



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Conformity and standardisation, new approach, industries under new approach
Mechanical and electrical equipment (including telecom terminal equipment)
TCAM Secretariat

Brussels, 20 August,
2002

M/322

STANDARDISATION MANDATE ADDRESSED TO CEN, CENELEC AND ETSI IN THE FIELD OF ELECTROTECHNOLOGY, INFORMATION TECHNOLOGY AND TELECOMMUNICATIONS

TITLE

Alignment of Harmonised Standards for the R&TTE Directive¹ with those of the Medical Devices² and Medical Implant Directives³

PURPOSE

The purpose of this mandate is to establish Harmonised standards covering Radio Equipment and Telecommunications Terminal equipment which at the same time are covered by Council Directive 93/42/EEC or Council Directive 90/385/EEC to be recognised under Directive 1999/5/EC as giving a presumption of conformity with its requirements.

JUSTIFICATION

This mandate derives from Directive 1999/5/EC. This Directive, following the New Approach on Technical Harmonisation and Standards⁴, defines the essential requirements

¹ Council and European Parliament Directive 1999/5/EC of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (Official Journal L 91 of 7 April 1999).

² Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

³ Council Directive 90/385/EEC of 20 June 1990 on approximation of the laws of the Member States relating to active implantable medical devices,

⁴ Art. 1.(h) "harmonised standard" means a technical specification adopted by a recognized standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement, compliance with which is not compulsory.

R&TTE equipment must meet to be placed on the market and to put into service for its intended purpose. However the essential requirements which relates to the above said medical Directives have to be meet at the same time.

ORDER

The European Standardisation Organisations are mandated to:

- Analyse which harmonised standards adopted under Directives 93/42/EEC and 90/385/EEC are suited to give presumption of conformity to essential requirements of the R&TTE Directive.
- On the basis of this analysis to propose to the Commission such standards formally as harmonised standards under the R&TTE Directive, if necessary after revision.
- Maintain a work programme enabling to maintain coherence between standards develop under these three Directives.
- Report the progress of the work to the Commission at regular intervals and at least prior to each meeting of the TCAM⁵;

RECOMMENDATIONS

The experts should liaise intensively with regulatory bodies and their experts in both areas.

1. PROPOSED SCHEDULE

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| May 2003 | Adoption of harmonised standards |
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2. ALIGNMENT WITH INTERNATIONAL WORK

Where appropriate alignment with equivalent activities in the ITU and in ISO/IEC should be ensured.

3. STANDSTILL

For the terms of Article 7 of the Directive 98/34/EC, the standstill applies for the fields and risks covered by the standards developed or revised within the present mandate.

⁵ Telecommunications Conformity Assessment and Market Surveillance Committee, which is the standing Committee set-up by the Directive.

4. **PUBLICATION IN THE OFFICIAL JOURNAL OF THE REFERENCES OF THE STANDARDS**

A title and summary in the languages of the Community is required for each standard at the moment of the request by the European standardisation organisations of the publication of its references in the OJEC.