



COCIR recommendation¹ on the Declaration of Conformity (DoC) referring to European Directive 93/42/EEC as amended by 2007/47/EC after 21 March 2010

COCIR appreciates the Commission's Services Interpretative Document² on the Implementation of Directive 2007/47/EC amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC issued on 5 June 2009.

Since then, COCIR members have noticed different possibilities for issuance of the Declaration of Conformity referring to the amended Directive, or were advised on different options. This is the reason why COCIR decided to issue this recommendation to its members.

Description of the present situation:

Starting 21 March 2010 it is mandatory to fulfil the requirements from the amended Directives.

The information in the Commission's interpretative document related to the Declaration of Conformity (see more details in Appendix) has been diversely interpreted by manufacturers, Notified Bodies and Competent Authorities. This has led to a non-uniform and ambiguous situation where two formats of the DoC exist in practice: some mention "93/42/EEC", others mention "93/42/EEC" with the addition "as amended by 2007/47/EC", although both formats apply to devices complying with 93/42/EEC as amended by 2007/47/EC. Note that where only "93/42/EEC" is mentioned, the manufacturer must have documented elsewhere that the DoC refers to the amended version of the Directive.

Situation as of 21 March 2010 on issuance of a DoC:

- If issued prior to 21 March 2010 that includes the addition "as amended by 2007/47/EC", it is not required to issue after 21 March 2010 a revised DoC without that addition.
- If issued prior to 21 March 2010 that only mentions "93/42/EEC" but that does refer to the amended Directive (and where that is documented elsewhere), it is not required to issue after 21 March 2010 a revised DoC.
- If issued on or after 21 March 2010 it is sufficient to only mention "93/42/EEC", as was the case with the previous amendments of this Directive.

COCIR recommends its company members to reissue or revise the DoC on/after 21 March 2010, although there is no European legal requirement to do so. The reissued/revise DoC should mention only "93/42/EEC". This will gradually lead to an unambiguous and uniform situation where all DoCs are dated on/after 21 March 2010 and only mention Directive 93/42/EEC.

¹ This paper may be used by COCIR members in their communication with customers

² To view the Interpretative Document COM ENTR/F3/PBE/D(2009)19003 please go to www.ec.europa.eu/enterprise/sectors/medical-devices/files/guide-stds-directives/transitionalperiod_2007-47-ec_guidance_final_en.pdf



Appendix

Commission's Services Interpretative Document from 5 June 2009

The Interpretative Document of the Commission's Services states among others following:

(1) 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.

(2) Manufacturers are required to declare the conformity of their product with the applicable directive in form of a Declaration of Conformity. 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.

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