

**MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY
REGULATORY FRAMEWORK FOR MEDICAL DEVICES**

Version **1.8** (01-2011)

PLEASE NOTE: THE VIEWS EXPRESSED IN THIS MANUAL ARE NOT LEGALLY BINDING; ONLY THE EUROPEAN COURT OF JUSTICE (“COURT”) CAN GIVE AN AUTHORITATIVE INTERPRETATION OF COMMUNITY LAW.

MOREOVER, THIS MANUAL SHALL ONLY SERVE AS “TOOL” FOR THE CASE-BY-CASE APPLICATION OF COMMUNITY-LEGISLATION BY THE MEMBER-STATES. IT IS FOR THE NATIONAL COMPETENT AUTHORITIES AND NATIONAL COURTS TO ASSESS ON A CASE-BY-CASE BASIS.

THE CONTENT OF THIS MANUAL AND ALL UPDATES ARE PRESENTED TO THE WORKING GROUP ON BORDERLINE AND CLASSIFICATION FOR CONSULTATION. THIS GROUP IS CHAIRED BY THE COMMISSION AND IS COMPOSED OF REPRESENTATIVES OF ALL MEMBER STATES OF EU, EFTA AND OTHER STAKEHOLDERS

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INTRODUCTION

1. **Borderline cases are considered to be those cases where it is not clear from the outset whether a given product is a medical device, an in vitro diagnostic medical device, an active implantable medical device or not. Or alternatively, borderline cases are those cases where the product falls within the definition of a medical device but is excluded from the Directives by their scope. Where a given product does not fall within the definition of medical device or is excluded by the scope of the Directives, other Community and/or national legislation may be applicable.**
2. **Classification cases can be described as those cases where there exists a difficulty in the uniform application of the classification rules as laid down in the MDD (or where for a given device, depending on interpretation of the rules, different classifications can occur).**
3. **There may be cases where ‘claims’ of a medical nature are made for certain products, where those claims cannot be substantiated by technical, clinical and scientific data. If there is insufficient clinical, technical and scientific data to support the claims made, the product would not meet the requirements of the medical device directives and therefore may not be CE marked as a medical device. For such products no medical claim can be made.**
4. **Defining a given product as a medical device and interpretation of the application of the classification rules fall within the competence of the competent authorities of the Member States where the product is on the market.**
5. **Different interpretations of Community legislation occur, and, can put public health at risk and distort the internal market. Both issues are of great concern to Member States and the Commission. Therefore, the Commission finds it important to facilitate a dialogue among regulators and industry where diverse interpretations exist.**
6. **To this end, the working party on borderline and classification comprised of Commission services, experts of Member States and other stakeholders meet on a regular basis to discuss borderline and classification cases in order to ensure a uniform approach. The borderline and classification meeting’s primary aim is to provide for a forum to exchange opinions, and, possibly reach consensus.**
7. **This manual represents the views agreed in this group on products, or categories of products, which have raised doubts. The Commission, Member States and other stakeholders concluded that guidance is needed which goes beyond abstract rules and addresses their actual application.**
8. **However, please note that the views expressed in this manual are not legally binding, since only the European Court of Justice (“the Court”) can give an authoritative interpretation of Community law.**
9. **This manual does not relieve national competent authorities from their obligation to render decisions in these areas for any individual product, on a**

case-by-case basis. National authorities, acting under the supervision of the courts, must proceed on a case-by-case basis, taking account of all the characteristics of the product.

- 10. Therefore, this manual shall not “prescribe” which regulatory framework applies or how the classification rules must be applied by national authorities. Rather, it shall serve as one out of many elements supporting the national competent authorities in their case-by-case decision on individual products.**
- 11. In particular, this manual does not deprive a national authority to consult with colleagues from other regulated sectors concerned in order to reach a complete view on all aspects related to a given product.**
- 12. This manual will be updated in the light of the outcomes of the discussions of the working party on borderline and classification issues.**

1. MEDICAL DEVICE/IN VITRO DIAGNOSTIC MEDICAL DEVICE – MEDICAL INTENDED PURPOSE

Introduction

According to article 1 (2)a [MDD](#) “‘medical device’ means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;”

According to article 1 (2)b [IVDD](#) “‘in vitro diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients,

or

- to monitor therapeutic measures.”

From this definition it follows that in order to fall within the definition of an in vitro diagnostic medical device, the product must also meet the definition of a medical device.

It is suggested to consult [MEDDEV 2.1/1](#) for more detailed guidance on the interpretation of the definition of “medical device” and [MEDDEV 2.14/1](#) for more detailed guidance on the interpretation of the definition of “in vitro diagnostic medical device”.

1.1. Light box indicated to treat seasonal affective disorder (S.A.D)

- Background

The product in question is a light box that emits bright light and the manufacturer states that light therapy is ‘a convenient and effective way of compensating for the lack of light without resorting to medication’. The manufacturer also states: ‘in autumn and winter, the seasons with the least sunlight because the days are shorter, increased symptoms resulting from light deprivation may be experienced. Even standard artificial lighting in buildings cannot compensate for a shortage of natural light. The consequences of this may be depression, lack of drive, interrupted sleep and melancholia – the typical autumn winter blues’.

- Outcome

These statements are effectively claims for treatment of seasonal affective disorder (S.A.D.), which is a generally recognised medical condition, and therefore this product is considered a medical device.

For the classification of this product see [paragraph 8.1.](#)

1.2. AB0 and Rhesus (D) blood grouping intended for diet purposes

- Background

These products are tests for AB0 and Rhesus (D) Blood Grouping, which is sold through the internet and which is used by lay persons in the home environment.

The manufacturer states the following: HOME-KIT, For in Vitro Diagnostic Use, Not for Bed-Side Testing; and currently in the text, which describes interpretation of the result, the manufacturer states NOT FOR CLINICAL USE. The manufacturer has stated that the main reason and purpose of the tests is educational. It is indicated that the product enables the user to ascertain their blood group in order to determine whether a specific (food) diet should be followed. This decision was *not* related to following a specific diet for medical purposes.

- Outcome

According to the information given by the manufacturer, it is concluded that even though it can be argued that this product fits some parts of the definition of an in vitro diagnostic medical device, it does not meet the definition of a medical device. As the definition on in vitro diagnostic medical device (Article 1 (2) b IVDD) reads “‘*in vitro diagnostic medical device*’ means any medical device, the product must also meet the definition of medical device.

It can be concluded that as the intended purpose of this product can not be qualified as a medical purpose as described in definition of a medical device (Article 1 (2) a MDD), this product is not an in vitro diagnostic medical device. The product in question is not a blood typing test for a medical purpose.

This conclusion is reached in the light of the information provided by the manufacturer. It would be necessary to check if these statements are correct, and, consequently do not contain a deceptive and misleading labelling. Therefore, no reference to in vitro diagnostic medical device (e.g. 'for in vitro diagnostic use') can be made. Also, as the product is intended to be used by lay persons, there is a need for a strong and clear disclaimer which is understandable for lay users; i.e. a statement that the test results cannot be used for transfusion purposes or for blood group determination for medical purposes. It has to be noted that only a statement that the product is not a medical device can not constitute a reason to escape from the Directive and to avoid the CE marking if the criteria of the definition of a medical device are satisfied.

1.3. Pharmacy compounders

- Background

Pharmacy compounders may be used in a hospital pharmacy or in an industrial environment. They are products that are intended for the production of fluids for administration to a patient, usually as intravenous fluids (IV fluids) for administration parenterally. They are intended to be used by clinical nutritionist specialists and pharmacists. They mix a number of ingredients that are subsequently administered to the patient. These fluids may be nutritional solutions or pharmaceuticals. They may also be used for compounding formulas for cardioplegia, hydration, fluid drugs and renal replacement therapy.

The issue is whether pharmacy compounders are medical devices, particularly if the compounder is specifically intended to be used by clinical nutritionist specialists and pharmacists to correctly prescribe nutritional solutions for Total Parenteral Nutrition.

- Outcome

Pharmacy compounders are regarded as processing equipment and should not be qualified as medical devices. The compounder is only used for mixing the solution to be administered to patients, but it does not administer itself anything to a patient. It should therefore not be qualified as a medical device.

1.4. Dental disclosing products

- Background

Dental disclosing products are intended to ‘disclose’ plaque, *i.e.* to highlight the areas around the teeth where the plaque is in order to aid its removal. There may be claims to ‘aid oral hygiene’, to ‘aid correct brushing regimes’ or simply to identify the plaque for its removal.

Dental disclosing products may be in the form of solutions, tablets or an applicator containing the solution and may be intended for use by dentists or by individuals at home.

The question is to whether these products should be qualified as medical devices, or whether they are simply intended for oral hygiene and therefore shall not be considered as medical devices.

- Outcome

Although in severe cases, in addition with other contributory factors, plaque may lead to dental decay or gum disease, plaque is not considered to be a disease in its own right.

Therefore dental disclosing products, intended to disclose plaque in order to help its removal, cannot be qualified as medical devices.

1.5. Mixer

- Background

The product is a Thermomixer (mixer) intended to control the temperature of (and mix) liquids in closed micro test tubes and micro test plates. The manufacturer claims that this

mixer is specifically intended for the preparation and processing of samples from the human body within the scope of *in-vitro* diagnostic applications, in order to allow the *in-vitro* diagnostic medical device to be used as intended. Therefore the manufacturer considers this Thermomixer, being an *in-vitro* diagnostic accessories, to fall within the scope of Directive 98/79/EC.

- Outcome

MEDDEV 2.14/1 rev.1, states that *"if, however, the product does not in fact possess specific characteristics that make it suitable for one or more **identified** in vitro diagnostic examination procedures, then the manufacturer is not free to bring it within the scope of the IVDD merely by affixing the CE marking to it. In other words, a manufacturer is not able to bring within the scope of the IVDD a product that, in reality, is a piece of general laboratory equipment simply by affixing the CE mark to it"*.

For example, the point 4 of MEDDEV 2.14/rev.1 mentions that laboratory centrifuges are not usually considered to fall within the scope of the IVD directive.

According MEDDEV 2.14/1 rev.1, the fact that this mixer is intended by the manufacturer to be used especially for *in vitro* diagnostic procedures is not sufficient to qualify it as an IVD medical device, if this mixer does not possess specific characteristics that make it suitable for one or more identified *in vitro* examination procedures.

If this mixer possesses such specific characteristics, the manufacturer will have to demonstrate these specific characteristics and the link with one or more identified *in vitro* examination procedures.

This case is similar to the cases of pipettes or glass slides, considered as products for general laboratory use, already published in the manual.

On the basis of the above this mixer could not be considered as an *in vitro* diagnostic medical device.

1.6. Non-corrective contact lenses with a medical purpose



- Background

In general, non-corrective contact lenses (commonly known as ‘plano’ lenses) are not considered to be medical devices as they have no corrective function.

Some non-corrective contact lenses, coloured or not, however may have a medical purpose. They serve to treat a number of congenital or traumatic conditions. They are often used in clinical practice or post-surgical setting as a medical prosthesis.

Examples of non-corrective contact lenses with medical purpose are:

- UV blocking contact lenses that help protect against transmission of harmful UV radiation to the cornea and into the eye so as to alleviate photophobia as seen in albinism.
- Contact lenses for therapeutic use as a bandage lens for the following acute and chronic ocular conditions:

- For corneal protection in lid and corneal abnormalities such as entropion, trichiasis, tarsal scars and recurrent corneal erosion. In addition they are indicated for protection where sutures or ocular structure malformation, degeneration or paralysis may result in the need to protect the cornea from exposure or repeated irritation;
- For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, and postkeratoplasty,
- For use as a barrier during the healing process of epithelial defects such as chronic epithelial defects, corneal ulcer, neurotrophic and neuroparalytic keratitis, and chemical burns;
- For post surgical conditions where bandage lens use is indicated such as post refractive surgery, lamellar grafts, corneal flaps, and additional ocular surgical conditions;
- For structural stability and protection in piggy back lens fitting where the cornea and associated surfaces are too irregular to allow for corneal rigid gas permeable (RGP) lenses to be fitted. In addition the use of the lens can prevent irritation and abrasions in conditions where there are elevation differences in the host/graph junction or scar tissue.

- Outcome

All the above are recognised medical conditions and therefore non-corrective lenses, coloured or not, which have the above mentioned functions are considered to be medical devices on the basis that they prevent, monitor, treat or alleviate disease.

Manufacturers of such products must, however, clearly indicate the specific intended medical purposes for these non corrective contact lenses both on the packaging / labelling and in the instructions for use. Non corrective contact lenses without specific claims (such as those listed above) would be regarded as having no medical purpose and therefore not medical devices.

2. BORDERLINE IN VITRO DIAGNOSTIC MEDICAL DEVICE

Introduction

The definition of in vitro diagnostic medical devices reads as follows:

Article 1 (2) b IVDD “‘*in vitro diagnostic medical device*’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: — concerning a physiological or pathological state, or

— concerning a congenital abnormality, or
— to determine the safety and compatibility with potential recipients,
or
— to monitor therapeutic measures.”

From this definition it follows that in order to fall within the definition of an in vitro diagnostic medical device, the product must also meet the definition of a medical device.

Article 1 (2)a MDD “‘medical device’ means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
— investigation, replacement or modification of the anatomy or of a physiological process,
— control of conception,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;”

Other relevant provisions are:

Article 1 (2) b IVDD “Specimen receptacles are considered to be in vitro diagnostic medical devices. ‘Specimen receptacles’ are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.”

Article 1 (2)b IVDD “Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;”

It is suggested to consult MEDDEV 2.14/1 for more detailed guidance concerning in vitro diagnostic medical devices.

2.1. Sample receptacles and sampling devices which are intended to be used for the collection by the lay user of samples, which are subsequently examined by third persons.

- Background

The products in question are IVD kits which are being supplied to the public for a variety of medical conditions including tests for food allergies and infections such as Chlamydia. These tests are being supplied by post to members of the public in the following manner:

The patient orders the kit from the company concerned and the kit is despatched to him. The kit contains the required equipment to take a sample. The patient is instructed to take the sample (for example, usually a urine sample or blood sample – either via a lancet, or they are advised to take their kit to their doctor for a blood sample to be taken). The sample is then placed in some type of storage container. Once the sample is obtained, the patient is instructed to send it back to the company supplying the kit. The patient is then supplied with the result of

the test, indicating whether or not they have a positive result. None of these activities involve healthcare professionals.

- Outcome

These kits are in vitro diagnostic medical devices by means of applying article 1 (2) b IVDD which states that: *“Specimen receptacles are considered to be in vitro diagnostic medical devices. ‘Specimen receptacles’ are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.”*

The question arises whether these specimen receptacles could be considered as a ‘device for self-testing’ in accordance with article 1 (2)d IVDD according to which *‘device for self-testing’ means any device intended by the manufacturer to be able to be used by lay persons in a home environment;*

In this determination, the notion ‘used’ is essential. Firstly, it is necessary to examine the instructions for use. Where the instructions for use require an action to be taken by the end-user of the device in question, the notion ‘used’ is fulfilled. In addition, the definition of ‘self-testing’ provides guidance on the action to be taken i.e. “testing”.

Thus where a specimen receptacle is simply used by the patient to contain a specimen it remains a specimen receptacle. To become a ‘device for self-testing’, either the filling of the receptacle with a specimen should result directly in a result being given or the patient should need to do something directly to the specimen prior to its despatch in order to fulfil the concept of ‘used’.

2.2. CE labelled microscope slides

This product is a microscope slide which is made of a thin sheet of glass used to hold objects for examination under a microscope. Unless the manufacturer’s intended purpose falls within the definition of an in vitro diagnostic medical device, it must be regarded as a general laboratory product. The latter are excluded from the IVDD by article 1 (2) b IVDD.

In addition, MEDDEV 2.14/1 rev.1 states in this context:

*"if, however, the product does not in fact possess specific characteristics that make it suitable for one or more **identified** in vitro diagnostic examination procedures, then the manufacturer is not free to bring it within the scope of the IVDD merely by affixing the CE marking to it. In other words, a manufacturer is not able to bring within the scope of the IVDD a product that, in reality, is a piece of general laboratory equipment simply by affixing the CE mark to it".*

2.3. Single or multiple channel pipettes

The single or multiple channel pipettes are used for aspirating and dispensing specific volumes in the microlitre scale. The volume is set by rotating the thumbwheel or the push-button. These pipettes have various laboratory purposes.

Unless the manufacturer's intended purpose falls within the definition of an in vitro diagnostic medical device, these pipettes must be regarded as a general laboratory product. The latter is excluded from the IVDD by article 1 (2) b IVDD.

In addition, MEDDEV 2.14/1 rev.1 states in this context:

*"if, however, the product does not in fact possess specific characteristics that make it suitable for one or more **identified** in vitro diagnostic examination procedures, then the manufacturer is not free to bring it within the scope of the IVDD merely by affixing the CE marking to it. In other words, a manufacturer is not able to bring within the scope of the IVDD a product that, in reality, is a piece of general laboratory equipment simply by affixing the CE mark to it".*

Moreover, the MEDDEV 2.14/1 rev. 1 specifically refers to pipette. Under point 4 “Products for general laboratory use”, it is mentioned that pipettes are laboratory products that are not usually considered to fall within the scope of the IVD directive.

3. BORDERLINE ACTIVE IMPLANTABLE MEDICAL DEVICE – MEDICAL DEVICE

3.1. Bone anchored hearing aids

- Background

Bone anchored hearing aids consist of a titanium implant (that is screwed into the patients cranium), an abutment to transfer vibrations and a sound processor (hearing aid). The sound processor collects sound, amplified the vibrations and passes them on to the implant (via the abutment). The vibrations find their way to the inner ear without the help from any other devices and make it possible for the patients to hear. The sound processor relies on an electrical power source, while both the abutment and the implantable titanium piece are passive.

It must be noted that bone anchored hearing aids are different from cochlear implants which are intended to stimulate the hearing nerve directly via an electrode array inserted into the cochlea (inner ear). According to MEDDEV 2. 1/2 rev 2, cochlear implants activated by an external power transmitter are regarded as active implantable medical devices as the implanted component clearly depends on a power source for its function and its purpose is to convert the power it receives into electrical signals which trigger appropriate sensory channels in the brain.

The question is whether bone anchored hearing aids fall under the Directive 93/42/EEC on medical devices or under the Directive 90/385/EEC on active implantable medical devices.

- Outcome

Guidance MEDDEV 2. 1/2 rev 2 states that a product falls under the definition of an active implantable medical device if it is at the same time both active and implantable. Under its point 2.1.2 the MEDDEV 2.1/2 rev.2 excludes that a device is active if the function of the

device is only a mere transmission of vibration. With the bone anchored hearing aid the implantable component is not an active medical device – it is a titanium ‘rod’. The sound processor, which is the active component, is not implanted.

On the basis of the above, bone anchored hearing aids fall under Directive 93/42/EEC on medical devices. The sound processor shall be classified as class IIa medical device according to classification rule 9 while the implant is regarded as class IIb medical device according to classification rule 8 of Annex IX of Directive 93/42/EEC. Where the two elements are supplied as one system, the higher classification applies to the overall product and the system is therefore classified as class IIb medical device.

4. BORDERLINE MEDICAL DEVICE – MEDICINAL PRODUCT

Introduction

It is suggested to consult [MEDDEV 2.1/3 rev 3](#) for more detailed guidance on the borderline issues concerning medical devices and pharmaceuticals.

The definitions of medical device and medicinal product, as well as the Article 2(2) of [Directive 2001/83/EC](#) are reproduced here for reference.

- **Medical device definition (Article 1(2)a of Directive 93/42/EEC, as amended):**

(a) 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- investigation, replacement or modification of the anatomy or of a physiological process,*
- control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

- **Medicinal product definition (Article 1(2) of Directive 2001/83/EC, as amended):**

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;

or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions

by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

- **Article 2(2) of Directive 2001/83/EC, as amended:**

In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “medicinal product” and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.

Note: It must be noted that for the purposes of determining whether a product falls within the definition of a medicinal product by function, the national authorities must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

4.1. Product for testing patient reflex cough

- Background

The product may be used, following initial diagnosis, by health care professionals as a part of a neurological evaluation to assess the patient's laryngeal cough reflex (LCR), neurological airway protection and the vagal (cranial nerve X) component of reflex cough. The test uses 1-3 inhalations of a nebulized 20% solution of L-(+)-tartaric acid in a medicinal nonventilatory nebulizer. Tartaric acid acts as a mild irritant to the mucosa of the larynx.

The resultant involuntary reflex response, i.e., cough, is indicative of whether the upper airway is neurologically protected. The expected result of a normal test is an immediate series of a forceful coughs, which are primarily expiratory "airway cleaning" in character. The expected result of an abnormal test is represented by an absence of coughing, or a diminished (weak) coughing, or coughing not immediately after administration of the test stimulus. The testing is terminated when the subject either elicited a cough or failed to cough after three valid inhalations.

According to the manufacturer's statements the test functions like many other devices which assess neurological pathways, including the reflex hammer, nerve conduction stimulators, and the fiberoptic endoscopic evaluation of the swallowing with sensory testing, where a physical stimulus (either electrical or physical) challenges a neurological pathway to elicit a response.

The manufacturer regards 20% tartaric acid (TA) solution used to induce cough as a physical stimulus, although it cannot be denied that it induces chemical changes to the sensory nerves and that there may be "pharmacological" agents involved. Another consideration given by the manufacturer is that TA in the dose used will have no measurable effect on general body metabolism, and it should therefore not be considered to have a "metabolic" action. Finally the manufacturer stresses that the purpose of the TA test is not diagnostic. As with the use of other physical stimuli, the patient's diagnosis will already have been established (e.g. stroke) and the test will be used to determine appropriate treatment for the individual patient.

The manufacturer will market 20% L-(+)-tartaric acid in normal saline as a sterile, pure solution. The item will be used with a commercially available disposable jet nebulizer for single-patient use (the nebulizer is not pre-filled with the solution). Continuous flow will deliver the agent through the inspiratory cycle, and will allow re-charge of the agent during the exhalation phase. According to the manufacturer's statements the use of the solution is deemed ancillary to the nebulizer, as the solution can not be administered without nebulization.

- Outcome

The tartaric acid is intended to be used for neurologically impaired patients to test the functioning of their laryngeal cough reflex in order to determine appropriate treatment. A pharmacological action on the patient can not be excluded. The tartaric acid is used as an irritant to produce a cough reflex and is a substance administered for in-vivo diagnostic purposes. The administration of this substance could be considered as a component of the general medical diagnosis since it consents to improve definition of the extent of neurological damage.

On the basis of the above, the product does not meet the definition of a medical device.

4.2. Elastoviscous fluids

- Background

This product is a sterile, nonpyrogenic, elastoviscous fluid containing hyalans (derivatives of hyaluronan-sodium salt of hyaluronic acid that consists of repeating disaccharide units of N-acetylglucosamine and sodium glucuronate). It is biologically similar to hyaluronan which is a component of synovial fluid which is responsible for its viscoelasticity. The product achieves its therapeutic effect through viscosupplementation, a process whereby the physiological and rheological states of the arthritic joint tissues are restored. Viscosupplementation is a treatment to decrease pain and discomfort, allowing more extensive movement of the joint. The product has to be injected in the affected joint to achieve its effect. Hyalans are degraded in the body by the same pathway as hyaluronan.

- Outcome

The data presented does not allow issuing a general statement for the qualification of the elastoviscous fluids.

Viscoelastic materials with intended use for mechanical/physical purposes such as protection of tissues during and after surgery and separation of tissues are considered to be medical devices. Such materials are also used as synovial fluid replacements where viscosupplementation provides support and lubrication. Additional pharmacological benefits claimed which are ancillary to the mechanical action do not alter the medical device status. However, certain of these materials such as some hyaluronan based products, where the predominant claims are of a pharmacological nature and not primarily related to any viscoelastic characteristics, are classed as medicinal products.

Therefore it is appropriate to follow a case by case approach, taking into account all product characteristics and in particular:

- The intended purpose of the product and the claims of the manufacturer, taking into account the way the product is presented;
- The nature of the principal intended action. For example, is there any pharmacological or metabolic action (e.g. anti-inflammatory effect, stimulation of in vivo hyaluronic acid synthesis etc.) not ancillary to the mechanical/physical action of the product?

4.3. In-Vitro Fertilisation (IVF) and Assisted Reproductive Technologies (ART) products

- Background

The In-Vitro Fertilisation (IVF) and Assisted Reproductive Technologies (ART) products cover a large spectrum of products.

For some of these products the principle intended action is clearly a pure physical or mechanical action. On the other hand, a number of products that fall within this category contain substances that act by pharmacological, immunological or metabolic action. In the latter cases, it is of utmost importance to assess whether such a pharmacological, immunological or metabolic action represents an ancillary or primary action. It is concluded that this analysis should be done on a case by case basis.

- Outcome

IVF/ART products may be qualified and regulated as medical devices provided that they meet the definition of a medical device as laid out in Directive 93/42/EEC, taking into consideration the principal intended action and intended purpose of the product. The concept of ‘used for human beings’ is interpreted in the broadest sense. The whole IVF/ART procedure and related products would be seen as (indirectly) “*(...) used for human beings for the purpose of (...) replacement or modification of (...) a physiological process*” by promulgating pregnancy. Therefore, the definition of medical devices can include IVF/ART products.

Examples of products which could be qualified as medical devices (classification is only indicative and must be assessed on a case by case basis taking into account all product characteristics):

- Devices that act in a physical or mechanical way intended to be used for IVF/ART (such as pipettes or syringes) should be classified according to the rules set out in Annex IX of Directive 93/42/EEC, depending mainly on their intended use;
- Devices, such as washing, separating, sperm immobilizing, cryoprotecting solutions, which are liable to act with close contact on the inner or outer cells during the IVF/ART are likely to be considered as Class IIb medical devices, in particular by analogy of Rule 3.¹

¹ These products are considered to present the same level of risk as non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body

- Devices manufactured utilizing animal tissues or derivatives rendered non-viable are considered as Class III medical devices according to rule 17;

- Devices incorporating, as an integral part,

- (i) a human blood derivative or

- (ii) a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices,

are considered as Class III medical devices according to rule 13. The assessment of the ancillary nature of the pharmacological, immunological or metabolic action of any medicinal product contained in IVF/ART products should be done on a case by case basis, taking also into account the purpose of the inclusion of this substance into the product. Although case by case analysis should always be performed, media intended for use in the IVF process to support the growth / storage of the embryo may generally be considered to be Class III medical devices.

In case of doubt where taking into account all product characteristics, and provided that the concerned product meets both definitions of a medicinal product and of a medical device, Article 2(2) of Directive 2001/83/EC could apply.

4.4. Peritoneal dialysis solutions

- Background

Solutions for peritoneal dialysis are preparations for intraperitoneal use which contain electrolytes in a similar concentration to that in plasma, and also contain glucose or another suitable osmotic agent.

Peritoneal dialysis solutions always contain sodium, chloride, and hydrogen carbonate or a precursor. They may also contain calcium, magnesium, and potassium.

In peritoneal dialysis, the solution is infused into the peritoneal cavity, where exchange of electrolytes takes place by diffusion and convection, and excess fluid is removed by osmosis, using the peritoneal membrane as an osmotic membrane. Such exchange of electrolytes induces a metabolic effect.

- Outcome

Peritoneal dialysis solutions are used for specific and restricted medical conditions to be administered parenterally to patients with an identified medically diagnosed condition and have a metabolic mode of action. Therefore such solutions cannot be qualified as medical devices.

4.5. Agents for transport, nutrition and storage of organs intended for transplantation²

- Background

Historically, solutions for the transport and storage / preservation / nutrition of organs for transplant have been regarded as medicinal products.

However these products are not currently regulated in all Member States as medicinal products since some authorities do not consider that they fit the definition of a medicinal product.

There is a direct parallel between IVF media and these solutions for the preservation, storage, nutrition and transport of organs, cells or body parts. The solutions are intended to store and / or maintain the viability of the organs / cells until such time as they are reintroduced to the human body.

- Outcome

Some agents for transport, nutrition and storage of organs intended for transplantation may be qualified and regulated as medical devices provided that they meet the definition of a medical device as laid out in Directive 93/42/EEC, taking into consideration the principal intended action and intended purpose of the product. In this case, the transplantation procedure would be seen as *used (indirectly) for human beings for the purpose of replacement or modification of the anatomy*.

1) The physical containers for the transport of organs are regulated as medical devices and are given as an example in MEDDEV 2.4/1 under classification rule 2, second indent ‘devices intended for temporary storage and transport of organs for transplantation’ and ‘devices intended for the long term storage of biological substances and tissues such as corneas, sperm, human embryos etc’.

2) Agents for transport, nutrition and storage of organs intended for transplantation usually act through pharmacologic, immunologic or metabolic means. Therefore the assessment of the ancillary nature or not of the pharmacological, immunological or metabolic action of the product is a crucial element for the qualification of the product.

According to Article 1 (2)a of Directive 93/42/EEC, medical devices do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means but may be assisted in its function by such means.

Provided that they meet the definition of a medical device as laid out in Directive 93/42/EEC:

- Devices manufactured utilizing animal tissues or derivatives rendered non-viable are considered as Class III medical devices according to rule 17;
- Devices incorporating, as an integral part,
 - (i) a human blood derivative or

² Corresponding section in MEDDEV 2.1/3 rev.2 is currently under revision

(ii) a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices,

are considered as Class III medical devices according to rule 13.

The assessment of the ancillary nature of the pharmacological, immunological or metabolic action of any medicinal product contained in agents for transport, nutrition and storage of organs intended for transplantation should be done on a case by case basis, taking also into account the purpose of the inclusion of this substance into the product.

In accordance with Article 2(2) of Directive 2001/83/EC, in case of doubt where taking into account all product characteristics, and provided that the concerned product meets both definitions of a medicinal product and of a medical device, the provisions of Directive 2001/83/EC shall apply.

4.6. Zinc oxide containing creams

- Background

Products containing zinc oxide are available as creams for local administration.

Some zinc oxide containing products, depending on their claims and intended use, might be covered by Directive 76/768/EEC on cosmetic products.

The discussion below only concerns zinc oxide containing products used to treat or prevent minor skin irritations (*e.g.* burns, cuts, nappy rash, eczema etc).

- Outcome

A medical device should not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

For zinc oxide containing products, according to the literature, a pharmacological and metabolic action is demonstrated, *e.g.* may play a role in enzymatic processes, support of wound granulation.

The pharmacological action may, however, be ancillary when the product concerned is primarily a barrier cream.

In such cases the qualification of zinc-oxide containing products is defined taking into account the claims, the intended purpose and the relevant primary mode of action. Some products that act primarily as a barrier may therefore be acceptable as Class III medical devices in accordance with rule 13 of Annex IX of Directive 93/42/EEC.

In accordance with Article 2(2) of Directive 2001/83/EC, in case of doubt where taking into account all product characteristics, and provided that the concerned product meets both definitions of a medicinal product and of a medical device, the provisions of Directive 2001/83/EC shall apply.

4.7. Eye drops intended for related to the alleviation of ‘soreness’ , ‘discomfort’ or ‘irritation’ caused by environmental factors (such as dust, heat, smoke etc)

- Background

On the EU market there are many different types of eye drops used for different purposes.

1) Eye drops regulated as medicinal products:

Eye drops used in or administered to human beings with a view to making a medical diagnosis are regulated as medicinal products in accordance with article 1(2) of Directive 2001/83/EC.

Eye drops with pharmacological, immunological or metabolic principal mode of action will fall under the definition of a medicinal product if they may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions.

2) Eye drops regulated as medical devices:

Products specifically intended to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are medical devices.

Eye drops with a physical mode of action that are clearly indicated for a medical purpose are acceptable as medical devices (*e.g.* for the treatment of hay fever).

Therefore, the discussion below only concerns products for which no ‘medical’ claims are made, nor any claims associated with the use of contact lenses. Commonly the only claims made relate to the alleviation of ‘soreness’ , ‘discomfort’ or ‘irritation’ caused by environmental factors (such as dust, heat, smoke etc) or simply ‘for tired eyes’.

- Outcome

The qualification of a particular eye drop products shall depend upon the intended purpose and mode of action of the product, and must be assessed on a case by case basis.

Some products may claim indications such as ‘treatment’ of a physiological response to external factors (*i.e.* dust, smoke, dry heat, air conditioning) and are used to create a humidification of the eyes or to treat minor irritations of the eyes. As such, they are designed to complement physiological functions provided by normal tears to help meet an increased demand for humidification / lubrication of the eyes.

These products do not need to stimulate physiological functions of the natural tears. The intended effect may be achieved by physical means only, *i.e.* by washing the eye surface (effect of dust, smoke), or supplement the aqueous layer of natural tear film with additional water under conditions of significantly increased evaporation (dry heat, air conditioning). By

decreasing the exposure to irritants they may be helpful in treatment of ‘minor irritations’ of the eye.

Therefore products which claim to treat damage caused by environmental factors may be acceptable as medical devices (or medicinal products, dependant on their mode of action) provided that they clearly claim to treat or alleviate damage to or irritation of the eye (*e.g.* via repairing damage to the tear film caused by environmental conditions).

These products must not claim to be artificial tears, or any kind of replacement of natural tears. Products called ‘artificial tears’ are usually those that replace or complement natural tear functions when natural tear function has been compromised. The term ‘artificial tears’ should therefore only be used for products that replace the function of natural tears. Such products may be regulated as either medical devices or medicinal products, depending upon their mode of action.

4.8. Product for use in acute sore throat

- Background

The product is intended to be used, according to the instruction for use, in acute sore throat with irritated mucosa. This product contains Icelandic Moss and benzocaine.

The mechanism of action of Icelandic Moss is a mucilaginous drug which spreads on the oral and pharyngeal mucosa, forming an internal coating on the mucosa, acts by covering the mucosa with a protective layer. The benzocaine helps reducing further sensitivity.

The European Pharmacopoeia contains monographs for “Iceland Moss” and “Benzocaine (benzocainum)”.

Icelandic moss may be considered as a medicinal substance and is described as having pharmacological properties including anti-inflammatory, antibacterial and antiviral activities.

Benzocaine is a known medicinal substance with pharmacological action as local anaesthetic and is found in several medicinal products intended for temporary local relief of pain associated with sore throat.

- Outcome

A pharmacological action of Icelandic moss cannot be excluded, as it is described to have pharmacological properties including anti-inflammatory, antibacterial and antiviral activity.

Furthermore, even if the Icelandic moss may be considered as providing a physical barrier, the benzocaine contained in this product could not be considered having an ancillary action.

On the basis of the above, it is concluded that this product achieves its principal intended action by pharmacological means and therefore do not meet the definition of a medical device.

4.9. Plaster with capsaicin

- Background

The products in question are warming plasters (adhesive) containing capsaicin (capsicum oleoresin or capsicum extract). These plasters are intended for heat-treatment, local analgesia and are indicated to treat muscular, rheumatic and neuralgic pains.

The European Pharmacopoeia contains monographs for “Capsici fructus” and “Capsicum Oleoresin”. The European Scientific Cooperation on Phytotherapy (ESCOP) has classified “Capsici fructus” as an herbal medicinal product.

According to classification rule 13, devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the device, are in Class III.

- Outcome

The adhesive plaster described appears to be acting as a carrier for the substance (Capsaicin) in order for the substance to be delivered to the body to produce the analgesic effect. It therefore cannot be excluded that this product achieves its principal intended action by pharmacological means. Therefore warming plasters with capsaicin may not be qualified as a medical device.

4.10. Gold implants for treatment of osteoarthritis

- Background

Various gold salts are available for systemic treatment of painful joint diseases, mainly arthritis and arthrosis. There is increasing evidence that the gold salts exert their effect by a direct intervention with the cellular immune response. It is generally assumed that the active part of the gold salts is the gold ions.

Solid gold implants for local treatment of painful joint diseases in animals have been used by veterinarians in a number of years. Several studies have documented a therapeutic effect of solid gold implants in animals. Research has provided evidence that gold ions are released from the implanted gold and diffuse into the surrounding tissue, where they can be detected in connection with inflammatory cells from the immune system. The researchers concluded that solid gold implants as a local treatment, mimics systemic treatment with a gold-containing drug.

The question is whether gold implants should be qualified as medical devices or not.

- Outcome

In the view of the above mentioned mode of action which mimics systemic treatment with a gold-containing drug, gold implants for treatment of osteoarthritis exert their effect by a direct intervention with the cellular immune response and therefore cannot be qualified as medical devices.

4.11. Substances for chemical peeling

- Background

Skin exfoliation is widely used to reduce the signs of aging in the skin since it diminishes imperfections by peeling away the skin's top layers (solution to sun-damaged, unevenly pigmented, and finely wrinkled facial areas). It is also used on acneic skin and on acne scars. Skin exfoliation could be obtained by different means such as mechanical peeling (also called dermabrasion which consists of a sand blasting technique with particles), physical peeling (carbon dioxide ultrapulsed laser, erbium:YAG laser) and chemical substances. In this case, the depth of peeling depends of many factors such as the substance used (e.g. alpha hydroxy acids (AHA), beta hydroxyl acids as salicylic acid, trichloroacetic acid (TCA) and phenol), its concentration, the pH of the solution, and the length of the application.

Considering their intended use on acneic skin some manufacturers requested an opinion about placing chemical peeling containing salicylic acid (and glycolic acid) as class I medical device. The question is whether these chemical peeling must have a specific action on treatment of acnea to be considered as a medical device or whether the claim that they are indicated in case of acneic skin could be sufficient to qualified them as medical device.

- Outcome

It is concluded that, depending on their principal mode of action and in the case they have a specific medical purpose (for example treatment of acne), these products might be qualified as medical devices. However the claim that they may be used on acneic skin is not considered sufficient to indicate a medical purpose.

When these products could be qualified as medical devices they shall be classified as class III medical devices according rule 13 if they contain a medicinal substance with ancillary action.

5. BORDERLINE MEDICAL DEVICE – BIOCIDES

Introduction

General disinfectants fall under the [Biocides Directive](#)³. Article 1 (2) of this Directive exclude products that are defined or within the scope of Directive 93/42/EEC on medical devices (MDD) and Directive 90/385/EEC on active implantable medical devices (AIMDD).

A [guidance document](#) exists for borderline cases between the Biocides Directive and the Cosmetics Directive as well as a [manual](#) of decisions for implementation of the Biocides Directive.

³ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123, 24.4.1998, p. 1–63.

5.1. Hand disinfectants

- Background

A manufacturer directed a request to the Commission services on the qualification of a range of products. These products are hand disinfectants.

- Outcome

Hand disinfectants do not appear to be qualified as an accessory to a medical device. These products are for disinfecting the hands and not devices. Such products are likely to be covered by other Community legislation, for example the Biocides Directive.

5.2. Insect repellent

- Background

The product is an insect repellent packaging in a spray and consisting of lactic acid. According to the manufacturer's claims the product is intended to be applied on the human skin and is intended to prevent diseases by preventing human exposure to diseases transferred by mosquitoes. The manufacturer also claims that the product alleviates injuries on the skin since the product reduces the amount of skin penetration caused by the bites of mosquitoes. According the manufacturer, the mode of action is that the product acts as a barrier on the skin against mosquitoes and other blood sucking insects, with an effect during four hours. Therefore, the manufacturer intends to put its product on the market as a medical device.

- Outcome

This product is primary intended to repel insects in order to prevent mosquitoes and insects bites. This product is not intended to be used principally for a medical use. According to Annex V of Directive 98/8/EC, repellents and attractants products including those that are used for human or veterinary hygiene either directly or indirectly are considered biocides products. In addition, insect repellents are considered to have a primary effect on the insects and not on the human body.

On the basis of the above this insect repellent cannot be consider as a medical device.

6. BORDERLINE MEDICAL DEVICE –COSMETIC PRODUCTS

Introduction

Article 1(5) d MDD states that the MDD does not apply to cosmetic products covered by [Directive 76/768/EEC](#) on cosmetic products.⁴

⁴ Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p. 169, as last amended

It is suggested to consult MEDDEV 2.1/1 section 1.1. (d) for more detailed guidance on the borderline issues concerning cosmetics.

7. ACCESSORY TO A MEDICAL DEVICE OR A IN VITRO DIAGNOSTIC MEDICAL DEVICE

Introduction

The definitions of accessory read as follows:

Article 1 MDD (b) ‘*accessory*’ means 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;

Article 1 (2)c IVDD “‘*accessory*’ means an article which, whilst not being an in vitro diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose. For the purposes of this definition, invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/ EEC shall not be considered to be accessories to in vitro diagnostic medical devices;”

It is suggested to consult MEDDEV 2.14/1 for more detailed guidance concerning in vitro diagnostic medical devices, and MEDDEV 2.1/1 on the definition of accessory for medical devices.

7.1. Haemodialysis water test strips

- Background

The matter at hand concerned the question whether the following two products can be considered as an accessory to a haemodialysis machine which is a medical device. Both products are used together with the haemodialysis machine, one is a residual peroxide reagent strip, which confirms, when used, that the residue of disinfection agents used in the haemodialysis machine have been reduced to safe levels. The other is a reagent strip used to test the water in the haemodialysis machine to ensure that the level of water hardness has been reduced to a level where it is safe to proceed with haemodialysis.

- Outcome

From the information provided by the manufacturer of the strips, they do not enable the haemodialysis machine to be used. The strips are used for testing and are not necessary for the functioning of the machine.

According to Article 1 (2) b of Directive 93/42/EEC and the developed guidance (MEDDEV 2.1/1) the decisive criterion to decide whether a product is an accessory to a medical device is whether or not the product is specifically used together with a medical device to enable it to be used in accordance with the use intended by its manufacturer.

The notion “enabled it to be used” implies that the accessory is necessary for the medical device to function.

Therefore, such strips are not considered to be ‘accessories’ of a medical device within the meaning of Article 1 (2) (b) MDD.

If a manufacturer can claim, substantiated with a solid reasoning that the strips are necessary for the proper functioning of the machine, then these products might be qualified as ‘accessories’.

7.2. Surgical instrument decontamination products

- Background

A manufacturer directed a request to the Commission services on the qualification of a range of products. The products in question are surgical instrument decontamination products.

- Outcome

Surgical instrument decontamination products are covered by the definition of accessories to medical devices in Article 1 (2) b of Directive 93/42/EEC. The respective guidance (MEDDEV 2. 1/1) expressly mentions disinfectants specifically intended for invasive medical devices as one example for accessories.

For the classification of these products see [paragraph 8.9](#)

7.3. Dental Water Line Disinfectants

- Background

A manufacturer directed a request to the Commission services on the qualification of a range of products. The products in question are Dental Water Line Disinfectants.

- Outcome

Dental Water Line Disinfectants are covered by the definition of accessories to medical devices in Article 1 (2) b of Directive 93/42/EEC.

For the classification of these products [see paragraph 8.10](#)

8. CLASSIFICATION

Introduction

It is suggested to consult [MEDDEV 2.4/1 rev 9](#) for more detailed guidance concerning the classification rules for medical devices.

8.1. Light box indicated to treat seasonal affective disorder (S.A.D)

- Background

The product in question is a light box that emits bright light and the manufacturer states that light therapy is 'a convenient and effective way of compensating for the lack of light without resorting to medication'. The manufacturer also states: 'in autumn and winter, the seasons with the least sunlight because the days are shorter, increased symptoms resulting from light deprivation may be experienced. Even standard artificial lighting in buildings cannot compensate for a shortage of natural light. These statements are effectively claims for treatment of seasonal affective disorder (S.A.D.), which is a recognised medical condition and therefore this product is considered a medical device.

- Outcome

In the classification of this product, it must be decided whether it performs any active action as defined in Annex IX I - Definition 1.5 'Active therapeutic device'.

That is, does it support, modify, replace, or restore biological functions or structures with a view to treatment or alleviation of a disease? If the device performs an 'active' function, then it is class IIa.

8.2. Oxygen delivery

- Background

These products are intended to deliver oxygen to the patient and are connected to active devices such as ventilators, anesthetic machines etc and / or to a pressure regulator. These devices may be connected to the different kind of oxygen delivery systems with regulators; via oxygen piping to the oxygen supply/oxygen delivery centre, to oxygen bottles/oxygen cylinders or to oxygen concentrators.

- Outcome

In the classification of this product, Class IIa is appropriate based upon rule 2, 5 or 11 of Annex IX.

8.3. Examination gloves coated with polyhexamethylene biguanide (PHMB)

- Background

The case relates to examination gloves with PHMB which is a broad spectrum bactericide. This substance is also used as an ingredient in various products (contact lens solutions and surgical scrubs and swimming pools). The intended use is to reduce bacterial transfer between the healthcare professional and the patient. The gloves would be single use.

- Outcome

Examination gloves are usually considered to be Class I medical devices, however MEDDEV 2.1/3 in section A.5 states that ‘wound dressings, surgical or barrier drapes (including tulle dressings) with antimicrobial agent’ are considered to be devices incorporating medicinal substances and therefore Class III devices.

Antimicrobial agents on surgical or barrier drapes intended to come in to contact with the patient have no ‘ancillary’ effect on the patient and neither would an antimicrobial coating on an examination glove, however the MEDDEV implies that these examination gloves with a PHMB coating should be considered as Class III medical devices.

Medical devices may incorporate substances as an integral part which, if used separately, may be considered to be a medicinal product. This is specifically addressed in article 1(4) MDD which makes it clear that such products are devices, provided that the action of the medicinal substance is ancillary to that of the device, as reflected in the product claim and as supported by the scientific data provided by the manufacturer of the devices. Rule 13 places these devices in Class III.

In essence two issues need to be considered: a) is the substance (PHMB), if used separately a medicinal product; b) is the substance liable to act on the human body with action ancillary to that of the devices?

a) Taking into account the published literature, it can be concluded that the PHMB is a substance which could be administered topically to human beings in view to restore or modify physiological functions by mainly means of pharmacological action (e.g. treatment of *Acanthamoeba keratitis*). As such it could be regarded as a medicinal product in accordance with Article 1(2) of Directive 2001/83/EC as amended.

b) The risk that the PHMB acts on the patient highly depends on the intended use of these gloves. For example, an examination of a wound or a mucous membrane will lead to a considerably increased risk of action of PHMB on the patient.

On the basis of the above and taking into account the Rule 13, the classification of these gloves as Class III would appear the most appropriate.

8.4. Picture Archiving and Communication Systems (PACS)

- Background

Basically, a PACS workstation is specifically designed to be networked with a wide variety of diagnostic imaging systems, e.g. x-ray, nuclear medicine, magnetic resonance imaging (MRI) or ultrasound, as well as laboratory or hospital information systems. It does not contain controls for the direct operation of a diagnostic imaging system and is designed to receive, archive, and transmit data both on-line and off-line. It is typically located at a site remote

from imaging systems and is configured to provide limited or extensive capabilities to further process, manipulate and/or view patient images and information collected from diagnostic imaging systems. The manufacturer of the PACS states that the system does not influence the radiation of the diagnostic x-ray machine.⁵

Generally speaking there are various types of PACS:

(a) PACS used for viewing, archiving and transmitting images.

(b) Where the post-processing of the image for diagnostic purposes is such as:

- image processing functions which alter the image data (e.g. filtering, multiplanar reconstruction, 3D reconstruction)
- complex quantitative functions (e.g. arterial stenosis evaluation, ventricular volume calculation, calcium scoring, automatic indication (detection) of potential lesions)

(c) With image enhancing by controlling image acquisition

- Outcome

In cases where the PACS falls under the definition of a medical device, *i.e.* is specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the medical device definition, the following situations can be foreseen:

(i) In relation to **PACS (a)** intended by its manufacturer to be used for viewing, archiving and transmitting images, it is considered that applying rule 12 could be appropriate and accordingly this type of PACS are generally classified as Class I medical devices. However, PACS that are only intended for archiving or storage of data may not fall within the definition of a medical device provided that data is not manipulated.

(ii) Those types of **PACS (b)** which drive a device or influence the use of a source device fall automatically in the same class in accordance with implementing rule 2.3, which classifies them as Class IIa or IIb. If this type of PACS does not drive or influence the use of the source device, this type of PACS can be classified under rule 10 if such PACS are intended to allow direct diagnosis, classifying them as Class IIa.

(iii) PACS with image enhancing by controlling image acquisition **(c)** should fall into the same class as the source device. This is based upon, firstly, implementing rule 2.3 "*Software, which drives a device or influences the use of a device, falls automatically in the same class.*" and the last paragraph of MEDDEV 2.4/1 - rev. 8, Section 3.2 stating that: "*Standalone software, e.g. software which is used for image enhancement is regarded as driving or influencing the use of a device and so falls automatically into the same class. Other standalone software, which is not regarded as driving or influencing the use of a device, is classified in its own right*". Applying this classification rule and the interpretation of the MEDDEV allows this type of PACS to be classified as Class IIa or IIb medical devices according to the classification of the device itself.

⁵ GMDN code 40943

8.5. Blood refrigerators, freezers and defrosters

- Background

The product in question concerns blood product cooling devices/blood bank refrigerators. A blood storage refrigerator and a blood storage freezer are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures. Plasma defrosters are designed for defrosting of blood plasma.

- Outcome

Blood storage refrigerators, freezers and defrosters sold for the specific intended purpose of dealing with blood should be medical devices in their own right.

The cooling device or refrigerator store substances that will be eventually delivered into the body and are Class IIa (rule 2). The plasma defrosters are in Class I (rule 1).

8.6. Warming blankets

- Background

This matter relates to the classification of warming blankets. It concerns a manufacturer who markets warming blankets on the basis of warm air, produced by an extra warming device.

The manufacturer considers the blanket to be an accessory to the active device and as such the manufacturer considered it Class I.

- Outcome

1/ Medical device or not?

The medical purpose has to be clearly identified and substantiated to qualify these products as medical devices

2/ If the blanket and the generator are sold as a single medical device:

Classification rule 9 would classify these products as class IIa or class IIb medical devices depending on the state of the patient (which is inherently linked to different levels of risks). When the product is intended to be used on an unconscious patient (who therefore cannot remove the blanket), *e.g.* in reanimation services, the device is to be classified as class IIb medical device. If the device is intended to be used on a conscious patient (who therefore can react), the device is to be classified as class IIa medical device.

3/ If the blanket and the generator are sold separately:

The blanket sold separately cannot be considered as an active medical device and is a Class I medical device in accordance with rule 1.

The generator sold alone would be class IIa or class IIb in accordance with classification rule 9. The manufacturer will have to specify the use of such generator.

8.7. Products evaluating the condition of respiratory muscles

- Background

The product assists in evaluating the condition of the respiratory muscles. It is a small battery operated device that performs two tests: the Pmax and the Sniff tests. Both tests measure pressure.

The Pmax test operates through the mouth through a voluntary respiratory manoeuvre. This test requires a maximal respiratory effort by the patient. The test starts by a deep breath filling the full capacity of the lungs and then the patient tries to breath out into a plastic tube which is closed from all sides except the connection to the mouth. The device measures the maximum pressure that is developed in the tube and sustained for at least one second. This pressure is then compared to normal pressures. This is done for both expiratory and inspiratory pressures. The Sniff test measures the pressure that develops in the nose during a sniff manoeuvre. Both tests are supposed to give similar results.

It gives an indication whether the respiratory muscles are working properly. Bad readings do not necessarily indicate a disease but an indication that further clinical investigation might be appropriate. Neither does it monitor any physiological process since it does not allow air flow through it, so it cannot monitor respiration.

- Outcome

The product measures how fast a person can exhale air. It is one of many tests that measure the function of the airways, which are commonly affected by diseases such as asthma. This product is intended to measure the condition of the respiratory muscles and as such is to be classified as a Class IIa medical device in accordance with classification rule 10 third indent.

8.8. Neutral electrodes for high frequency surgery

- Background

The issue relates to the classification of neutral electrodes which are accessories for High Frequency (HF) surgery. In general there are two types of electrodes used in high frequency surgery: those which are 'active' concentrate the energy and convert it into heat and those which are 'neutral' and simply transfer the energy between two points.

The MEDDEV does not make this distinction and places both electrodes active and neutral under rule 9, consequently they are both considered to be in Class IIb. This is the result from discussions a few years ago, and that is why the MEDDEV puts both electrodes in the same Class IIb. However, manufacturers do make this distinction.

- Outcome

Current guidance (MEDDEV 2.4/1 under rule 9) indicates that all such electrodes should be considered as Class IIb products, irrespective of their nature (active or neutral) as they may be potentially hazardous. It is concluded that the neutral electrodes are medical devices which involve potentially hazardous exchange of energy and should be Class IIb medical devices.

8.9. Surgical instrument decontamination products

- Background

A manufacturer directed a request to the Commission services on the classification of a range of products. The products in question are surgical instrument decontamination products.

- Outcome

These products should be classified according to Rule 15 of Annex IX of Directive 93/42/EEC. This rule has been further developed in MEDDEV 2.4/1, according to which this rule covers substances used principally in a medical environment to disinfect medical devices.

Examples listed in the MEDDEV 2.4/1 include disinfectants specifically intended for instance for endoscopes or haemodialysis equipment, sterilizers specifically intended to sterilize medical devices in a medical environment and washer disinfectors.

8.10. Dental water line disinfectants

- Background

A manufacturer directed a request to the Commission services on the qualification of a range of products. The products in question are Dental Water Line Disinfectants.

- Outcome

These products should be classified according to Rule 15 of Annex IX of Directive 93/42/EEC. This rule has been further developed in MEDDEV 2.4/1, according to which this rule covers substances used principally in a medical environment to disinfect medical devices.

8.11. Dental curing lights

- Background

The dental curing lights are intended for curing of dental filling substances in situ.

A number of dental filling materials need for hardening (a kind of polymerisation) after application to the tooth to be treated with light. During this application of light, the energy transmitted with this light is absorbed by the filling material as well by the surrounding parts of the body (surface of the tooth, other neighboured fillings and crowns, internal part of the tooth surrounding the filling which is warming up, gum if the filling is close to the gum). It is

not possible to avoid the surroundings of the filling to be treated together with the filling; this is an undesired but unavoidable and accepted side effect.

Because of the considerable changes in the design of the lights, it is questioned whether a reclassification would be needed.

- Outcome

It is confirmed that no reclassification is needed and that these products shall be considered as Class I medical devices in accordance with classification rule 12. Also, the guidance MEDDEV 2.4/1 on classification lists the example of “dental curing light” under classification rule 12.

8.12. Bacterial/viral filter for use on patient undergoing pulmonary function testing

- Background

The product is a bacterial/viral filter indicated for single use on patients undergoing pulmonary function testing and its main function is to avoid secretion and moisture deposition in the equipment, reducing the need of frequent decontamination procedures. The equipment is a spirometer, a class IIa active medical device, according Directive 93/42/EC.

The manufacturer states that the product should be classified as class I, because the product does not interfere at all with the diagnostic function of the test machine, and because the energy used by the active device (spirometer) is not exchanged with the patient. In consequence the manufacturer applies the rule for devices not intended for connection to an active medical device.

- Outcome

The product is an invasive device since it is partially inserted inside a natural body orifice (patient’s mouth).

The product is intended for transient use, as the duration of contact seems to be usually less than 60 minutes and is intended for connection to a Class IIa active device (spirometer).

On the basis of the above and taking classification rule 5 into account, this device should be classified as Class IIa medical device.

8.13. Hydrocolloid plaster for blisters

- Background

Blisters are resulting from frictional forces that mechanically separate epidermal cells and dermal cells and the separation fills with a fluid. The epidermal cells will be weakened. The blister management could be done by protecting the blister without puncture it or puncturing the blister with a sterile needle and removing the skin on the blister area before placing the plaster.

Hydrocolloids are more effective than ordinary first aid plasters and claim that they promote rapid healing. Indeed, some of hydrocolloid dressing mentions the principle known as moist wound healing to provide the ideal treatment for blisters. Moisture enhances wound re-epithelization since occlusive dressings that maintain moisture and warmth were optimal for healing.

- Outcome

A blister is injured skin.

Hydrocolloid acts by its proprieties on the microenvironment of the blister and is not placed on a blister to act simply as a mechanical barrier for absorption of exudates.

On the basis of the above and taking classification rule 4 and guidance MEDDEV 2.4/1 – rev 8, part 2 into account, it is considered that hydrocolloid which claims promoting rapid healing should be classified as class IIa medical devices.

8.14. Movement monitor for babies

- Background

The manufacturer claims that this product is recommended for all babies, especially during their most vulnerable first 6 months, to help guard against life-threatening events such as Apnoea and Sudden Infant Death Syndrome (SIDS or Cot Death).

A little vibrating motor is used to stimulate babies in neonatal wards that suffer apnoea episodes and can indicate if they are rhythmic or general movements. If the baby becomes dangerously inactive, this product will provide a small tactile stimulation even before human intervention. If breathing effort stops, slows down too much or becomes too shallow the built-in stimulator will gently stir baby to breathe, failing which a loud alarm will alert the nearest adult and consequently should be help by a doctor. The problem is to know whether this product could be considered as a general product or as a medical device or as an active medical device.

- Outcome

This product is intended to help preventing life-threatening events such as apnoea and Sudden Infant Death Syndrome (SIDS or Cot Death). Taking this medical purpose into account this product fulfils the definition of a medical device.

This product is to be connected with a source of electrical energy and could then be considered as an active medical device. According to classification rule 10, this product should be classified as Class IIb medical device.

8.15. Medical devices containing silver

- Background

There are many medical devices being placed on the market containing silver (*e.g* wound dressing containing silver, coated catheters or secondary bandage to cover primary dressings...). The claims for these products are usually that the silver is acting as an antimicrobial agent in an ancillary manner.

Silver is well known as an antimicrobial agent and is active at low levels. It is considered to be a medicinal substance in its own right when such claims are made.

The question is whether or not silver containing medical devices should be classified as class III medical devices under classification rule 13 of Annex IX.

- Outcome

In general, medical devices containing or coated with silver, specifically those making antimicrobial claims, should be considered as Class III medical devices under classification rule 13 of Annex IX. This is because in order for the silver to act as an antimicrobial agent, it has to be in an available form and therefore would be liable to act on the body.

The Directive 93/42/EEC states that if a device incorporates as an integral part a medicinal substance and that this substance is liable to act on the body with ancillary action to that of the device then the device should be classified as class III medical device. The Directive does not state that the medicinal substance must be intended to act on the body. The fact that the silver is not intended to reach the body or act on the body does not preclude the silver from being liable to act on the body.

There may be some exceptions to this:

If a device does not come into direct contact with the body (for example a secondary bandage intended to cover primary dressings) then a lower classification might be possible, provided that the manufacturer has clear data to support the claims being made and the fact that the silver is not liable to act upon the human body.

If it is claimed that the silver in the product will not act on the body or that it is intended to maintain specific characteristics of the device and would therefore not have any ancillary action, the manufacturer must demonstrate the claim via clinical and scientific data, using suitably rigorous testing to prove that the silver does not leach out of the device. If there is clear data to support such a claim then a product could potentially be classified in a lower class. In the absence of valid data to support such a claim then the product would remain Class III under rule 13.

8.16. Ethyl chloride spray for local refrigeration anaesthesia

- Background

A manufacturer of a spray for local anaesthesia containing ethyl chloride wants to place this product on the market as a medical device. Several other products with a similar intended use and mode of action are already placed on the market as medical devices but with some discrepancies regarding their classification.

In some countries, ethyl chloride is regulated as a medicinal product because of its toxicity and its narcotic properties.

Ethyl chloride is used as local anaesthetic in minor operative procedures and is used also to alleviate pain associated with bruises, contusions, etc...

The rapid vaporization of ethyl chloride when applied as a spray to the skin produces freezing of superficial tissues to -20°C, which results in insensitivity of peripheral nerve endings and a local anesthesia.

- Outcome

In the present case the principal mode of action of ethyl chloride is not pharmacological, immunological or metabolic and therefore this product could be qualified as a medical device.

As stated in MEDDEV 2.4/1 rev.9, medical devices using prestored gases and/or vacuum as a power source are regarded as active devices. Consequently this product could be qualified as an active medical device and, according to rule 9 of Annex IX of Directive 93/42/EEC, could be classified as Class IIa medical device.

8.17. Pathogen inactivation system for platelets

- Background

These specific systems for storing platelets are used to protect patients against transfusion-transmitted disease by inactivating pathogens in platelets. The system is designed to inactivate viruses, bacteria, other pathogens and white blood cells in platelets intended for transfusion. This system is composed of a blood bag, a chemical compound and if necessary an illumination device. The compounds have a high affinity for nucleic acids of viruses, bacterias and others pathogens and prevent the replication of the pathogens by damaging the nucleic acid. The chemical compounds could be psoralen-derivatives, riboflavin, ethylene imines and methylene blue. Psoralen-derivatives and riboflavin require a photo-activation by an illumination device to be active.

After the pathogen inactivation process, the chemical compounds could be removed and the platelets are transferred to the final blood bag where they are stored until transfusion.

The question is on the classification of such devices, the blood bag with chemical compounds and the illumination device,

- Outcome

According to MEDDEV 2.1/3 rev 3, “systems intended for the collection, storage and preservation of blood or blood components and as an ancillary function, the treatment of blood or blood components where this effect is achieved outside the human body, are classified as devices provided that any residual material is not intended to achieve its intended effect when the blood or cells are reintroduced into the body, *e.g.* systems incorporating

chemicals activated by light to reduce the viral load where the quantity of chemical remaining has no intended effect when transfused”.

According to MEDDEV 2.4/1 rev 9, blood bags are class IIb except if they “ have a function greater than for storing purposes and include systems for preservation other than anti-coagulants the other rules (*e.g.* rule 13) may apply”. Therefore, if the compound has an ancillary pharmacological or metabolic action, the blood bag with the compound has to be classified as Class III medical device under rule 13.

In the present case, the compound which inactivates pathogens is used to provide an antimicrobial effect and not for the purpose of the preservation of the solution. This antimicrobial effect is considered to be a pharmacological action and therefore the blood bag with the compound should be classed class III under rule 13.

The illumination device is considered to be an accessory of the device as it enables the action of the blood bag with the chemical compound and therefore could be classified as Class IIa medical device under rule 3, as the illumination process modifies the biological composition of blood and consists on exchange of energy.

8.18. Pre-transfusion confirmatory tests

- Background

Pre-transfusion devices are made of a support on which anti-A and anti-B reagents are applied. Those devices are used by nurses and doctors for the pre-transfusion compatibility testing at the patient's bedside. The purpose is to verify the ABO system compatibility between the recipient and the red blood cell component to be transfused immediately before transfusion to prevent any incidental incompatibility.

The simultaneous comparison of agglutination between the recipient's blood and the blood of the donor's bag allows a last verification of the ABO system compatibility between recipient and donor. These devices are considered as In vitro Diagnostic medical devices. The question is whether these devices are falling under Annex II list A of Directive 98/79/EC, which includes *"Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system..."*.

- Outcome

Although the Pre-transfusion devices are not specifically used for the determination of the ABO system blood groups, those devices include anti-A and anti-B reagents used for the determination of the ABO system blood groups, which are falling under Annex II list A. Therefore, these devices are falling under Annex II list A of Directive 98/79/EC.

9. APPENDIX

Below are listed the examples mentioned in the [MEDDEV 2.1/3 rev 2](#) that have not been included in the [MEDDEV 2.1/3 rev 3](#).

These examples will be subject to further discussion in the future and will be added to the relevant sections of this Manual.

However at present these products are regulated as per MEDDEV 2.1/3 rev 2.

Therefore, in order to avoid any gap in the guidance for manufacturers and notified bodies, information on their current qualification according to MEDDEV 2.1/3 rev 2 can be found below:

9.1. Products currently qualified as medical devices according to MEDDEV 2.1/3 rev 2

- Products containing collagen where adhesion of platelets to the surface triggers platelet adhesion and aggregation

9.2. Products qualified as accessory to medical devices according to MEDDEV 2.1/3 rev 2

- Challenge tests specifically intended to assess the tolerance to a given medical device, or its constituents (*e.g.* injectable collagen).

9.3. Products currently qualified as medicinal products according to MEDDEV 2.1/3 rev 2

- Haemofiltration substitution solutions,

8.4 Products qualified as medical devices incorporating a medicinal substance with ancillary action according to MEDDEV 2.1/3 rev 2

- Blood bags containing anticoagulant or preservation agents
- Haemostatic devices enhanced by the incorporation of collagen, where the primary action of the device is mechanical even though there may be ancillary action due to the presence of collagen having demonstrable action with platelet receptors resulting in platelet adhesion through a pharmacological process

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