Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Guidance on legislation

Borderlines with medical devices

May 2016

Contents

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V1.0	February 2014	n/a
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Disclaimer
The guidance given presents the MHRA's current views on the interpretation of the medical devices legislation as it relates to borderline products. It is intended as general guidance and should not be regarded as an authoritative statement of the law or as having any legal consequence. This guidance should not be relied on solely – manufacturers and others should consult the relevant legislation referred to and seek the views of their own professional advisors. The MHRA does not accept liability for any errors, omissions, misleading or other statements whether negligent or otherwise.

1. Introduction

Many manufacturers have difficulty in interpreting whether or not their product would be considered a medical device within the terms of the Medical Devices Directive 93/42/EEC (referred to as the MDD in this document). This guidance document has been developed to aid with some of the more common areas of confusion.

It is often assumed that because a product is considered a medical device in some countries, for example in the USA, Canada or in Japan, that it will also be a medical device within the European definitions. This is not the case and manufacturers should always refer to the definitions of a medical device when making any borderline determinations. Any such decision will be based on the stated intended purpose of the product and its mode of action. Manufacturers should also consult the available published guidance in order to determine whether or not their product is considered a medical device within the European Union. The available guidance is listed in section 23 of this document.

In general, medical devices must have a 'medical purpose' which is determined by the definition of a medical device. They must also act primarily in a way that is not metabolic, immunological or pharmacological. Should they function in any way that is metabolic, immunological or pharmacological, in conjunction with having a medical purpose, they are likely to come within the remit of the regulations covering medicinal products instead. Further information on the borderline with medicinal products is available – see the list at the end of this document

The word 'manufacturer' in the context of the MDD means the person or company who is placing the product on the market or into service in their own name. It does not necessarily mean the physical manufacturer of the devices concerned. If a company is an 'own brand labeller' then they take on full legal responsibility as the manufacturer of the product as defined in the MDD.

This guidance document only covers borderline products with the Medical Devices Directive (Directive 93/42/EEC). Guidance on the borderlines with in Vitro Diagnostic Medical Devices (Directive 98/79/EC) and Active Implantable Medical Devices (Directive 90/385/EEC) has been published by the European Commission and are available from the European Commission website (see section 23).

The advice given in this document is by nature general and if manufacturers are uncertain they should seek further advice from the MHRA after consulting the other guidance documents.

Products falling outside the scope of the regulations for medical devices may still be covered by the Consumer Protection Act and must be safe for their intended purpose.

2. Medical purpose

Although the MDD does not use the phrase 'medical purpose', medical devices are considered to be items intended to be used in a 'medical' context. Whether or not a product is considered to have a 'medical purpose' will be defined by the manufacturer's intention for the product as defined in their labelling, instructions for use and promotional material and its mode of action in conjunction with the definition of a medical device as stated in the MDD.

Note that not all equipment used in a healthcare environment or used by a healthcare professional will be considered to come within the definition of a medical device.

3. Medical / cosmetic / toiletry purpose

As medical devices are considered to be specifically intended for a 'medical purpose', products that do not have such a principal intended purpose are not considered to be medical devices, even if they may be considered to be used for the prevention of disease as a secondary purpose.

Examples of the types of products that are **not** normally considered to be medical devices:

- baby nappies
- breast pumps
- deodorants for use with medical devices
- feminine hygiene products (sanitary towels, tampons)
- hand cleansing wipes (for general hand cleaning)
- hot water bottles, heat pads etc (with no medical claims)
- instruments for tattooing
- mattress protectors
- muscle toning products
- 'pill' dispensers for tablets and capsules / storage boxes with reminders
- slimming products
- tooth brushes, dental sticks, dental floss
- tooth whitening / bleaching products
- un-medicated chewing gum
- wigs
- wrinkle treatments (with cosmetic purpose).

Where there is a specific primary intended medical purpose, similar products may be considered to be medical devices. For example:

- breast pumps for treatment of inverted nipples
- external heat pads claiming pain relief, e.g. for the treatment of period pains
- incontinence products (e.g. adult nappies)
- muscle toning products with medical claims (such as treatment of incontinence)
- slimming products indicated for the treatment of clinical obesity which do not act in a metabolic, pharmacological or metabolic manner. *

  * note that such products may be considered to be medical devices or medicinal products and the determining factor will be the mode of action of the product concerned. Thus products for the treatment of obesity, which act by increasing metabolism or having a pharmacological or metabolic action, would be considered to be medicinal products and not medical devices.

4. General purpose products

Products that have a multiple purpose, which may occasionally be used within a medical environment, are not normally medical devices, unless a manufacturer ascribes a specific medical purpose to such products. Examples of such products are:

- disinfectants / cleaners intended for multi-purpose use, including hard surfaces (See also section 21 on Biocides)
- magnetoscope, screen
- multipurpose PC, scanner, printer etc.

5. Assistive technology products (aids for daily living)

Equipment intended for alleviation of, or compensation for a disability may or may not be considered as medical devices. The determining factor will be whether or not there is a direct link between the corrective function of the equipment and the individual concerned and that there is a stated medical purpose.
The following products are considered to be medical devices as there is such a direct link:

- baths with integral hoists
- external limb prostheses and accessories
- hearing aids
- mobility aids for the visually impaired
- orthopaedic footwear
- orthoses (lower/upper limb, spinal, abdominal, neck, head)
- patient hoists
- rehabilitation tricycles / mobility carts
- walking / standing frames
- walking sticks / crutches
- wheelchairs.

Other products, however, will be considered as ‘general equipment’ since it may be used ‘by all’ (rather than having a direct link with the individual concerned). Such products are usually considered as ‘aids for daily living’ and are not medical devices. For example:

- acoustic signals at traffic lights
- baths with doors
- grab rails (at doorways, stairs etc)
- personal alarm systems / home alarm systems
- portable ramps
- special water taps
- stair lifts
- toilet equipment for the disabled / elderly (e.g. toilet seats, shower seats, commodes).

In cases of doubt, contact the MHRA for further advice: email: devices.regulatory@mhra.gsi.gov.uk

6. Products for sports or leisure

In general, products for sport or leisure purposes are not considered to be medical devices. However, in some cases, products aimed at sports people may be considered to be medical devices. This is usually the case where specific claims are made for the treatment of pain or injury and the product acts in a physical manner. Examples of products considered to be medical devices are:

- heat / cold pads for pain relief
- bandages for sprains and similar
- support bandages
- gym equipment placed on the market specifically to measure, for example, heart rate or breathing rate. (Gym equipment that contains within it an element that measures heart rate is not a medical device because its primary purpose is as a piece of fitness equipment, not principally to measure a physiological function. Blood pressure monitors, even if intended to be used in a gym, however, would be considered to be medical devices).

7. Personal protective equipment

Some products may appear to have a medical purpose, but in fact are designed to protect the user. Such products are usually considered to be personal protective equipment (PPE) rather than medical devices. This will depend upon the intended purpose for the individual product concerned. For example:

- masks for the protection of the user (e.g. from the environment) are not medical devices, however, surgical masks (for use in an operating theatre) are medical devices as they are intended to protect the patient rather than the user
- latex / rubber gloves may be PPE or medical devices, or both – examination gloves and surgical gloves are medical devices. Gloves for other purposes would not be devices (e.g. for use in the home or in a laboratory). The key determining factor will be the principal stated purpose of the product by the manufacturer when he places it on the market
- ionising radiation protective clothing: if intended for the protection of healthcare professionals will be PPE but if intended for patient protection would usually be medical devices
- mouth guards are only medical devices when intended for a specific 'medical' purpose, for example as a retainer following orthodontic treatment or for use in the treatment of sleep apnoea. In most other cases these products will be PPE, including those intended for sports purposes
- self-rescue apparatus
- eye protecting visors with no corrective function.

It should be noted that amending Directive 2007/47/EC contained provisions for products that are intended to be used both as medical devices and personal protective equipment. In such cases the product should be CE marked as a medical device. However, the manufacturer must also fulfil the relevant basic health and safety requirements of Directive 89/686/EC on personal protective equipment.

8. Other products

Below are listed some general products that are not considered to be medical devices:

- non-prescription sunglasses
- non-sterile clothing / apparel for home, occupational or recreational use.

9. Software

Software may be considered to be medical devices provided that the purpose fits the definition of a medical device. The definition of a medical device includes standalone software and specifies that when software is used in combination with a device which is 'intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes' that it will be considered to be a medical device.
For example:

- software intended to enhance images from x-ray or ultrasound would be considered to be medical devices
- software that is simply a patient management system or a records storage system would not, however be considered to be a medical device
- telecare alarm systems are unlikely to be considered as medical devices, however some specific telehealth systems or products used with such systems may come within

the remit of the medical device regulations. Further advice should be sought from MHRA.

The European Commission's document MEDDEV 2.1/6 provides specific guidance on this issue.

10. Machinery

The Machinery Directive 2006/42/EC no longer contains a clause excluding medical devices from its provisions. The revision to the MDD (Directive 2007/47/EC) contains provisions relevant to machinery that is also a medical device. In such cases the machinery should be CE marked as a medical device. However, the manufacturer must also fulfil the essential health and safety requirements of the Machinery Directive 2006/42/EC where these are more specific than the essential requirements of the MDD.

11. Medical devices / medicinal products

For specific guidance on the borderline between medicinal products and medical devices, please refer to the specific guidance documents that are available via the MHRA website (see appendix).

12. Accessories

The Medical Devices Directive defines an accessory as:

'an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device'.

Within the meaning of Directive 93/42/EEC, accessories should be classified in their own right as a medical device and do not necessarily take the classification of the device with which they are intended to be used. As this is the case, the determination as to whether or not a product is an accessory will be based on whether or not the product is specifically intended, by its manufacturer, to be used together with a medical device in order for the accessory to enable the device to be used in accordance with its intended purpose/use by its manufacturer. A product can only become an accessory to a medical device if there is an established intended use in conjunction with a medical device.

Examples of such potential accessories are:

- steriliser for use with medical equipment
- pouches for packaging re-sterilised medical devices
- specific battery chargers for battery-driven electromedical devices
- contact lens care products
- disinfectants specifically intended for medical devices
- specialised water treatment devices for use with dialysis machines
- gas cylinders / pressure release devices for use in conjunction with anaesthesia machines.

13. Raw materials and component parts

A medical purpose will relate to the finished product (rather than component parts), irrespective of whether they are intended to be used in combination. Therefore raw materials, component parts or products at stages of intermediate manufacture are not normally considered to be medical devices. Manufacturers should be aware, however, that raw materials / components may have properties or characteristics which will affect the quality and safety of finished medial devices and therefore must take responsibility for the selection and control of such raw materials / components and ensure their compatibility for the finished device.

14. Spare parts

Spare parts, supplied for the replacement of existing components of a medical device that has already been CE marked are not usually considered to be medical devices unless they are likely to significantly change the characteristics or performance of the finished device. If this is the case then such spare parts are likely to be considered to be medical devices in their own right.

15. Repairs

Where a device is 'repaired' and returned to its original owner after the repair the components used in the repair would not require CE marking as medical devices and the repaired device will not require CE marking a second time. The device is not being 'placed on the market' but returned to its owner.

16. Second-hand and fully refurbished devices

Second-hand medical devices are those which are already on the market and have been 'pre-owned' and used and that are subsequently 'sold on' for the same continued use. These products are considered to be already CE marked and first placed on the market and do not require CE marking by their new owner.
A medical device that has been fully refurbished is not the same as one that has been repaired or undergone maintenance.
Fully refurbished medical devices are considered to come within the requirements of the medical device regulations and will require CE marking by the person undertaking the full refurbishment. They will be considered to be the 'manufacturer' under the regulations and are required to place the product on the market under their own name. 'Fully refurbished' is considered to mean that a device has been completely rebuilt / made as new from used devices and is assigned a new 'useful life'. It would also be considered as a new device if a new intended purpose was assigned. Further information may be obtained from the guidance document from the European Coordination of Notified Bodies 'Placing on the market of fully refurbished medical devices' NB-MED/2.1/Rec5.

17. Final processing

Some devices may not be supplied in their final state (i.e. may not be immediately available for use) once placed on the market. They may require some further processing prior to being 'usable', for example processing, preparation, installation, assembly or fitting. These activities are not usually undertaken by the manufacturer but are carried out by the healthcare professional or the final user.
Examples of such activities are:

- sterilisation of medical devices supplied non-sterile
- assembly of systems
- configuration of electronic equipment
- preparation of dental fillings
- fitting of contact lenses
- adaptation of a prosthesis to the needs of the individual patient.

Whilst the majority of these will not affect the CE marking of the medical device, a distinction must be made between activities carried out by a healthcare professional in the course of their expert activity and activities carried out by a specialist expert in such processing (for example assembly of spectacles from lenses and frames to a prescription). The latter may be considered to be processing or assembling activities and as such come within the remit of Article 11 or 12 of the MDD and thus require to be covered by the requirements of the Directive.

18. Custom-made devices

Custom-made devices are usually one-off devices made specifically for one individual patient on the basis of a written prescription from a healthcare professional. They are covered by the requirements of Article 11 (6) and Annex VIII of the MDD in terms of their conformity assessment. Examples of such devices are dental appliances, prostheses and hearing aid inserts. Intermediate products as described in the previous section may be considered as medical devices where they are specifically intended for these types of custom-made devices. This would include items such as dental alloys, dental ceramics, modular components for prostheses etc.

19. Article 12 – kits and procedure packs / assembling and processing

Article 12 of the MDD provides for manufacturers who put together medical devices already carrying the CE mark into kits or procedure packs for specific uses. Kits or procedure packs will come within the remit of the regulations and manufacturers need to comply with specific elements of the regulations, although the kit or procedure pack itself does not need to carry an additional CE mark. Such kits may also include non CE marked products. For example such a kit may contain a medicinal product, which must meet the requirements of the regulations covering medicinal products, including those covering labelling, packaging etc. Where such kits / procedure packs are sterilised after completion, the assembler will require certification via a notified body for the sterilisation process.

If any of the medical devices contained in such a kit are not CE marked by the original manufacturer, then the person putting the kit on the market is considered to be the manufacturer and the whole kit would need to be CE marked as a medical device in its own right under Article 11 of the MDD. That is, the ‘assembler’ in such cases would be regarded as the manufacturer of the whole kit.

In addition, if the CE marked devices are placed in the kit for a purpose not compatible with the original manufacturer’s stated intended purpose then the person assembling the kit will be deemed to be placing a medical device on the market in its own right and therefore must meet the full requirements of the MDD.

The assembling of medical devices is likely to come within the remit of the MDD, for example the assembling of CE marked spectacle frames and lenses for specific patients, along with associated processes such as glazing, and surfacing. MHRA’s website contains specific guidance on these types of products and activities.

20. In-house manufacturing

Under the Medical Devices Directive the manufacturer is defined as the natural or legal person responsible for the manufacturing activities related to a device with a view to it being placed on the market or put into service under the manufacturer’s own name. So in order to be a medical device, the product must be placed on the market or put into service. Where the device is manufactured by the user of a product (for example in a hospital) without being transferred to another person / legal entity or where it is supplied for use by the hospital’s own patients, it would not be considered to come within the remit of the MDD. The key is there is no transfer of ownership of the product. Where the manufacture of an ‘in-house’ design has been subcontracted to an external party by the user, this will still be considered to be ‘in-house’ provided that the product is not supplied to any third party.

Further details on in-house manufacturing are available on this web page.

21. Biocides

Products intended to disinfect may come within the remit of the biocides regulations, the medical device regulations or the regulations covering medicinal products for human use, depending upon their intended purpose, composition and the claims made for the products concerned.
In general, for a product to be acceptable as a medical devices it must be a disinfectant that is specifically indicated for the disinfection of medical devices. For example wipes for disinfecting stethoscopes.

Biocides intended as general purpose disinfectants for rooms, hard surfaces etc are not considered to be medical devices.

Regulation 528/2012 covering Biocides came in to force in September 2013 and contains provision for products intended for both general disinfectant use and use with medical devices. In such a case both the regulations covering medical devices and those covering biocides would apply to a single product and the product should be labelled in accordance with both sets of regulations.

Disinfectant products for use on humans may also be regulated in various ways.

- Hand gels / washes intended for general purpose use (including by healthcare professionals) are generally regarded as biocides, unless there are claims for the control of specific pathogens, in which case they may be considered to be medicinal products.
- Surgical scrubs are regarded as medicinal products.
- Pre-injection swabs / wipes: alcohol-based wipes are acceptable as medical devices, but those containing anti-microbial substances such as chlorhexidine, cetrimide or iodine are considered to be medicinal products (see additional advice on the MHRA website).

22. Other borderlines

In the majority of cases food supplements and herbal treatments would be unlikely to be considered medical devices, even when medical claims are made. These would come on the borderline with medicinal products – the MHRA's 'A guide to what is a medicinal product' should be consulted in the first instance.

If, after reading this document and consulting the published guidance available (listed at the end of this document) a manufacturer is still unsure of the correct regulatory route or classification of their product, further advice should be requested from MHRA prior to placing the product on the market.

23. List of guidance and contacts

MHRA guidance

Topics listed below are available from the MHRA's web pages on www.gov.uk

- 'A guide to what is a medicinal product'
- In-house manufacturing
- Guidance for manufactures of custom-made devices (including dental)

European Commission guidance documents (MEDDEV)

The documents listed below are available from the European Commission website.

Definitions and classification of medical devices

- MEDDEV 2.4/1 Guidelines for the classification of medical devices
- MEDDEV 2.1/1 Guidelines covering definitions of 'medical devices', 'accessory' and 'manufacturer'
- MEDDEV 2.1/5 Medical devices with a measuring function
- MEDDEV 2.1/6 Qualification and classification of stand alone software.

Borderlines with medicinal products

- MEDDEV 2.1/3 'Demarcation between Medical Devices and Medicinal Products'

Borderlines with in vitro diagnostic medical devices

- MEDDEV 2.14/1 IVD borderline issues
- MEDDEV 2.14/2 IVD research use only products
- MEDDEV 2.14/3 Supply of instructions for use for IVD medical devices

Borderlines with the Active Implantable Medical Devices Directive

- MEDDEV 2.1/2 Field of application for Directive 90/385/EEC

Borderlines with other directives

- MEDDEV 2.1/4 Electromagnetic compatibility & personal protective equipment

Other information

Contact the MHRA about borderlines with medical devices
via email: devices.regulatory@mhra.gsi.gov.uk

Information on specific borderline cases 'Manual on borderline and classification in the Community Regulatory framework for medical devices' from the Medical Devices Expert Group on Borderline and Classification:
http://ec.europa.eu/health/medical-devices/documents/borderline/index_en.htm

Additional guidance documents issued by Team NB (European Association of Notified Bodies) is available on the website: www.team-nb.org

Cosmetics Directive, Electromagnetic Compatibility Directive, the Low Voltage Directive, Personal Protective Equipment Directive and the General Product Safety Directive:
Department for Business, Innovation and Skills (BIS)
Website: http://www.bis.gov.uk/
Tel: 020 7215 5000 Email: enquiries@bis.gsi.gov.uk

Biocides:
The Health and Safety Executive (HSE)
Website: www.hse.gov.uk
Tel: 0151 951 4000 Email: biocides@hse.gsi.gov.uk

Appendix: Words and phrases

The words and phrases listed below are all likely to have contributed to a determination by the MHRA that the product they were associated with was a medical device. In some cases specific wording may imply that a product would be considered as a medicinal one (consult appendix 1 of the MHRA's 'A guide to what is a medicinal product' for details).

Aids treatment
Alleviates
Avoids
Can benefit those who suffer from...
Clinically proven
Combats
Compensates for …
Counteracts
Cure/cures
Diagnoses / assists diagnosis
Eases symptoms
Eliminates
Heals
Help/help with...
Investigation
Monitors
Pain relief / relief from pain
Prevents ……
Protects against...
Repairs
Stops
Traditionally used for....
Treats/clears infestations
Treats/Treatment/Treating

Although such words or phrases may contribute to such a determination, the intended and implied meaning of the words used will be considered in context with relation to the product concerned and its intended purpose. This is not an exhaustive list and should not be considered as such.

It should be noted that general disclaimers (for example 'this product is not a medical device') are not acceptable if medical claims are made or implied elsewhere in the product labelling or associated promotional literature.

Anecdotal quotes and testimonials are considered to be implied claims by the manufacturer if they are repeated in product literature.