






Examination of Interpretation document on Amending Directive 2007/47/EC

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The European Commission published an interpretation document about implementing of Amending Directive 2007/47/EC recently [Interpretative document of the Commission's Services. Implementation of Directive 2007/47/EC Amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC ENTR/F3/PBE/D (2009) 19003 (5 June 2009)] in order to guide uniform practice throughout the EU. The document was produced in response to questions elicited by the Amending Directive.

§II of the interpretation document covers five elements:

-  Compliance of medical devices with the new requirements
-  Evaluation by Notified Bodies according to new requirements
-  Certificates issued prior to the application of Directive 2007/47/EC
-  Consultation of authorities for pharmaceuticals
-  Overlap with the Machinery Directive

The origins of the questions posed that are covered by these elements are unknown, however, suggest the following:

- a. Whether each individual product must comply with the (new) requirements of the Amending Directive rather than the type of device – the interpretation confirms that each product not already Placed on the Market before 21 March 2010 must comply with the Amending Directive before such Placement.

Further, medical devices Placed on the Market according to the current applicable Directives need not undergo Conformity Assessment according to Amending Directive 2007/47/EC at the date of implementing (21 March 2010) in order to remain on the Market, however, would be subject to the prevailing general market surveillance provisions.

Since all medical devices Placed on the Market as of 21 March 2010 would need to comply with Amending Directive 2007/47/EC, the interpretation document indicates that only products Placed on the Market according to the Amending Directive before then should be declared as in compliance with the relevant Directive on the medical device as Amended by Amending Directive 2007/47/EC (and have fulfilled Conformity Assessment accordingly),

- b. Timing of renewal of CE certificate issued by Notified Body for a product Placed on the Market prior to 21 March 2010 according to current applicable Directive – the Manufacturer is expected to consider the new evaluation requirements for Conformity Assessment timeously to avoid interruption of supply and to secure Conformity Assessment in good time.

Since Amending Directive 2007/47/EC requires that CE certificate for any medical device Placed on the Market according to Annexes 5 Council Directive 90/385/EEC or V and VI Council Directive 93/42/EEC to specify period of validity (5 years maximum). Therefore, any device currently covered by a CE Certificate with un-limited validity would require re-issue with a limited validity as of 21 March 2010 (accommodating applicable requirements of Amending Directive 2007/47/EC),

- c. Validity of CE certificate issued by Notified Body for change to approved design¹, ² or QMS³ – any change must undergo Conformity Assessment (specifically re-examination for change to the approved design or QMS as appropriate) to be concluded by 21 March 2010 and receive renewed CE certificates accordingly,
- d. Medical device currently Placed on the Market with the CE Marking of Conformity where ECPC is altered by Amending Directive 2007/47/EC – Amending Directive alters the ECPC of certain medical devices Placed on the Market according to Council Directive 93/42/EEC, consequently such products must undergo Conformity Assessment and possess new CE certificates by 21 March 2010 in order to remain on the Market with the CE Marking of Conformity,
- e. Evaluation of an active implantable medical device incorporating a substance exerting action ancillary to that of the device (according to Annex 1 and §4.2 Annex 2 Council Directive 90/385/EEC) – in such cases, the opinion of the appropriate Competent Authority must be accommodated by 21 March 2010 in order for a new device to be Placed on the Market or an existing CE Marked device to remain on the Market with the CE Marking of Conformity,
- f. Dual medical device – machinery – since Council Directive 2006/42/EC no longer excludes medical devices, any medical device that is dually a medical device and machinery must fulfil the Essential Requirements (according to Council Directives 90/385/EEC and 93/42/EEC, respectively) and Essential Health and Safety Requirements (according to Council Directive 2006/42/EC).

Interpretative Document ENTR/F/3/PBE/pdw D (2009) 27250 stated that

¹ = Significant change within the meaning of Annex II and III Council Directive 93/42/EEC

² = Any modification to approved design or QMS according to Annexes II and III Council Directive 90/385/EEC

³ = Substantial change within the meaning of Annex II Council Directive 93/42/EEC

§(5) of the Interpretation document clarifies that Directive 2006/42/EC does not apply providing that certain EHSR of the Directive become part of the two Directives on medical devices. It does not mean that the ERs of Council Directive 90/385/EEC and 93/42/EEC as amended by Amending Directive 2007/47/EC already integrate applicable EHSR of Council Directive 2006/47/EC, contrary to practice being seen to date or as communicated by some Notified Bodies.




Unfortunately, however, scrutiny of Amending Directive 2007/47/EC reveals only the following:

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 to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex 1 to this Directive.

(*) OJ L 157, 9.6.2006, p. 24

Therefore, the Amending Directive does not add any ER relevant to machinery.

The window of application between Council Directive 2006/42/EC (29 December 2009) and Amending Directive (21 March 2010) may be fulfilled as specified by <newer> Interpretative document, to wit:

-  Full compliance with both the Machinery Directive and relevant Medical Device Directive
-  Compliance with all new requirements of the revised Medical Devices Directives or
-  Anticipation of compliance with the relevant EHSR of the Machinery Directive only while otherwise complying with the requirements of the current relevant Medical Device Directive, including the procedures for changes change^{3, 11} (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 only.

Bibliography

1. Interpretative document of the Commission's Services. Implementation of Directive 2007/47/EC Amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC ENTR/F3/PBE/D (2009) 19003 (5 June 2009).