GUIDANCE NOTE 20
Borderlines with Medical Devices.

First Published August 2009
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 Device Directive 93/42/EEC. 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, for example in the USA or 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 Appendix 1 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 medical device directive means the person or company who is placing the product on the market or in to 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 Regulations.

This guidance document only covers borderline products with Directive 93/42/EEC, the medical devices directive. 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 for download from the Commission website – see links in Appendix 1.

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

The guidance given presents MHRA’s current views on the interpretation of the Medical Device Regulations as they relate 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.

2. **Medical Purpose**

Although the medical device directive 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 manufacturers 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 regulations.

It should be noted 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 are:

- Baby nappies
- Breast pumps
- Feminine hygiene products (sanitary towels, tampons)
- Tooth brushes, dental sticks, dental floss
- Tooth whitening / bleaching products
- Un-medicated chewing gum
- Instruments for tattooing
- Slimming products
- Muscle toning products
- Wrinkle treatments (with cosmetic purpose)
- Hot water bottles, heat pads etc (with no medical claims)
- Wigs
- Mattress protectors
- Deodorants for use with medical devices
- Hand cleansing wipes (for general hand cleaning)
- ‘Pill’ dispensers for tablets & capsules / tablet / capsule storage boxes with reminders

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

- Incontinence products (e.g. adult nappies)
- Breast pumps for treatment of inverted nipples
- 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 *
- External heat pads claiming pain relief, e.g. for the treatment of period pains.

* 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:

- Multipurpose PC, Scanner, printer etc
- Magnetooscope, screen
- Disinfectants / cleaners intended for multi-purpose use, including hard surfaces (See also section 21 on Biocides)

5. Assistive Technology Products (aids for the handicapped)

Equipment intended for alleviation of, or compensation for a handicap 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:

- Wheelchairs
- Walking / standing frames
- Walking sticks / crutches
- Mobility aids for the visually impaired
- Patient hoists
- Rehabilitation tricycles / mobility carts
- Orthopaedic footwear
- External limb prostheses and accessories
- Orthoses (lower/upper limb, spinal, abdominal, neck, head)
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
- Special water taps
- Toilet equipment for the disabled / elderly (e.g. toilet seats, shower seats)
- Grab rails (at doorways, stairs etc)
- Portable ramps
- Stair lifts

In cases of doubt further advice may be sought from MHRA

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
- 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 which 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 actuality are designed to protect the user. Such products are usually considered to be personal protective equipment 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 the revision to the Medical Device Directive (Directive 2007/47/EC which comes into force in March 2010) contains 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 revised definition of a medical device includes standalone software in the definition of a medical device and includes the fact 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. This new addition to the definition of a medical device will not fully come into force until 21\textsuperscript{st} March 2010. Separate guidance will be produced on this area.

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.

10. Machinery
The Machinery directive 2006/42/EC no longer contains a clause excluding medical devices from its provisions. The revision to the Medical Device Directive (Directive 2007/47/EC which comes into force in March 2010) 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/EEC where these are more specific than the essential requirements of the medical device directive.

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 1).

12. Accessories
The medical device 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 medical 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 NB-MED2.1/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 health care 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 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 health professional. They are covered by the requirements of Article 11 (6) and Annex VIII of the Directive 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 & processing**

Article 12 of the medical device directive 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. 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 Regulations.

The assembling of medical devices is likely to come within the remit of the medical device directive, 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 device 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 manufacturers own name. Thus 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 medical device regulations. 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 may be obtained from the MHRA website at **www.mhra.gov.uk**

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, the only products acceptable as medical devices are disinfectants that are 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.

It should be noted that there is no provision under the medical device regulations for disinfectants intended primarily for use with medical devices to have subsidiary claims for multi-purpose use, therefore such products may only be CE marked where they are intended for use on medical devices. If a manufacturer wishes to make other claims (for example for general hard surface use), this must be done under the regulations covering biocides (i.e. two products placed on the market under the two separate sets of legislation).

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, however those containing anti-microbial substances such as chlorhexidine, cetrimde or iodine are considered to be medicinal products. (see additional advice on 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 – MHRA Guidance Note 8 ‘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.

MHRA contact details

Medicines & Healthcare products Regulatory Agency
European and Regulatory Affairs (Medical Devices)
8th Floor – Wing 2, Market Towers
1 Nine Elms Lane
London SW8 5NQ
Telephone: 020 7084 3300
Fax: 020 7084 3112
E-mail: era@mhra.gsi.gov.uk
**Additional Information:**

The following guidance documents are freely available for download from the MHRA website and the European Commission website:

All of these documents are available via the MHRA website at: [www.mhra.gov.uk](http://www.mhra.gov.uk) and [http://www.mhra.gov.uk/Howweregulate/Devices/index.htm](http://www.mhra.gov.uk/Howweregulate/Devices/index.htm) either directly or by following the links to external websites.

**Definitions & Classification of medical devices:**

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<tr>
<td>MHRA Bulletin 10</td>
<td>The Classification Rules</td>
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<td>Guidelines for the classification of medical devices</td>
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**Borderline with medicinal products:**

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<td>MHRA Bulletin 17</td>
<td>Medical Devices and Medicinal Products</td>
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<td>MHRA Medicines</td>
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**Borderlines with in vitro diagnostic medical devices**

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**Borderline with Active Implantable Medical devices**

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**Borderline with other directives:**

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<td>MEDDEV 2.1/4</td>
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**In house manufacturing:**

MHRA Bulletin 18 - The Medical Devices Regulations: Implications on healthcare and other related establishments plus additional information on MHRA website pages on the in-house manufacturing requirements.

**Information on specific borderline issues:**

Information will be published under ‘regulatory news’ and on the specific borderline pages

**Custom made devices**

- MHRA Guidance Note No 9: Guidance Notes for Manufactures of Custom made Devices
- MHRA Guidance Note No 16 Guidance Notes for Manufacturers of Prosthetic and Orthotic Appliances
- MHRA Guidance Note No 10 Guidance Notes for Manufacturers of Dental Appliances
- MHRA Guidance on ophthalmic products (MHRA specific webpage)

**Other information:**

Information relating to the Medical Device Expert Group and additional information relating to specific borderline and classification issues is available from the European Commission website at:


This webpage also contains the ‘Manual on borderline and classification in the Community Regulatory framework for medical devices’ which provides further guidance on borderline issues.

Additional guidance documents issued by NB Med may be accessed via: www.team-nb.org

Products falling outside the scope of the Regulations for Medical Devices may be still covered by the Consumer Protection Act and must be safe for their intended purpose.

Further information on other products and their relevant regulation may be obtained from:


Contact: Department for Business, Innovation and Skills (formerly the Department of Trade and Industry / BERR).

Telephone: 0207 215 5000

Website: http://www.bis.gov.uk/

E-mail: enquiries@bis.gsi.gov.uk

**Biocides:**

Contact: The Health and Safety Executive (HSE)

Website: www.hse.gov.uk

Telephone: 0870 545500

E-mail: biocides@hse.gsi.gov.uk
APPENDIX 1

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 MHRA Guidance Note 8 ‘A guide to what is a medicinal product’ - Appendix 1 for details).

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.

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