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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 DIRECTIVES 90/385/EEC AND 93/42/EEC CONCERNING (ACTIVE IMPLANTABLE) MEDICAL DEVICES AND DIRECTIVE 2006/42/EC ON MACHINERY

Background

- (1) Medical devices were previously excluded from the scope of Directive 98/37/EC on machinery. Article 1(3) of Directive 98/37/EC stated that: "The following are excluded from the scope of this Directive: [...] medical devices".
- (2) Directive 98/37/EC has been replaced by Directive 2006/42/EC on machinery² which does not contain such an "exclusion clause", but rather states a general principle of demarcation. This general principle is expressed in Article 3 of Directive 2006/42/EC which reads as follows:

"Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives."
- (3) In light of the fact that medical devices are no longer explicitly excluded from the revised Directive on machinery, the application of Directive 2006/42/EC on machinery in relation to the Directives concerning medical devices was brought into question.

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

² The Member States shall apply the measures transposing Directive 2006/42/EC with effect from 29 December 2009, see also http://ec.europa.eu/enterprise/mechan_equipment/machinery/index.htm

Revision of Article 3 Directive 93/42/EEC and of Directive 90/385/EEC

- (4) To ensure simplification in legislation, both Directive 93/42/EEC on medical devices and Directive 90/385/EEC on active implantable medical devices have been amended by Directive 2007/47/EC which added the following paragraph to their respective Article 3 which sets out the essential requirements:

“Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery shall also meet the essential health and safety requirements set out in Annex I of that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I of this Directive.” (emphasis added)

- (5) The amendment allows certain essential health and safety requirements of Directive 2006/42/EC on machinery to become part of the Directives concerning medical devices. According to a linguistic and systematic interpretation of the new paragraph of Article 3 of Directives 93/42/EEC and 90/385/EEC the relevant requirements of the Machinery Directive are incorporated into the Medical Devices Directives. The result is that Directive 2006/42/EC as such shall not apply (see Article 3 of this directive).

The result is different compared to the relation between Directive 93/42/EEC and other directives such as Directive 89/686/EEC on personal protective equipment (see the revised Interpretative Document on the relation between the MD Directive and the PPE Directive) for the following reasons: First of all, the reference in Article 3 of Directives 90/385/EEC and 93/42/EEC is made only to Annex I of Directive 2006/42/EC. Secondly, the link to the requirements of the Machinery Directive is made within the provision on essential requirements of the Medical Devices Directives and not, as for example the reference to the PPE Directive (Article 1(6) MD Directive), within the provision on the scope.

- (6) Consequently:
- only single conformity assessment is required, under Directives 93/42/EEC and 90/385/EEC (according to the procedures provided for by these Directives) for medical devices that are also machinery;
 - the risk assessment to be carried out for medical devices that are also machinery is the risk/benefit analysis as set out in the essential requirements of the Directives concerning medical devices.
- (7) Harmonized standards for medical devices which are also machinery should cover any requirements of Directive 2006/42/EC that are applicable to the devices in their scope. Such standards will therefore have to be reviewed and amended or revised if necessary.

Illustration

- (8) In order to determine which essential health and safety requirements of Directive 2006/42/EC on machinery are part of the Directives concerning medical devices, the following example can serve as an illustration.

- (9) Annex I, section 1.5.4. of Directive 2006/42/EC on machinery requires:

“Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk. Where necessary, the instructions must give further information on these risks. Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.”

- (10) There is no equivalent of such a specific requirement in Annex I of the Directives concerning medical devices. For certain medical device machinery, where a fitting error can present a hazard, quite clearly this essential requirement must also be met under the applicable Medical Devices Directive.
- (11) The application of the abovementioned principles requires a case by case examination of every individual hazard listed in Annex I of Directive 2006/42/EC. If a hazard is relevant for a specific medical device and if the corresponding essential health and safety requirement of Directive 2006/42/EC is either not provided for in Annex I of Directive 93/42/EEC / Annex 1 of Directive 90/385/EEC or is more specific than the essential requirements of the applicable Medical Devices Directive, this essential requirement of Directive 2006/42/EC will have to be met by the medical device concerned.
- (12) Assessment of compliance to these requirements will be carried out under the conformity assessment procedure to which this device is submitted within the framework of the applicable Medical Devices Directive.