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## INTERPRETATIVE DOCUMENT OF THE COMMISSION'S SERVICES<sup>1</sup>

### IMPLEMENTATION OF DIRECTIVE 2007/47/EC AMENDING DIRECTIVES 90/385/EEC, 93/42/EEC AND 98/8/EC

#### I. Provisions of Directive 2007/47/EC

Directive 2007/47/EC amends Directive 90/385/EEC on active implantable medical devices and Directive 93/42/EEC on medical devices. The changes concern, among others, the **essential requirements** which medical devices must satisfy in order to be lawfully placed on the market, the corresponding **conformity assessment procedures** and the **classification of devices**.

Directive 2007/47/EC was published in the Official Journal of 21 September 2007 and entered into force on the 20th day following this publication, i.e. on 11 October 2007. The transposition by the Member States was due by 21 December 2008. According to the second subparagraph of Article 4(1) of Directive 2007/47/EC, the Member States "shall apply [the transposition measures] from 21 March 2010".

Apart from the deadline for transposition and the date of application of the national transposition measures, the directive does **not make provision for a period of transition**. This has raised a number of questions and the following interpretation by the Commission's services shall guide a uniform practice throughout the EU. Since Directive 2007/47/EC is addressed to the Member States, preliminary transposition into national law is indispensable for the application of the corresponding provision by the various economic operators.

#### II. Questions relating to the implementation of Directive 2007/47/EC

##### 1. Compliance of medical devices with the new requirements

According to Article 2 of Directive 93/42/EEC, "*Member States shall take all necessary steps to ensure that devices may be **placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.***" (emphasis added)

Directive 90/385/EEC contains a similar provision.

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

The '**placing on the market**' is defined as "*the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished*" (Article 1(2)(h) Directive 93/42/EEC; Article 1(2)(h) Directive 90/385/EEC).

The '**putting into service**' is defined as "*the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose*" (Article 1(2)(i) Directive 93/42/EEC) or as the "*making available to the medical profession for implantation*" (Article 1(2)(g) Directive 90/385/EEC), respectively.

In the absence of transitional provisions, medical devices placed on the market or put into service after 21 March 2010 must be in conformity with the (new) requirements of the revised directives. The concepts of **placing on the market and putting into service** refer to **each individual product** and not to a type of device<sup>2</sup>.

Before 21 March 2010, manufacturers are not obliged to comply with the new requirements introduced by Directive 2007/47/EC. But they may do so on a **voluntary basis**. A conflict between old and new legislation is likely to be excluded since it can be assumed that a product that complies with the applicable Medical Device Directive as amended by 2007/47/EC continues to comply with the directive in its current version. Manufacturers may have an interest to **anticipate compliance with the new legislation**, for example in cases where they bring a new device type on the market for which the new requirements have been respected from the beginning, or where a device falls in a different class requiring another conformity assessment procedure, or where the adaptation to the new requirements introduced by Directive 2007/47/EC requires changes to the approved design of a medical device or to the approved quality system of the manufacturer which are subject to prior assessment by the responsible Notified Body.

In the absence of specific provisions regarding products already on the market, medical devices which have been lawfully placed on the market or put into service **prior** to 21 March 2010 can **continue to be marketed** and used after that date and are subject to the general market surveillance provisions (e.g. safeguard clause).

Manufacturers are required to declare the conformity of their product with the applicable directive in form of a **Declaration of Conformity**<sup>3</sup> (irrespective of the class of the device and the fact if a Notified Body is involved in the conformity assessment or not). If manufacturers place products on the market or put them into service which comply with the new requirements prior to 21 March 2010, they should document that their Declaration of Conformity states compliance with Directives 90/385/EEC or 93/42/EEC, respectively, as amended by Directive 2007/47/EC. If the involvement of a Notified Body in the conformity evaluation is required, the responsible Notified Body must have checked compliance with the new legislation (see below section 2).

Declarations of Conformity issued as of 21 March 2010 are automatically deemed to refer to the relevant directive in its revised version. As of that date the manufacturers

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<sup>2</sup> Guide to the implementation of directives based on the New Approach and the Global Approach ("Blue Guide"), 2.3.1; Commission communication on the application of transitional provisions of Directive 93/42/EEC relating to medical devices, published in OJ 98/C 242/05.

<sup>3</sup> For custom-made medical devices, the manufacturer must issue a statement according to Annex 6 (Directive 90/385/EEC) or Annex VIII (Directive 93/42/EEC).

must be in a position to provide prove of compliance with all requirements of the revised directives which are applicable to their respective product.

## **2. Evaluation by Notified Bodies according to new requirements**

Directive 2007/47/EC introduced several changes or clarifications which Notified Bodies have to respect when they carry out conformity assessment activities. For example, they will have to check the technical documentation of class IIa and IIb devices on a representative basis<sup>4</sup>. Where a manufacturer has subcontracted the design, manufacture, final inspection or testing of a medical device to another party, the Notified Body will have to assess that the manufacturer applies the appropriate control to this third party<sup>5</sup>. (See also below section 4 regarding the new consultation procedure for active implantable medical devices combined with a medicinal substance.)

### *Timing*

Any decision which a Notified Body takes **as of 21 March 2010** regarding the delivery or renewal of a certificate **must take account of the new evaluation requirements** as laid down in Directives 90/385/EEC or 93/42/EEC, respectively, as amended by Directive 2007/47/EC.

In order to avoid delays or interruption in the supply of medical devices as of 21 March 2010, manufacturers notably of

- **a new type** of medical device,
- devices that **change their class** due to the revised classification rules or
- devices which undergo **changes which are subject to prior assessment** by a Notified Body

may have an interest to request a Notified Body to carry out the relevant **conformity assessment** in accordance with Directives 90/385/EEC and 93/42/EEC as amended by Directive 2007/47/EC **prior to 21 March 2010** to ensure that they have the necessary certification as of that date. In such cases and in consideration of the well established practice that certificates refer to the parent Directive only (without mentioning subsequent amendments), the Notified Body shall document (e.g. in design-dossier examination reports/type-testing reports or audit reports) that the underlying conformity assessment procedure has been carried out in line with the revised Medical Devices Directives in a way which allows competent authorities to identify that the device complies with the legal requirements as amended by Directive 2007/47/EC.

This also applies to cases where certificates with unlimited validity need to be replaced by certificates with limited validity (see below under 3).

In **all other cases** the new legal requirements regarding the evaluation by Notified Bodies shall be **phased in** in the context of the **surveillance audits** to be carried out by the Notified Bodies on a periodical basis<sup>6</sup>. At this occasion, they will have to check that

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<sup>4</sup> See point 7 of Annex II of Directive 93/42/EEC.

<sup>5</sup> See point 3.2.(b), third indent, of Annex II of Directive 93/42/EEC.

<sup>6</sup> See point 5.3 of Annex II, point 4 of Annex V and point 4 of Annex VI of Directive 93/42/EEC; point 5 of Annex 2 and point 4 of Annex 5 of Directive 90/385/EEC. In cases of EC type-examination combined with EC verification, the check with the new requirements shall take place in the context of

manufacturers have undertaken the necessary measures to comply with the requirements introduced by Directive 2007/47/EC<sup>7</sup>. The result must be documented by the Notified Body.

It is to be noted that the directives do not make provision for the periodicity of the surveillance inspections. The Commission's services seize the opportunity to call upon the Member States to require Notified Bodies to ensure these audits **at least once a year** as specified in the standard EN ISO/IEC 17021<sup>8</sup>.

### **3. Certificates issued prior to the application of Directive 2007/47/EC**

Directive 2007/47/EC does not contain specific provisions with regard to the impact of the legislative changes on certificates issued prior to 21 March 2010 which have a validity beyond that date.

#### *Certificates with unlimited validity*

As of 21 March 2010, certificates issued in accordance with Annex 5 of Directive 90/385/EEC and Annexes V and VI of Directive 93/42/EEC need to be limited in time (max. 5 years)<sup>9</sup>. Products, for which these conformity assessment procedures have been used and which have not yet been placed on the market and/or put into service before 21 March 2010, need to be supported by a certificate in compliance with the applicable Directive as amended by Directive 2007/47/EC. This means that as regards medical devices to be placed on the market or put into service<sup>10</sup> **as of 21 March 2010**, existing **unlimited certificates need to be reissued** with a limited validity before that date, taking account of the other modifications introduced by Directive 2007/47/EC.

The validity of certificates for devices **already placed on the market or put into service prior to 21 March 2010** is not called into question.

#### *Certificates with a limited validity*

Certificates issued in accordance with annexes 2 and 3 (Directive 90/385/EEC) and annexes II and III (Directive 93/42/EEC), respectively, had to be limited to a maximum validity of 5 years already under existing legislation.

In the absence of specific provisions to the contrary, certificates issued **prior** to 21 March 2010, in principle, maintain their validity.

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the examinations and tests according to points 4 to 6 of Annex IV of Directive 93/42/EEC or points 5 to 6 of Annex 4 of Directive 90/385/EEC.

<sup>7</sup> Adaptation which would lead to changes that are subject to prior approval under the change control regime must have been certified by 21 March 2010 at the latest.

<sup>8</sup> See section 9.3.2.2 of EN ISO/IEC 17021:2006: Conformity assessment – Requirements for bodies providing audit and certification of management systems.

<sup>9</sup> See Article 9(8) of Directive 90/385/EEC and Article 11(11) of Directive 93/42/EEC, both as amended.

<sup>10</sup> NB: medical devices which have been lawfully placed on the market or put into service prior to 21 March 2010 can continue to be marketed and used after that date and are subject to the general market surveillance provisions, see above page 2.

However, a new certification is necessary in cases of changes to the approved design of a medical device or of the approved quality system of the manufacturer, triggered by the new requirements introduced by Directive 2007/47/EC, which are subject to prior assessment by the responsible Notified Body. In the case of medical devices covered by Directive 93/42/EEC, *significant* changes need to be approved by the Notified Body; in the case of active implantable medical devices covered by Directive 90/385/EEC, the Notified Body must approve *any* modification to the approved quality system or design. The usual regime regarding change control applies<sup>11</sup>.

When a medical device falls in a different class due to the modification of the classification rules (Annex IX of Directive 93/42/EEC), new certification in accordance with the conformity assessment procedure applicable to the reclassified device is necessary for devices placed on the market or put into service as of 21 March 2010.

#### **4. Consultation of authorities responsible for pharmaceuticals**

According to point 10 of Annex 1 and point 4.3 of Annex 2 of Directive 90/385/EEC, as amended by Directive 2007/47/EC, a Notified Body must consult a national pharmaceuticals' agency or the EMEA "before taking a decision" regarding the evaluation of an active implantable medical device (AIMD) which incorporates a medicinal substance with ancillary action to the one of the device.

The situation when a Notified Body must consult a competent pharmaceuticals' agency thus occurs when it is called upon to decide, as of 21 March 2010, about a manufacturer's application for a new certificate, the renewal of an existing one or the approval of modifications concerning the approved quality system or the approved design.

#### **5. Overlap with the Machinery Directive**

The new Machinery Directive 2006/42/EC is applicable as of 29 December 2009. This directive does not any more exclude medical devices from its scope as the old Machinery Directive 98/37/EC did, but states that it shall not apply, or cease to apply, where the hazards referred to in its essential requirements are wholly or partly covered more specifically by other Community directives.

Directive 2007/47/EC introduced a new paragraph in the Articles 3 of Directive 90/385/EEC and Directive 93/42/EEC, respectively, which states that where a medical device is also machinery, it shall meet the essential health and safety requirements (EHSR) of the Machinery Directive to the extent to which they are more specific than the essential requirements of the Medical Device Directives. The latter ones thus incorporated the relevant essential requirements of the Machinery Directive and it is common ground that in that way the Medical Devices Directives are to be considered more specific and the application of the Machinery Directive excluded<sup>12</sup>.

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<sup>11</sup> See points 3.4 and 4.4 of Annex II, point 6 of Annex III, point 3.4 of Annex V or point 3.4 of Annex VI of Directive 93/42/EEC; point 3.4 and 4.4 of Annex 2, point 6 of Annex 3 or point 3.4 of Annex 5 of Directive 90/385/EEC.

<sup>12</sup> See Interpretative Document of the Commission's services regarding the relation between the revised Directives 93/42/EEC and 90/385/EEC and Directive 2006/42/EC on machinery; [http://ec.europa.eu/enterprise/medical\\_devices/guide-stds-directives/interpretative\\_fiche\\_machinery.pdf](http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/interpretative_fiche_machinery.pdf)

During the period between the date of application of the Machinery Directive (29 December 2009) and of the revised Medical Devices Directives (21 March 2010), manufacturers can choose

- to fully comply with the Machinery Directive and with the relevant Medical Device Directive,
- to comply with all new requirements of the revised Medical Devices Directives or
- to anticipate only compliance with the relevant EHSR of the Machinery Directive while otherwise complying with the requirements of the current relevant Medical Device Directive, including the usual regime regarding change control (see above under 3, in particular footnote 11).

As of 21 March 2010, the Machinery Directive will cease to apply and the device will be subject to the revised Medical Devices Directives.