
**Medicines and Healthcare products Regulatory Agency**

Safeguarding public health

**COMPETENT AUTHORITY (UK)**

**BULLETIN No. 19**

# OWN BRAND LABELLING AND RENTED PRODUCTS

FORWARD

This information bulletin is the 19th in the series and was written after consultation with representatives of The Association of British Healthcare Industries. The Association of Contact Lens Manufacturers, Surgical Dressing Manufacturers Association and the UK Medical Devices Notified Bodies Group. It sets out the position of rented products and own brand labelling under the Medical Devices Regulations(MDR).

This bulletin aims to present the Department of Health's current views on the interpretation of the Medical Devices Regulations where enquiries from medical device manufacturers and others have shown that there is uncertainty as to what the requirements are. It is intended as general guidance and should not be regarded as an authoritative statement of the law, nor as having any legal consequence. It follows that manufacturers and others should not rely on the bulletin but should consult the legislation referred to, making their own decisions on matters affecting them in conjunction with their lawyers and other professional advisers. The Department of Health does not accept liability for any errors, omissions or misleading or other statements in the bulleting whether negligent or otherwise. An authoritative statement could be given only by the courts.

The Medical Devices Regulations 2002 (SI 2002 No. 618) which consolidates all the existing medical devices regulations with a single piece of legislation, came into force on 13 June 2002. These Regulations implement the Medical Devices Directive (93/42/EEC), the *In Vitro* Diagnostic Medical Devices Directive (98/79/EC)and the Active Implantable Medical Devices Directive (90/385/EEC).

RESPONSIBILITY OF THE MANUFACTURER

The Regulations concerning medical devices define the manufacturer as the "person who is responsible 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 of a third party". It is the manufacturer's responsibility to "ensure the application of the quality system".

OWN BRAND LABELLING

An "Own Brander" is the person who places the product on the market under his own name or trademark and is therefore the manufacturer (as defined) for the purpose of the regulations. He may not be the person who actually designed, manufactured, packaged or labelled the product but nevertheless the regulatory responsibility rests with him alone. He must ensure that:

a. the appropriate conformity assessment procedure is correctly followed by him and any sub-contractor;
b. if appropriate, an application is lodged with a Notified Body. (In MHRA's view any existing Notified Body approvals to the sub-contractor remain valid and must be recognised by any subsequent Notified Body. The subsequent Notified Body may thus only need to review the contract

between the “Own Brander” and the sub-contractor, and the documents confirming existing Notified Body approval);

c. any Notified Body which may be involved and the Competent Authority have access to the appropriate documentation necessary for them to fulfil their respective responsibilities;

d. he makes a Declaration of Conformity for the products concerned, and retains them for future reference by the Competent Authority;

e. the CE marking of conformity is properly applied;

f. post-marketing obligations such as vigilance are satisfied.

When any of the manufacturer’s responsibilities are subcontracted to another person, contractual arrangements should ensure that the obligations of the regulations are met.

A distributor whose name appears on the packaging, labels or instructions for use is not considered to be an Own Brander if it is clear that the product is sold under the actual manufacturer’s own name. It will depend under whose name the product is being placed on the market.

RENTED PRODUCTS

If a person purchases CE marked devices and rents them out (ie products such as wheelchairs and crutches) without changing their performance, design or intended purpose (ie without assembly, packaging, processing, fully refurbishing, labelling and/or assigning to them their intended purpose as a device with a view to their being placed on the market under his own name, putting them together as a system or procedure pack, or sterilising them) there are unlikely to be obligations in the regulations which apply to him. On the other hand, if the person renting out the device changes its characteristics then it is likely that he will need to comply with all relevant obligations under the Regulations (see in particular regulations 14 and 17).

PLACING ON THE MARKET

Placing on the market means, in relation to a device, making available in return for payment or free of charge of a new or fully refurbished device other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Community market.” According to the Commission’s view as set out in its guide on the New Approach Directives, (which includes those on medical devices), “making available” means either:

“ – transfer of the product, that is, either the transfer of ownership, or the physical hand-over of the product by the manufacturer, his authorised representative in the Community or the importer to the person responsible for distributing the product on the Community market or the passing of the product to the final customer or user in a commercial transaction, for payment or free of charge,

regardless of the legal instrument on which the transfer is based (sale, loan, hire, leasing, gift, or any other type of commercial legal instrument). The product must comply with the Directive at the moment of transfer;

or

- the offer of transfer, in cases where the manufacturer, his authorised representative in the Community or the importer, makes a product available in his own commercial distribution chain with a view to direct transfer to the final consumer or user. The product must comply with the Directive from this point onwards."

POST-PRODUCTION OBLIGATIONS

The Regulations (read with the relevant annexes of the Directive) impose obligations on manufacturers (as defined with respect to:-

i. post production monitoring, and

ii. the reporting of adverse incidents, and any malfunction or deterioration which might lead to an adverse incident, to the Competent Authority.

Manufacturers (which for these purposes includes Own Branders – see under OWN BRANDERS above) should acquaint themselves with the precise terms of these obligations. All obligations to report to the Competent Authority should be taken seriously (there are criminal sanctions for failure to comply) but the consequences of not reporting incidents involving products for which there may be several Own Branders could be particularly serious. MHRA considers that responsible Own Branders will also ensure that incidents or potential incidents will also be brought to the attention of the actual manufacturer. Where the actual manufacturer is aware of an issue resulting in "unsafe" products which are out in the market place all relevant Own Branders should be informed to enable them to take appropriate action (eg recall) with regard to their own products.

TRANSITIONAL PERIOD

In the case of *In Vitro* Diagnostics, the UK implementing regulations came into force on 7 June 2000 and include a transitional period until 7 December 2003, after which date manufacturers must comply with the legislation. IVD's which conform with existing national legislation already in the distribution chain at the end of the transitional period can continue to be supplied to the end user for a further two years (ie. Until 7 December 2005).

FURTHER INFORMATION

Further information on medical devices directives generally and copies of other bulletins in our series can be obtained from our website http://www.mhra.gov.uk or by leaving a message on 020 7972 8203 (24 hours) for more detailed enquiries ring 020 7972 8300 send a fax 020 7972 8112 or write to:

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