

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

VERSION 1.0 (04-2008)

**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
CHAIRD 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.**
- 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. Defining a given product as a medical device and interpretation of the application of the classification rules falls within the competence of the competent authorities of the Member States where the product is on the market.**
- 4. 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.**
- 5. 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.**

- 6. 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.**
- 7. 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.**
- 8. 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.**
- 9. 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.**
- 10. 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.**
- 11. 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 7.1.

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.

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

If a product is a microscope slide which is made of is 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".*

3. BORDERLINE MEDICAL DEVICE – MEDICINAL PRODUCT

Introduction

It is suggested to consult [MEDDEV 2.1/3 rev 2](#) 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.

3.1. 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.

3.2. 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. Hylans 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.

MEDDEV 2.1/3 rev. 2 states in this context that:

Viscoelastic materials with intended use for mechanical/physical purposes such as protection of tissues during and after surgery and separation of tissues are 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,

In accordance with the above mentioned guidance, 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. BORDERLINE MEDICAL DEVICE – BIOCIDES

Introduction

General disinfectants fall under the [Biocides Directive](#)¹. 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).

5. 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.²

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

¹ 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.

² 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

6. ACCESSORY TO A MEDICAL DEVICE OR TO 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.

6.1. 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. CLASSIFICATION

Introduction

It is suggested to consult [MEDDEV 2.4/1 Rev 8](#) for more detailed guidance concerning the classification rules for medical devices.

7.1. 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.

7.2. 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.

7.3. 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 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.