



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Consumer goods
Cosmetics and Medical Devices

Brussels, 24th November 2008
M/432 EN

Standardisation mandate addressed to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to Medical Devices

GENERAL

This mandate relates to Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 on medical devices, amending Directive 90/385/EEC and Directive 93/42/EEC.

Directive 2007/47/EC came into force on 11 October 2007. Its provisions must be transposed into the national law of the Member States by 21 December 2008 and will become applicable on 21 March 2010.

According to Article 3 of Directive 93/42/EEC and of Directive 90/385/EEC, as amended by Article 1 and Article 2 of the Directive 2007/47/EC, medical devices subject to the Directives must meet the relevant essential health and safety requirements set out in the respective Annex I.

Article 5 of Directive 93/42/EEC and of Directive 90/385/EEC, as amended states that medical devices in conformity with the relevant national standards adopted pursuant to Harmonised Standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to comply with the essential health and safety requirements of the directives.

I BACKGROUND

Directive 2007/47/EC (Annexes I and II) introduced major changes to the essential health and safety requirements applicable to medical devices. Several of these requirements, such as those relating to clinical evaluation, have been made more precise.

A number of new essential health and safety requirements have been introduced to deal with risks brought into the scope of the Directives. Furthermore, certain requirements that are currently applicable only to specific products have been made applicable to any medical device presenting the risks concerned.

II MOTIVATION AND NEEDS

As a result of the publication of Directive 2007/47/EC, it has become necessary to issue a mandate to CEN and CENELEC to revise the approximately 200 published Harmonised Standards under Directive 93/42/EEC and Directive 90/385/EEC and if necessary to develop new standards.

III DESCRIPTION OF THE MANDATED WORK

The Commission requests CEN and CENELEC to check the existing body of standards for medical devices and, where necessary, to draw up new standards or to amend or revise the existing standards in order to ensure that they cover the scope and satisfy the essential health and safety requirements of the amended Directives 93/42/EEC and 90/385/EEC.

The existing standards concerned by this mandate are the standards, the references of which have been published in the OJEU in support of Directive 93/42/EEC and Directive 90/385/EEC and that were developed in response to mandates relating to these Directives. This mandate also concerns new and revised standards for medical devices to be adopted during the period leading up to the application of Directive 2007/47/EC.

The standardisation tasks covered by this mandate are as follows:

- Ensure that harmonised standards are available to cover the requirements introduced into the scope of the revised Directives;
- Make the necessary adjustments to standards to take account of the fact that Directive 2007/47/EC amends Directive 93/42/EEC and Directive 90/385/EEC;
- Ensure that the harmonised standards intended to support the amended Directive 93/42/EEC and Directive 90/385/EEC fully satisfy the relevant essential health and safety requirements of the revised Directives or, failing that, include an indication as to which of the requirements are not satisfied;
- Ensure that the standards intended to support the amended Directive 93/42/EEC and Directive 90/385/EEC include an indication of the relationship between the clauses of the standard and the essential health and safety requirements as introduced or amended by Annex I and II of Directive 2007/47/EC in accordance with the agreement on this subject between the Commission and the European Standardisation Organisations.

To ensure simplification in legislation, Directive 93/42/EEC and Directive 90/385/EEC have been amended by the addition of new provisions with regard to the relation with Directive 89/686/EEC on personal protective equipment (PPE) and Directive 2006/42/EC on machinery. These new requirements must be evaluated and, in case of relevance, be addressed in the requested standards revision.

IV EXECUTION OF THE MANDATE

CEN and CENELEC are requested to communicate to the Commission, within three months of the acceptance of the mandate, a work plan for the execution of the abovementioned standardisation tasks, indicating the new standards that need to be developed, the standards requiring revision or amendment.

CEN and CENELEC are requested to communicate to the Commission within two months of the acceptance of the mandate, an interim report on the progress of the tasks set out in this mandate, indicating any possible difficulties encountered.

CEN and CENELEC will revise standards which need adaptation to Directive 2007/47/EC within one year from accepting the mandate. CEN and CENELEC are also requested to communicate to the Commission, within one year from accepting the mandate a list of harmonised standards supporting the implementation of Directive 2007/47/EC. The list shall include the titles of the standards in all of the official languages of the EU.

CEN and CENELEC will develop the missing standards within three years from accepting the mandate.

CEN and CENELEC are requested to draw up the work plan and execute the above mentioned tasks in close cooperation in order to ensure consistency and avoid overlapping standards.

When executing the standardisation tasks covered by this mandate, CEN and CENELEC are requested to take due account of feedback from the stakeholders. Wherever possible, when the abovementioned tasks involve the development of new standards or the revision of existing standards, the tasks should be executed within the framework of the Vienna and Dresden Agreements with a view to preparing international standards that satisfy the relevant essential health and safety requirements of Directives 93/42/EEC and 90/385/EEC, as amended by Directive 2007/47/EC.

Acceptance by CEN of this mandate starts the standstill period referred to in Article 7 of Directive 98/34/EC of 22 June 1998 (OJ N° L 204/37 of 21 July 1998).

V BODIES TO BE ASSOCIATED

As appropriate, CEN and CENELEC will invite the representative organisations of consumers' interests (ANEC), patients (EPF), workers (ETUI-REHS), hospital and healthcare services (HOPE) and small and medium-size enterprises (NORMAPME) to take part in the standardisation work.