Issue Date: 25 June 2014**

MANUFACTURER / SUPPLIER	IMB CASE REFERENCE
Several	CP20600

ISSUE

Different products used in a healthcare setting may be similar based on appearance but may have a different intended purpose assigned to them by their manufacturer. Medical devices always have a specific medical purpose intended and claimed by their manufacturers.

As it is the intended purpose assigned by the manufacturer that determines whether a product meets the definition of a medical device, one product may be considered a medical device whereas another apparently similar product may not. The medical device must bear a CE mark* on the device or its labelling, indicating conformity with the relevant Directive.

Products should only be used as specifically intended by the manufacturer of that product and not based on similarities with other products or medical devices.

ACTION OR RECOMMENDATIONS

The IMB advises that users:

(1) Ensure medical devices are used in accordance with the intended purpose specified by the manufacturer.
(2) Ensure that medical devices and other products are indicated for the particular purpose for which they are being used.
(3) Ensure that all medical devices purchased bear a CE mark* on the device, labelling or instructions for use.

TARGET GROUPS

Procurement groups
Risk assessment managers
Clinical engineers
Equipment managers
Purchasing managers
Health and safety managers
Laboratory managers
Theatre managers
Central Sterile Supply Department (CSSD)

BACKGROUND

All medical devices placed on the Irish market are required to bear a CE mark*, indicating conformity with the medical device legislation**. Whether or not a product meets the definition of a medical device is dependent on the intended purpose assigned by the manufacturer. The "intended purpose" is defined in the legislation** as "the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials".

It has come to the attention of the Irish Medicines Board (IMB) that products that do not meet the definition of a medical device are being used for a medical purpose based on their similarity in appearance to medical devices. These 'general products' are not placed on the market as medical devices by the manufacturer and are not intended by the manufacturer to be used for the same intended purpose as the similar medical device. However, due to similarities between the two products, the user may mistakenly assume that the intended purpose of the medical device applies to the general product also.

The labelling of a medical device is required to provide important information on the use of the device e.g. whether the device is sterile, single use etc. This information is important in selecting whether that medical device is suitable for the particular purpose being performed by the user. A 'general product' may not have the same information on its labelling and it is important to ensure that assumptions are not made based on similarities to a medical device e.g. that the general product is sterile when the labelling does not state that it is sterile.

Examples:

- Plastic tray liners can be indicated for the transportation of general equipment but can also be CE marked and specifically intended for the transportation of medical devices.
- Cotton wool is available as a general product but is also available as a sterile CE marked medical device.
- Gloves are available as general purpose personal protective equipment and also as CE marked medical devices.

* with the exception of custom made devices, those intended for clinical investigation or performance evaluation

** Directive 93/42/EEC concerning medical devices; Directive 98/79/EC on in vitro diagnostic medical devices or Directive 90/385/EEC relating to active implantable medical devices, as amended

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to: Refer to information on device label.

IMB CONTACT INFORMATION

Queries regarding this issue should be addressed to:

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