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INTERPRETATIVE DOCUMENT

of the Commission's Services¹

(This document replaces the interpretative document of 18 January 2008 on the same subject)

INTERPRETATION OF THE RELATION BETWEEN THE REVISED DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES AND DIRECTIVE 89/686/EEC ON PERSONAL PROTECTIVE EQUIPMENT

Background

- (1) Some products may be intended to be used both as a personal protective equipment and as a medical device. These products thus pursue a double purpose. For example, gloves with a medical purpose in the patient environment are medical devices (e.g. examination gloves²), but as they may also be designed to provide protection to the user, they can fall into the definition of personal protective equipment. Masks used by surgeons during operation may also be designed as a filtering respiratory device to protect the user against body liquids or other infective agents. Sunglasses or other protective glasses/goggles or visors with correction are another frequent example of devices with a double purpose.
- (2) According to the original Article 1(6) of Directive 93/42/EEC (MD Directive), prior to amendment by Directive 2007/47/EC, the MD Directive did not apply to personal protective equipment covered by Directive 89/686/EEC (PPE Directive)³. The principal intended purpose of the product was decisive for deciding whether either the PPE Directive or the MD Directive was applicable.

¹ This interpretative document is not legally binding. The ultimate interpretation of Community law lies with the European Court of Justice.

² NB: Examination gloves may be coated with a medicinal substance (e.g. polyhexamethylene biguanide PHMB); in such a case, they would be considered as a medical device in terms of Article 1(4) of Directive 93/42/EEC and be subject to a consultation of a pharmaceuticals authority in accordance with point 7.4 of Annex I of Directive 93/42/EEC (see Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices, version 1.3 (2.12.2008) chapter 7.3).

³ See http://ec.europa.eu/enterprise/mechan_equipment/ppe/index.htm for more information regarding PPE.

- (3) This legal situation was considered unsatisfactory for those products which aimed at pursuing the purposes of both the PPE Directive and the MD Directive. Article 1(6) of the MD Directive was therefore revised⁴.

Revision of Article 1(6) MD Directive

- (4) In the light of the discussions during the negotiations of the proposed revision, it became apparent that, where the manufacturer wants to market a product as a medical device and also as a personal protective equipment, the essential requirements of both Directives need to be applicable.
- (5) The amended Article 1(6) MD Directive now reads:
- "Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC and this Directive, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled." (Article 2(1)f of Directive 2007/47/EC).
- (6) This revised provision clarifies that products for which a manufacturer claims a double purpose (MD and PPE) are covered by the MD Directive and must comply with the legal requirements of this directive. In addition they must meet the relevant basic health and safety requirements (BHSR) of the PPE Directive. On the other hand, the provision lacks clarity as regards the control that the relevant BHSR of the PPE Directive are satisfied.

Compliance with the relevant essential requirements

- (7) It is clear from Article 1(6) MD Directive that products which, according to the intention of its manufacturer, are to be used as a medical device and as a PPE at the same time must fulfill the relevant essential requirements of both directives.
- (8) The amendment specifically uses the term 'relevant' since only certain requirements of the PPE Directive are applicable while others are not. The general requirements of Annex II of the PPE Directive are applicable to all PPE. For example, information details which are specific to PPE may need to be supplied by the manufacturer in accordance with the requirement 1.4 of Annex II of the PPE Directive. As regards additional requirements applicable to either specific classes or types of products or particular risks, the requirement 3.9.1 regarding non-ionizing radiation must be observed for sunglasses with corrective lenses. When a mask or other equipment shall protect the user against the transmission of infections, the essential requirement 3.10 regarding protection against dangerous substances and infective agents may need to be fulfilled.
- (9) The above are only examples and do not provide an exhaustive list of the applicable "relevant" basic health and safety requirements of the PPE Directive. The manufacturer must decide on a case-by-case basis which requirements are applicable to his product taking into account its specific intended purpose.

Verification of the compliance with the relevant essential requirements

- (10) The application of the "relevant" basic health and safety requirements of the PPE Directive leads to the question how and by whom their fulfillment is verified. As spelt out in chapter 2.2.1 of the Guide to the Implementation of Directives Based on New

⁴ The proposal of the Commission COM(2005)681 suggested the deletion of the exclusion clause of Art. 1(6) MD Directive

Approach and Global Approach ("Blue Guide")⁵, in case of simultaneous application of two or more directives the product has to undergo the conformity assessment procedures according to all applicable directives, unless otherwise provided for.

- (11) In the absence of a provision to the contrary, devices with a double purpose must undergo the conformity assessment procedures according to the MD Directive and, in respect to the relevant BHSR of the PPE Directive, also the corresponding conformity assessment procedure required by that directive. Contrary to provisions in other directives (e.g. Directive 2006/42/EC⁶) the MD Directive does not declare its conformity assessment procedure as solely applicable for devices with a dual purpose. This result is in line with the overall objective pursued by Directive 2007/47/EC which is to increase the level of safety of medical devices. It would be contrary to this objective if in some cases a device, when placed on the market only as PPE would be subject to an assessment by a Notified Body, but would be subject to self-certification when it is also to be used as a medical device.
- (12) In addition, the reference in Article 1(6) MD Directive is made within the provision on the scope and not within the provision concerning the essential requirements as for example the reference to Annex I of Directive 2006/42/EC on machinery in the new subparagraph 2 of Article 3 of the MD Directive which (for devices which are also machinery) incorporates into the MD Directive the essential health and safety requirements of the Machinery Directive to the extent to which those are more specific than the essential requirements of the MD Directive⁷.
- (13) Moreover, Article 1(4) of the PPE Directive does not exclude the application of other provisions of the PPE Directive. In fact, Article 1(4) PPE Directive makes provision for the inapplicability of this directive only when another directive is designed to achieve the same objectives as the PPE Directive with regard to placing on the market, free movement of goods and safety. Although the objectives of both directives (like most of the 'New Approach' directives) are similar in terms of placing on the market, free movement and safety protection, they are not totally the same. The aim of the MD Directive is that the device does not compromise the clinical condition and safety of the patient, the safety and health of the user and of other persons. The PPE aims at the protection of the safety and health of the users against external risks.

CE marking

- (14) Even though a device with the double purpose as medical device and PPE needs to comply with the requirements of both directives, the manufacturer shall affix only one CE marking. This corresponds to Article 4(5) of the MD Directive which states that "[w]here the devices are subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the devices also fulfil the provisions of the other Directives."⁸

⁵ <http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm>

⁶ Section 1.5.1 of Annex I of Directive 2006/42/EC on machinery states: "The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive." During the discussions in Council, a similar provision was suggested for Article 1(6) MD Directive (see Council document DS 132/1/06 Rev 1 of 14 April 2006), but it was not kept during further negotiations.

⁷ See Interpretative Document regarding the relation between the revised Directives 90/385/EEC and 93/42/EEC concerning (active implantable) medical devices and Directive 2006/42/EC on machinery.

⁸ Article 5(6)(a) of the PPE Directive contains a similar provision.

Article 13(1) PPE Directive requires that the identification number of the Notified Body accompanies the CE marking when the Notified Body was involved in the production control phase for "complex design" PPE. For medical devices this is required when the Notified Body was involved in one of the conformity assessment procedures set out in Annexes II, IV, V or VI of the MD Directive (see Article 17 MD Directive). If for a given product the intervention of a Notified Body is required to check compliance with, on the one hand, the relevant BHSR of the PPE Directive and, on the other hand, with the essential requirements of the MD Directive, the identification numbers of two Notified Bodies may need to be indicated specifying under which directive the assessment was carried out⁹.

Illustration

- (15) For corrective spectacle lenses which, according to the manufacturer's intention, also shall protect the wearer against sunlight, the manufacturer of the uncut finished lenses can declare compliance with the essential requirements of both directives since a product which protects against sunlight is a "simple design" PPE in terms of Article 8(3) of the PPE Directive and corrective lenses are class I medical devices.
- (16) A respiratory mask for healthcare professionals for which the manufacturer claims that it protects the user against mortal danger or serious and irreversible harm to health ("complex design" PPE) would be subject to one of the conformity assessment procedures set out in Article 11 of the PPE Directive which requires the involvement of a Notified Body designated under the PPE Directive while as a medical device it would fall in class I.

Final remarks

- (17) In order to further clarify the legal situation, the Commission's services will propose that Article 1(6) MD Directive is amended accordingly in the context of the next revision of the MD Directive or the PPE Directive.

⁹ A Notified Body may carry out the assessment in its own name or subcontract the assessment to another competent body designated to

