



Brussels, 13 June, 2002

M/320 EN

**Standardization mandate to CEN concerning the development of European
standards relating to medical devices**

(Subject: breast implants)

GENERAL

Several standardization mandates are already issued in the field of medical devices.

- Mandate BC/CEN/CENELEC/09/89 concerns active implantable devices
- Mandate BC/CENELEC/02/89 concerns horizontal aspects of medical devices.
- Mandate BC/CEN/03/023/93-08 is a general mandate to produce level 1, 2 and 3 standards. This mandate is further extended by mandate M/295.
- Mandate BC/CEN/03/91 concerns specifically condoms.
- M/252 covers the specific requirements for In-Vitro diagnostic devices.

This present mandate is a specific mandate to cover additional requirements for breast implants and relates to the Council Directive on Medical Devices: 93/42/EEC Directive on Medical Devices.

I BACKGROUND

Commission mandate M/023/93-08 included a request to prepare a standard to address the specific requirements for breast implants. Subsequently, CEN TC 285 developed a semi-horizontal standard on non-active surgical implants – General requirements (EN ISO 14630:1997). In addition work was established to develop a specific standard on mammary implants resulting in a document EN 12180-2000.

There have been a number of reports over the past 10 years in USA and Europe reflecting concerns in relation to post-market evidence suggesting the possibility of patient vulnerability due to the presence of certain characteristics of such implants (especially related to the materials used).

Following petitions introduced to the European Parliament in 1998, the European Parliament ordered a study on “Health risks posed by silicone implants in general with special attention to breast implants”. The study was carried out by a team of scientific advisers led by Prof. Moreno. The report presented¹ confirmed the absence of scientific evidence establishing a link between disease and silicone breast implants. It identified, however, that problems do occur, mainly because of the design and characteristics of the product. These relate mainly to bleeding (diffusion of small molecules of the liquid component of silicone through the intact shell), capsular contracture (shrinkage of the fibrous capsule, notable as an apparent hardening of the breast) and rupture of the shell (phenomenon that can be due to handling and trauma).

In the light of the parliament report, and subsequent discussions in the parliament and with national authorities, the Commission adopted on 15th November, 2001 a "Communication from the Commission on Community and national measures in relation to breast implants".²

It has been emphasised that any future work in developing standards addressing specific requirements for breast implants, is urgent and shall include the participation of all interested parties including, in particular, input from patient organisations.

II MOTIVATION AND NEEDS

It is recognized that the present standard EN 12180-2000 on Mammary implants, developed by the CEN working group on breast implants (CEN TC285 WG6), is not sufficient to address the conclusions reached between the Commission, the European Parliament and national authorities.

There is thus a need to further develop the standard EN 12180-2000 to cover the specific additional identified matters. These include the need for information on post-market surveillance, advice on information to be given both to the practitioner and to the potential patient and additional labeling requirements. Additional test requirements are also indicated.

III STANDARDIZATION MANDATE

Having identified the needs for further development of EN 12180-2000 on Mammary Implants the Commission assigns to CEN the task of preparing a revised version of this standard to identify and establish additional requirements as identified in the "Communication from the Commission on Community and national measures in relation to breast implants", COM (2001) 666 final. The

¹ Health risks posed by silicone implants in general, with special attention to breast implants. PE 168.396/Fin.St/rew; http://www.europarl.eu.int/stoa/publi/pdf/99-20-02_en.pdf

² COM (2001) 666 final.; http://europa.eu.int/comm/enterprise/medical_devices/com2001_666/com_2001_666_final-el.pdf

commission expects CEN to reconsider the standard in particular in relation to the contents of Annex 1 of the Commission communication.

Certain features, for which the need for revision of the standard has already been identified, include the following:

- Tests for establishing the potential migration of the filler (diffusion of small molecules of liquid component through the intact shell as experienced in silicon-gel filled breast implants).
- Consideration of the need for procedures to determine the resistance of the shell to abrasion and possible rupture. This could be caused by handling, trauma or capsular contracture. Potential problems of abrasion will be different in relation to alternative implant designs.
- In relation to the potential risks, consideration should be given to EN ISO 14971 “Medical devices – application of risk management to medical devices”. With the particular needs for clinical evaluation in relation to breast implants reference should be made to EN ISO 14155 “Clinical investigation of medical devices for human subjects. Part 1 (General requirements) and Part 2 (Clinical investigation plans)”.

Other elements should be considered as appropriate, taking into account Communication from the Commission - COM(2001) 666 final, for further development of the standard EN 12180-2000.

The Commission also invites CEN to consider the need for the manufacturer to improve information to be transmitted to the practitioner, and where appropriate, to pass to the patient, taking into consideration the various elements contained in Annex 2 of the Commission communication - COM(2001) 666 final.

Issues in relation to traceability and surveillance needs should be improved. Work should take into consideration the guidance given in CEN report CR 14060 “Medical device traceability”.

The Commission therefore invites CEN to prepare a further standard, bearing in mind matters of privacy and confidentiality, indicating how the manufacturer can institute and keep up-to-date the most appropriate systematic procedure to review experience gained with breast implants in the post-production phase. In this respect, the Commission invites CEN to consider how such improvements can be made whilst accepting the prime responsibility of Member States to ensure the appropriate patient information.

IV EXECUTION OF THE MANDATE

1. An indication of a provisional title for the identified work presented in a systematic manner, including a target date for a draft standard and for the final adoption, will be provided by CEN.
2. The work will be carried out in close consultation with the Commission, taking into account the fact that the concerned directives are already applied.

3. Within 6 months after the adoption the EN harmonized standard will be transposed into national standards. Divergent national standards will be withdrawn in the Member State of the European Union taking into account the transitional period indicated in the Directives.
4. Acceptance by CEN of this mandate will initiate the standstill period referred to article 7 of the Directive 98/34/EEC of 22 June 1998 (OJ no. L204 of 21 June 1998).
5. The Commission highlights the importance of the possibility for all interested parties, including patient organisations, to take part in or to be associated to the preparation of the work supported by this mandate.
6. If, during the drafting of the standards, the structure of this programme would need to be modified, CEN will have to inform the Commission who will then inform the Committee for Standards and Technical Regulations. This new or modified work will normally be included in the present mandate.
7. The Commission reserves the right to specify more precisely, if necessary, the terms of the mandate. The work following this mandate may be updated by common agreement if that proves to be necessary during the course of the work.