	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	**Recommendation** **NB-MED/2.5.5/Rec1**

Title:	**Conformity assessment procedures of breast implants**
Chapter:	**2.5.5** Conformity assessment procedures; **Conformity assessment for particular product groups**

Text:	**"..."**
Key words:	**Conformity assessment, breast implants**

The NB-MED Recommendation

NB-MED/2.5.5/Rec1 *Conformity assessment procedures of breast implants*

(stage 3, Rev.-Nr. 4, Rev. date 27.06.97.98)

was superseded by

the MedDev-document

MedDev 2.5/6 *Guidelines for conformity assessment of breast implants according to MDD*

(July 98,
distributed to NB-MED as **NBM/125/98**)

(reasons see also attached *Rationale and history sheet*)

A rationale and history sheet is available; please contact Technical Secretariat.

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD		
MDD	Annex: II, III	see chapter 3, references
IVDD		

Stage	**proposed by**	**Rev.-Nr.**	**Rev. date**	**accepted**	**amended**	**withdrawn**	**Page**
deleted		**5**	**03.02.2000**	**03.02.2000**			**1/6**

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	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	**Recommendation** **NB-MED/2.5.5/Rec1**
Title:	**Conformity assessment procedures of breast implants**	

~~Foreword~~

~~Due to continuous public interest and regulatory actions taken by some countries on manufacturing and distribution of breast implants the NB-MED Meeting on September 11 and 12, 1995 decided to establish a project group. The task of this group consisting of representatives of Notified Bodies, Competent Authorities, EQUAM, manufacturers and consumer groups was to develop recommendations for an adequate approach to be taken by Notified Bodies in conformity assessment procedures of those products.~~

~~1 Scope~~

~~Breast implants are usually Class IIb products, in some cases they are class III according to MDD, Annex IX, Rules 8, 13 or 17. This document is intended to give guidance to Notified Bodies for the conformity assessment of breast implants according to Annexes II and III of the MDD.~~

~~2 Recommendations~~

~~The product related hazards of breast implants can be divided into the following categories:~~

~~- hazards associated with the design and manufacture of the device~~

~~- hazards associated with the surgery and inherent hazards associated with the clinical use of breast implants.~~

~~In the following the hazards and the respective requirements to be considered are listed. The manufacturer must evaluate the risk associated with each hazard listed below. The second column of the table gives the respective requirements to be considered. The information is not exhaustive and can be completed by further considerations.~~

~~This information can be considered as a basis for the risk analysis which may be performed in accordance with prEN 1441.~~

~~2.1 Hazards associated with the design and manufacture of the device~~

~~Hazard~~	**~~Requirement~~**

~~Mechanical failure~~	~~Results of mechanical testing according to prEN 12180, 7.1 and adequate quality control at different steps of manufacture must be available.~~ ~~The aspects of aging and biodegradation have to be addressed in the technical documentation.~~
~~Capsular contraction~~	~~To be addressed in the clinical evaluation.~~
~~Lack of sterility of the product~~	~~The product must be supplied sterile. The EN 550 series of standards can be used where appropriate.~~ ~~The sterilization process must have been validated adequately and documented in the technical file.~~ ~~The validation must demonstrate the fulfilment of EN 556.~~
~~Lack of biocompatibility~~	~~Biological evaluation according to prEN 14630 and prEN 12180,6 and 7.1.7 in combination with EN 30993-1, ISO/DIS 14538, and prEN 1441, Annex B covers the risks to demonstrate conformity.~~
~~Physical/chemical incompatibilities~~	~~Data about compatibility between shell and filler must be available.~~
~~Osmotic changes~~	~~Data about the osmotic situation must be available, if applicable.~~
~~Interference with medical diagnosis and treatment~~	~~Information about possible interference with diagnosis and treatment must be addressed in the labelling.~~
~~Lack of traceability~~	~~prEN 12180, 11.6 has to be applied.~~

~~Limited lifetime~~	~~Expected lifetime of implants (stability after implantation) must be demonstrated according to available information and adequately documented. Data shall be available to justify expected lifetime of all components (durability and age related changes). The manufacturer has to provide adequate information in the instructions for use in relation to limitation of lifetime.~~
~~Unknown shelf-life~~	~~The expiry date based on stability data has to be given and is addressed in prEN 1041 and prEN 980~~

~~The Notified Body shall during the conformity assessment procedure review the clinical evaluation in the technical file in compliance with MDD, Annex I, Section 14 in conjunction with Annex X.~~

~~The manufacturer must institute and keep up to date a systematic procedure to gain and review experience from devices in the marketing phase including reviews of risk analysis and plans for any necessary corrective action. During each surveillance audit the Notified Body shall review the experience gained by the manufacturer in the marketing phase and the consequences taken.~~

~~2.2 Hazards associated with the surgery and inherent hazards associated with the clinical use of breast implants~~

~~Information about the risks associated with the surgery shall be provided in the labelling. These shall include:~~

~~1. clear indications for the use of the implant,~~

~~2. clear contraindications,~~

~~3. known adverse reactions,~~

~~4. a statement that breast implants are single use devices and must not be resterilized and/or reused.~~

~~Risks associated with lack of expertise of the surgeon and the need for follow up of the patient shall be addressed.~~

~~There are certain risks particularly inherent in the use of breast implants or postulated from their use. These are addressed specifically during consultation between physician and patient and subject to informed consent.~~

~~Note 1: The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken (MDD, Annex I, Essential Requirements, 13.6).~~

~~Note 2: The manufacturer of breast implants should refer in the instructions for use to the 'Patient Information and Consent Form on Silicone Breast Implants' developed and issued by EQUAM (European Committee on Quality Assurance and Medical Devices in Plastic Surgery) or equivalent information.~~

~~3 References~~

~~EN 550: 1994 Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization~~

~~EN 552: 1994 Sterilization of medical devices - Validation and routine control of sterilization by irradiation~~

~~EN 554: 1994 Sterilization of medical devices - Validation and routine control of sterilization by moist heat~~

~~EN 556: 1994 Sterilization of medical devices - Requirements for devices to be labelled 'Sterile'~~

~~EN 30993-1: 1993 Biological evaluation of medical devices - Part 1: Guidance on selection of tests~~

~~prEN 980: 1995 Graphical symbols for use in the labelling of medical device~~

~~prEN 1041: 1994 Terminology, symbols and information provided with medical devices; information supplied by the manufacturer with medical devices~~

~~prEN 1441: 1994 Medical devices - Risk analysis~~

~~prEN 12180 Non active surgical implants - Body contouring implants - Specific requirements for mammary implants~~

~~prEN 14630 Non-active surgical implants - General requirements~~

~~ISO/DIS 14538: 1996 Methods for the establishment of allowable limits for residues in medical devices using health based risk assessment~~

~~Note: This document refers to applicable standards. Other applicable solutions may be used by the manufacturer to demonstrate compliance with the essential requirements.~~

Rev. 4: Notified Body Meeting, Brussels, June. 24 & 25. 1997:
The draft document „Recommendation for conformity assessment procedures of -breast implants“ was revised on 25.09.96 and subject to discussion by the Medical Device Experts Group at their meeting on 25 February 1997. This document was prepared by NB-MED **Task Force „Conformity assessment for breast implants“** (Convenor: Dr. Müller-Lierheim/MDC; Members: Mr Binard/G-MED, Mr Chitarrini/,Laboratoires Sebbin, Mr Dawids/DMDC, Dr. de Jong/MENTOR Medical Systems, Dr. Eisenmann-Klein/Caritas Krankenhaus St. Josef, Mr Gügel/TÜV Product Service, Mr Hüser/Polytech Silimed Europe, Ms Jeanty/LPI - Laboratoire Perouse Implant, Dr. Laufer/Collagen/LipoMatrix, Ms Meyer/SSF, Mr Rentschler/MDC, Mr Thalen/IAPM, Mr Tinkler/MDA Medical Device Agency, Dr. Tschöpe/BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte, Ms White/McGhan, Mr Wild/SHG-D).
With some minor changes requested by the Medical Device Experts Group the document was tabled on the Notified Body Meeting on 24./25.06.97. The document was approved by the NB-MED plenary.

Meeting of NBR Group, Brussels, June 26 & 27 1997:
The NBRG has brought the document into the format of a NB-MED recommendation and issued it among their „stage 3“-recommendations. It was decided to give a proposal to the Medical Device Expert Group concerning a concluding discussion of the use of „shall“/“should“ and the consideration of *Liquid Implants*.
Confirmed at stage 3.
New revision no: 4

Meeting of NBR Group, Essen, September 29 & 30 1997:
It was decided to fit the document in the new *recommendations nomenclature system* (chapter **2.5.5** *Conformity assessment procedures;* ***Conformity assessment for particular product groups***). Therefore the recommendation gets the number **NB-MED/2.5.1/R1**.

Rev. 5: Notified Body Meeting, Brussels, November 2 & 3. 1999:
It was mentioned that the stage 3 Recommendation on breats implants needs some further development; since the adoption in 1997 the Commission has done a lot of work to this subject which is not be reflected by the present Recommendation. The French Competent Authority is waiting for a “strongest” Commission’s document to withdraw banning of such devices.

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Meeting of NBR Group, Brussels, November 3, 1999:
It was propsed by Mr. V. and subsequently agreed at the NBRG meeting that NB-MED Recommendation No. 2.5.5/Rec1 on Breast Implants should be withdrawn from the list of NB-MED Recommendations because a revised MedDev 2.5/6 is in preparation, the context of which more accurately identifies the requirements relating to this product. The revised MedDev will be included when agreed and published; in the meanwhile the former and existing MedDev 2.5/6 (issued as final draft 07/98) is still valid and supersedes this Recommendation. The Technical Secretariat was asked to rework the rationale & history of this Recommendation and the list of NB-MED Recommendations and to withdraw this Recommendation.

Meeting of NBR Group, Cologne, February 3, 2000:
NBRG agreed with tabled document and the described procedure to handle this Recommendation.
Confirmed at stage **delete**.
New revision no: 5