

## **MEDICAL DEVICES : Guidance document**

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**MEDDEV 2.10-2 Rev 1**

**April 2001**

(NOTE: For attachment 1 to 4 see separate documents)

### **DESIGNATION AND MONITORING OF NOTIFIED BODIES WITHIN THE FRAMEWORK OF EC DIRECTIVES ON MEDICAL DEVICES**

These guidelines aim at promoting a common approach by, the notified bodies involved in the conformity assessment procedures according to the relevant annexes of the Medical Devices Directives and by the Competent Authorities charged with safeguarding public health.

They have been carefully drafted through a process of consultation with various interested parties during which intermediate drafts were circulated and comments were taken up in the document. Therefore, this document reflects positions taken in particular by representatives of Competent Authorities, Commission services, Notified Bodies, industry and other interested parties in the medical sector.

These guidelines are not legally binding. It is recognised that under given circumstances an alternative approach may be possible to comply with the legal requirements.

Due to the participation of the aforementioned interested parties and of experts from Competent Authorities, it is anticipated that these guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions. It is intended that this document will also be useful to Regulatory Authorities, Designating Authorities and Conformity Assessment Bodies in the context of mutual recognition agreements with third parties.

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## I. INTRODUCTION

These guidelines describe in more detail the criteria and conditions for the designation of Notified Bodies in the framework of EC Directives on medical devices.

This guideline does not address the specific requirements for Notified Bodies dealing with in vitro diagnostic medical devices. It is intended that this guideline will be revised in due course to address the requirements of the directive relating to in vitro diagnostic medical devices. Directive 98/79/EEC of 7 December 1998 relating to in vitro diagnostic medical devices (IVMDD)<sup>1</sup>

Relevant legal requirements are laid down in :

- Directive 90/385/EEC of 20 June 1990 relating to active implantable medical devices (AIMD)<sup>2</sup> – Article 11; Annex 8
- Directive 93/42/EEC of 14 June 1993 relating to medical devices (MDD)<sup>3</sup> – Article 16; Annex XI
- Amendments to Article 16 in 93/42/EEC described in Directive 98/79/EEC of 7 December 1998 relating to in vitro diagnostic medical devices (IVMDD)<sup>4</sup>

Associated responsibilities are described in annexes 2,3,4 and 5 of the active implantable directive and annexes II, III, IV, V and VI of the medical devices directive.

Further provisions on the same subject are contained in Council Decision 93/465/EEC of 22 July 1993<sup>6</sup> concerning the modules for notification monitoring, co-ordination and operation of Notified Bodies as well as in the Guide to the implementation of directives based on New Approach and Global Approach; September 1999<sup>7</sup> and other documents of the "High Officials for Standardization Policy" (Appendix B). Special aspects for medical devices are addressed in the MEDDEV-documents (Appendix C). Furthermore reference is made to the European standards of the EN 45000 series where definitions of terms and principles of accreditation are laid down. Further European standards relevant to the subject are listed in Appendix D.

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<sup>1</sup> OJ L 331 of 7 Dec 1998

<sup>2</sup> OJ L 189 of 20 July 1990

<sup>3</sup> OJ L 169 of 12 July 1993

<sup>4</sup> OJ L 331 of 7 Dec 1998

<sup>6</sup> OJ L 22 of 30 August 1993

<sup>7</sup> <http://europa.eu.int/comm/enterprise/newapproach/legislation.htm>

Where, in this document, reference is made to “the Competent Authority responsible for designation”, this includes any appointed body, in particular accreditation body to which, in accordance with the national system, given tasks are assigned.

## **II. CRITERIA FOR THE DESIGNATION AND OPERATION OF NOTIFIED BODIES**

### **1. General requirements**

- a) Resources: The Notified Body shall provide the resources for conformity assessment of medical devices as specified in the directives in a competent, transparent, neutral, independent and impartial manner.

A body may be designated to offer the services set out in one or more of the relevant annexes of the directives.

The applicant must be capable of taking full responsibility for all tasks required of a Notified Body in relation to the (or those) annexe(s) of the directives and the medical devices for which it is being designated.

Once designated, the Notified Body shall, without delay, inform the Competent Authority responsible for designation of any change regarding availability of resources, including sub-contractors, and compliance with designation conditions which may have an impact on the maintenance of the designation and of the assignment of tasks.

- b) The Notified Body shall be a legally defined entity and shall make available to the Competent Authority responsible for designation on request:
- i. documentation clearly identifying its legal status;*
  - ii. documentation which clearly shows both the authority and the responsibility of individuals within, and the reporting structure within the Notified Body;*
  - iii. documentation about its financial situation.*
- c) If the Notified Body is a legal entity, which is part of a larger organisation, the links and relationship between the Notified Body and the larger organisation shall be clearly documented.

#### Guidance

- a) Where the Notified Body uses the services of a subcontractor, the Notified Body is responsible for all contracted actions of its subcontractor and shall be liable for them as if the Notified Body itself performed the action (see also clause 8 Subcontractor requirements).
- b) Where subcontractors are already notified/accredited in respect of the relevant requirements by the Competent Authority responsible for designation or the authorized national accreditation body, this may be taken into account by the Notified Body. They may be assumed to fulfil the requirements.

## 2. Independence requirements

- a) The Notified Body and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user \* of medical devices, nor the authorised representative of any of those parties engaged in these activities. The assessment and verification staff including subcontractors shall be impartial and free from engagements and influences, which could affect their objectivity, and in particular shall not be:
- involved in the design, construction, marketing, installation, servicing or supply of the devices within the scope of the audit;
  - involved in the design, construction, implementation or maintenance of the quality system being audited;

nor represent the parties engaged in these activities.

\* NB The term 'user' in this context is not meant to exclude the use of individual clinicians as assessment and verification staff.

- b) Links with manufacturers: The directors, executives and personnel (whether directly employed or subcontracted) responsible for carrying out the evaluation and verification activities shall be independent of both the manufacturers for whom the Notified Body conducts assessments and the commercial competitors of those manufacturers, during their employment by the Notified Body. They shall not have been involved in the design, construction, marketing or maintenance of the devices.
- c) Consultancy: Notified Body personnel (whether directly employed or subcontracted) shall not offer or provide (or have offered or provided) consultancy or advice to the manufacturer, the authorised representative, a supplier or their commercial competitor as regards the design, construction, marketing or maintenance of the products under assessment. <sup>8</sup>(see also clause 3 Impartiality requirements ).

### Guidance

- a) The Notified Body should have documented procedures for the identification, review and resolution of all cases where conflict of interests is suspected or proven. Records of such reviews and decisions should be kept.
- b) The Notified Body should require all staff acting on its behalf to declare any potential conflict of interest. Records of such declarations should be kept.
- c) Marketing material produced by the Notified Body should not give any impression that consultancy activities are offered.
- d) If the Notified Body is linked to any organisation which itself provides consultancy services, then the documented quality system of the Notified Body should include a policy statement and documented procedures ensuring that assessment and consultancy

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<sup>8</sup> Guide to the implementation of the directives based on new approach and global approach - dated September 1999.

services are separate. The Notified Body should ensure, by means of a documented agreement, that its subcontractors are aware of this guidance.

- e) Notified Bodies should refrain from offering to manufacturers, with whom they maintain a Notified Body relationship, additional markings unless these marks fulfil a different function from that of CE marking. Thus they should provide an added value in signifying conformity with objectives that are different from those to which CE marking relates. Such additional marks should not create confusion with the CE mark from the point of view of the parties who are likely to come into contact with them.<sup>9</sup>
- f) The requirements of this clause do not preclude exchange of technical information and guidance between a Notified Body and a company seeking their assessment.
- g) In relation to consultancy the notified body should take into account the period of time which has elapsed since any consultancy was offered on the design, construction, marketing or maintenance of the products in question. It is envisaged that after 5 years the relevance of the consultancy will be minimal but that this should be evaluated on a case by case basis by the notified body management and records kept (see also guidance a).

### **3. Impartiality requirements**

- a) The Notified Body shall guarantee the impartiality of all assessment and verification personnel and ensure that the remuneration of personnel shall not depend on the number of inspections and verifications that they carry out, nor on the results of their activities.
- b) The Notified Body shall ensure by implementation of documented procedures that personnel are free from pressures and inducements, particularly financial, which might influence their judgement during any assessment or inspection that they perform.

#### Guidance

- a) The Notified Body should document the means by which it ensures that the principle of impartiality is made known and safeguarded throughout its organisation.

### **4. Competence requirements**

- a) The Notified Body shall employ within the organisation the necessary administrative, technical, medical and scientific personnel, which possess satisfactory knowledge and experience relating to the medical devices, technologies and conformity assessment

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<sup>9</sup> Guide to the implementation of the directives based on new approach and global approach - dated September 1999.

procedures assigned to them. Knowledge and experience related to the scope of assignment of tasks shall include in particular:

- regulatory requirements and enforcement policies;
  - European and international standardization activities;
  - methodology of risk analysis and risk management regarding relevant medical technology, production methods and the applicable verification procedures; the personnel shall be capable of assessing the medical function and performance of devices and the processes to determine compliance with essential requirements especially for those cases where no specific standards are available;
  - clinical evaluation, conduct of clinical investigations and normal conditions of use of relevant medical devices.
- b) The Notified Body shall have documented the competence and training requirements for assessment and verification staff. Records shall be available to demonstrate that personnel have the appropriate experience and have received appropriate training relevant to the Notified Body's scope.
- c) Notified Bodies shall participate in co-ordination activities at European and/or national level in order to attain maximum coherence in performing conformity assessment.
- d) Notified Bodies carrying out assessments under annexes 2 and 5 of the active implantable medical devices directive, and annexes II, V and VI of the medical devices directive shall require that such quality system audits are conducted by a team that includes at least one member who is experienced in the evaluation of the technologies used by the manufacturer.

#### Guidance

- a) The management of the Notified Body should satisfy themselves that personnel who administered and perform assessment and verification operations are competent to fulfil the tasks required of them.
- b) One or more members of an assessment team involved in conformity assessment should be trained and/or experienced in each of the following skills, as relevant to the assessment being made. This includes in particular:
- i. *the assessment of design documentation and clinical evaluation data to determine that all aspects of the design are in compliance with the requirements of the regulations ( relevant to annexes 2(AIMDD)/II(MDD) and 3(AIMDD)/III(MDD));*
  - ii. *for sterile medical devices, microbiological assessment, including environmental control, and validation and routine control of sterilization process according to harmonised standards;*



- iii. *for devices in contact with human bodies, biocompatibility assessment (relevant to annexes 2(AIMDD)/II(MDD) and 3(AIMDD)/III(MDD)) according to harmonised standards;*
  - iv. *for devices manufactured from animal tissues, assessment of all aspects related in particular to sourcing of raw material, processing and inactivation/elimination of transmissible agents;*
  - v. *for active devices, assessment of safety and performance of programmable electronic systems including software;*
  - vi. *the application of statistical controls to device verification (relevant to all annexes);*
  - vii. *medicinal products.*
- c) Personnel involved in the assessment of quality systems (i.e. procedures according to annexes 2(AIMDD)/II(MDD), 5(AIMDD)/V(MDD) and VI(MDD)) should be qualified and capable of functioning in accordance with “Guidelines for regulatory auditing of quality systems of medical device manufacturers: Part 1 general requirements . The management of quality systems assessments should be in accordance with “Guidelines for regulatory auditing of quality systems of medical device manufacturers: Part 1 general requirements <sup>10</sup>.
- d) For each assessor, an up to date record<sup>11</sup> should be maintained and include the following information:
- i. *name of assessor;*
  - ii. *designated areas of competence and responsibility within the scope of activities for which the Notified Body has been notified;*
  - iii. *educational and professional qualifications, skills, languages;*
  - iv. *work experience (relevant to the activities being performed);*
  - v. *audits conducted;*
  - vi. *details of training<sup>12</sup> received relating to assessment activities, including training in the requirements of the directive(s), relevant standards and other appropriate documents.*

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<sup>10</sup> Available from the following sources <http://www.ghcf.org> document reference SG4(99)28 or appendix C MEDDEV 2.5/2

<sup>11</sup> Form for **the preparation of a curriculum vitae for a Medical Device Expert is enclosed at Attachment 1.**

<sup>12</sup> **An example of a training course format is enclosed in Attachment 2.**

- vii. *for all auditors, including sub-contractors, documentation to confirm that there has been no conflict of interest concerning the manufacturers audited .*

## **5. Internal procedures and facilities - requirements**

- a) The Notified Body shall have appropriate structures and procedures to ensure that conduct of conformity assessment and issuing of certificates is subject to a review process. Relevant procedures shall in particular address obligations and responsibilities in relation to suspension and withdrawal of certificates, imposition of corrective measures to manufacturers and reporting to Competent Authority.
- b) The Notified Body shall have available the appropriate facilities to enable it to carry out the assessment and verification activities for which it has been notified.

### Guidance

- a) The facilities should enable the Notified Body to perform the technical and administrative tasks connected with evaluation and verification, whether those tasks are carried out by the Notified Body itself or under its responsibility (see also clause 8).

The Notified Body shall apply appropriate procedures of quality control in relation to services provided.

If verification and testing procedures require use of technical equipment normally controlled and used by the manufacturer, the Notified Body should be able to demonstrate that it both had access to, and full control of, the equipment during the relevant procedures. In addition, the Notified Body should be able to demonstrate that the technical equipment was appropriately maintained, serviced and in calibration at the time when verification and testing procedures are conducted.

## **6. Confidentiality requirements**

- a) The Notified Body shall have made adequate arrangements to ensure confidentiality of the information obtained in the course of carrying out its tasks under the regulations. These arrangements shall ensure that no details, records, results or information of any kind are disclosed to any other party except the relevant Competent Authorities and the manufacturer.

### Guidance

- a) Documented procedures should describe the means by which the Notified Body maintains confidentiality between itself and the manufacturer. These should include the mechanism through which assessment personnel are made aware of confidentiality requirements. For example staff may be required to give a written undertaking not to divulge any information gained about clients to third parties.

- b) Guidance subclause 6(a) does not relate to :
- i. *the provision of access to certification information requested by other Notified Bodies or Competent Authorities in accordance with the directives, or,*
  - ii. *the requirement to communicate information relating to the issue, refusal, suspension or withdrawal of certificates to Competent Authorities and other Notified Bodies, or;*
  - iii. *information pertaining to devices that when correctly put into service and used in accordance with their intended purpose have been found to compromise the health and/or safety of patients or users.*

## **7. Liability insurance – requirements**

- a) Provisions for misadventure : the Notified Body shall take out appropriate liability insurance to provide for claims and litigation in the event of misadventure, unless liability is assured under the domestic legislation of the Member State responsible for the designation of the Notified Body.

### Guidance

- a) The scope and overall financial value of liability insurance should correspond to the level of activities of the Notified Body. The liability insurance should in particular cover cases where the Notified Body may be obliged to withdraw or suspend certificates.
- b) The coverage of liability insurance should be notified to the Competent Authority.
- c) The coverage of liability insurance should be notified to the manufacturer on request.

## **8. Subcontracts – requirements**

- a) Contract requirements: where specific tasks relating to conformity assessment are carried out by subcontractors, the Notified Body shall ensure that these subcontractors conform to all the requirements of the regulations that would apply, had the task been performed by its own personnel. The manufacturer's approval shall be obtained before activities are subcontracted.
- b) Limitation to scope: the Notified Body shall not subcontract the overall responsibility for reviewing the outcome of assessment and verification activities, which are the essential tasks for which it was notified. Subcontractors shall fulfil only an objective role, that is, one, which is restricted to factual reporting and/or supported recommendations, on the basis of which the Notified Body shall make assessments and judgements in relation to the requirements of the regulations.
- c) Documented agreement: a documented agreement shall be drawn up between the Notified Body and the subcontractor reflecting these requirements, including

confidentiality and the provision of access for the Competent Authority. This agreement shall also prohibit subcontractors from further subcontracting their duties.

- d) Subcontractor's documentation: the Notified Body shall ensure that the subcontracted activities are carried out according to detailed documented procedures which are the same as, or judged by the Notified Body to be equivalent to, those followed by the Notified Body itself in the context of conformity assessment.
- e) Competence: the competence of subcontractors may be assumed where they are accredited by the Competent Authority or the authorised national accreditation body according to Annex XI of 93/42/EEC or Annex 8 of 90/385/EEC and EN 45001 for the scope under consideration..
- f) Register: the Notified Body shall inform the Competent Authority of its intention to subcontract duties in relation to the scope for which it was appointed. The Notified Body shall keep an up to date register of all its subcontractors, which shall be provided to the Competent Authority responsible for the designation on request. The Notified Body shall maintain documentary evidence that the subcontractor has the necessary technical competence and facilities to carry out the subcontracted activities.

#### Guidance

- a) A Notified Body, which subcontracts duties in relation to the scope for which it was notified remains in all cases responsible for all activities, covered by the notification. The Notified Body should determine and specify in advance the tasks to be carried out (e.g. test plans). Subcontracting does not entail the delegation of powers of responsibilities. The subcontractor register maintained by the Notified Body should include the following information:
  - i. *the name of the subcontractor,*
  - ii. *its legal status and details of any relationship with a parent company, group of companies, or any other organisation to which the subcontractor is linked,*
  - iii. *names of staff carrying out the subcontracted activities and evidence that they are competent to do so (see also clause 4);*
  - iv. *the precise duty performed by the subcontractor (e.g. auditing, testing, etc.) and details of the procedures used in carrying out the subcontracted duties*
- b) A Notified Body which subcontracts duties should document the means by which it ensures that the principle of impartiality is made known to subcontractors and safeguarded by the subcontractor carrying out tests or audits on behalf of the Notified Body.
- c) The conditions of this clause apply to any subcontractor whether or not it is located on Community territory. Subcontractors are not necessarily resident in the Community but their activities are defined by contract, which is interpreted under the law of the Member State responsible for the designation of the Notified Body.

## 9. Notified Body's quality system – requirements

- a) The Notified Body shall establish and maintain up to date documented procedures and records which, together, demonstrate its compliance with the regulations. As appropriate, this documentation shall include the following.
  - i. *a description of the legal status of the Notified Body, including the links and relationship with parent organisation, if relevant,*
  - ii. *documentation showing the responsibilities and reporting structure of the Notified Body,*
  - iii. *a rationale for defining the scope of the responsibilities for each of the assessment personnel,*
  - iv. *the names of assessment personnel, both internal and subcontracted, their assessment responsibilities, and records of their relevant training and experience (see also clause 4);*
  - v. *procedures for the identification review and resolution of all cases where conflict of interests is suspected or proven;*
  - vi. *a description of the application process by which manufacturers can obtain third party approval by the Notified Body. The document shall specify which languages are acceptable for submissions and correspondence from manufacturers relating to their demonstration of compliance with the requirements of the directives,*
  - vii. *procedures to review applications in respect to the manufacturer's classifications of his medical devices,*
  - viii. *procedures to review the completeness of application against the details provided in the annex under which approval has been sought,*
  - ix. *procedures to evaluate and verify manufacturers' compliance with their chosen annexes,*
  - x. *procedures detailing the rationale for fixing time limits for completion of evaluation and verification activities,*
  - xi. *procedures for the demarcation between other Directives such as 65/65/EEC,*
  - xii. *procedures for the assessment of clinical data: if applicable, where the results have been derived from clinical investigations the Notified Body shall ensure that the conclusions drawn by the manufacturer are valid in the light of the plan of clinical investigation submitted to the Competent Authority.*
  - xiii. *procedures to take account of information on medical devices subject to pre-existing national law, regulations or administrative provisions,*
  - xiv. *records to demonstrate the conclusions of the assessment including a reasoned evaluation of the manufacturer's compliance with the requirements of the relevant*

*directive. For quality assessments, records should be available which provide a discernible audit trail (e.g. procedures, processes, records, products etc that were assessed),*

- xv. *procedures for the consideration of appeals against decisions made by the Notified Body regarding :*
  - \* *the interpretation of classification rules, including referral to the Competent Authority where necessary;*
  - \* *a manufacturer's compliance with the requirements of the directives.*
- xvi. *procedures relating to the issue, expiration, withdrawal and suspension of certificates, including action to be taken in the event of the Notified Body learning that a CE mark has been wrongly affixed to a device or to a product outside the scope of medical devices directives. These procedures shall include a requirement to inform the Competent Authority forthwith of any such action taken,*
- xvii. *details of obligations regarding communications with other organisations, including Competent Authorities, the Commission and other Notified Bodies (ie about all certificates suspended or withdrawn and on request about certificates issued or refused and any additional relevant information), and the means adopted for these communications. The documentation shall also include records of all communications with the Commission and action taken as a result of such communications. (e.g. in respect to safeguard issues) These records shall be made available to the Competent Authority on request,*
- xviii. *procedures for assessing and monitoring the competence of subcontractors, if used,*
- xix. *details of record keeping facilities including means to ensure security and confidentiality,*
- xx. *details about liability insurance,*
- xxi. *documentation about its financial situation, including accounts,*
- xxii. *details about fees and financial conditions for the conduct of conformity assessment,*
- xxiii. *procedure for the provision of information in relation to the EUDAMED database.*
- b) **Control:** a system shall be maintained to control all quality system documentation and to ensure that current issues of procedures are available at all relevant locations
- c) The Notified Body shall ensure that the defined quality system procedures are effectively implemented

## Guidance

- a) The description of the application process, subclause 9a(vi.), may be the “description of the certification system” required to be made available in published form by the EN45000 series of standards

### **III. RELATIONSHIP BETWEEN COMPETENT AUTHORITY RESPONSIBLE FOR DESIGNATION AND NOTIFIED BODIES**

#### **1. Reporting**

Notified Bodies shall without delay inform the Competent Authority responsible for their designation of any changes/additions to personnel, facilities or subcontractors which might affect their ability to cover the Annexes and product range which they have been designated (e.g. change in management, replacement/addition/loss of specific expertise, change in facilities).

Information on Certificates suspended or withdrawn must be forwarded without delay to the Competent Authority and other Notified Bodies for information and also forwarding to EUDAMED. On request, the Notified Body shall provide information about certificates issued or refused and shall also make available all additional relevant information.

#### **2. Designation of Notified Bodies operations by the Competent Authority responsible for designation.**

Pre assessment prior to designation by the Competent Authority.

**Scope:** Prior to designation by the Competent Authority there will be a pre-assessment to ensure that the candidate Notified Body fulfils the requirements detailed in section II of this document. The Competent Authority will obtain evidence about the competence and independence of the candidate Notified Body and its subcontractors by an assessment of relevant documentation. If successful the Competent Authority will inform the Commission and Member States ref. article 11 of the AIMDD, and article 16 of the MDD.

**Timing:** The pre-assessment of the candidate Notified Body should take place within six months after their application to the Competent Authority for designation.

**Personnel:** Assessment personnel shall be competent for the functions they perform. They shall have knowledge and experience in Medical Devices Directive regulations, the EN 45000 and EN46000 series and other harmonized standards, and the application of this document.

**Reference document:** Section II and the relevant Appendices of this document. Annex 8 of the AIMDD and Annex X1 of the MDD



### **3. Monitoring of Notified Bodies operations by the Competent Authority responsible for designation.**

#### **A. Initial and Surveillance Audits**

Initial and surveillance audits are performed by the Competent Authority at a Notified Body's, and if applicable its subcontractor's, facilities

Scope: Initial audits are intended to cover all the operational activities set out in section II and the relevant Appendices of this document in order to check compliance against the Directive/Regulations/Standards and the body's own procedures. Surveillance audits are intended to cover specific operational activities set out in section II and the relevant Appendices of this document in order to check compliance against Directive/Regulations/Standards and the body's own procedures. Special attention should be focused on case review of the certification process under all the Annexes within the notified body's scope including initial application by the manufacturer to the Notified Body, assessment, certification and ongoing manufacturer surveillance.

Frequency: Initial audits are the first audits performed by the Competent Authority.

Surveillance audits of the Notified Body site should take place at least every 18 months unless the Notified Body has performed no assessments since the previous surveillance. However such audits could be brought forward if considered necessary for example

- Major problems at initial or previous surveillance audit.
- Extension to scope
- Significant vigilance or regulatory compliance cases for a manufacturer covered by the Notified Body
- Complaints received on a Notified body
- Large volume of work

Subcontractors who are solely carrying out a testing function need not be audited if they have national accreditation for those tests and fulfil the relevant criteria of Annex 8 of 90/385/EEC or Annex XI of 93/42/EEC. However it may be necessary to perform random surveillance audits on sub-contractors carrying out tests for which they have no such accreditation.

Personnel: Audit personnel shall be competent for the functions they perform. The team should consist of assessors with knowledge and experience in Medical Devices Directive regulations, the EN 46000 series and harmonized standards, and the application of this document with related medical expertise and medical devices specialists if review of design dossiers or testing is involved.

Duration: This will depend on the scope of Annexes and products covered, along with the number of clients for which certification has been granted. A minimum of 3 man days should be applied for initial audits and a minimum of one man day should be applied for surveillance audits.

Reference document: section II and the relevant Appendices of this document

## **B. Observed audits**

Observed audits are performed by the Competent Authority during a Notified Body Quality Assurance audit of a manufacturer during the process of an Annex 2(AIMDD) /II(MDD), 5(AIMDD)/V(MDD)/ and VI(MDD) approval or where design dossier review or NB testing is carried out by the Notified Body at the manufacturer's site.

Scope: Observed audits are intended to cover specific operational activities in order to check the Notified Body's compliance against the Directive/Regulations/Standards and the body's own procedures. Where a pre-assessment is performed as part of the overall assessment this should also be "observed" (Note: wherever possible relevant observed audits should be conducted during a full Notified Body assessment rather than a more limited interim assessment by the Notified Body)

Frequency: observed audits of the Notified Body may be considered under the following circumstances but at least every 18 months:

- one of the Notified Body's first QA assessments following designation;
- the number of certificates granted
- where relevant in conjunction with, or as a result of, an initial or surveillance audit
- extension to scope
- significant vigilance or regulatory compliance cases for a manufacturer covered by the Notified Body
- complaints received on a Notified Body
- where testing is carried out by the Notified Body at the manufacturer's site.
- significant growth involving new personnel, training methods, etc
- large volume of work

Personnel: The assessor should have knowledge and experience in Medical devices directives regulations, the EN 46000 series and harmonised standards and the application of this document see also initial and surveillance audits.

Duration: dictated by Notified Body's audit plan

Reference Documents:

- Guidelines for regulatory auditing of quality systems of medical device manufacturers: Part 1 general requirements.
- The responsibilities of the Notified Body under the Medical Device Directives Document, Attachment 3,
- Special rules of accreditation for Certification Bodies of Quality Systems (scope "Sterile Medical Device"), Attachment 4.

**C. Spot checks**

Competent Authorities should follow up with Notified Bodies specific cases, which have been reported to them (eg Vigilance reports, regulatory compliance cases, information received from other Competent Authorities)

## **A1. Introduction**

The following requirements are detailed in the specific annexes of the Directives under which Notified Bodies offer their services. Further details can be found in the relevant annexes of the particular directives. A document detailing the responsibilities of the Notified Body under Medical Device Directive 93/42/EEC is at attachment 3.

## **A2. Annex 2 of AIMDD and Annex II of MDD**

### a) Quality system

- i. Notified Bodies have to approve the quality system, which must ensure that the medical devices conform to the provisions of the relevant Directive, which apply to them at every stage, from design to final inspection. Based on relevant technical documentation, Notified Bodies shall review the elements, requirements and provisions adopted by the manufacturer including those in relation to fulfilling the essential requirements including the risk analysis. This shall be performed in reference to the class of the device. The documentation samples shall be chosen to reflect the risks associated with the intended use for the device, the complexity of the manufacturing technologies, the range of devices produced and any available post market surveillance data;
- ii. Notified Bodies shall ensure that personnel (whether directly employed or subcontracted) carrying out quality assurance audits are appropriately trained and experienced in the application of the Medical Devices Regulations and relevant harmonised standards;
- iii. Notified Bodies and/or their subcontractors shall have appropriate facilities for conducting quality systems audits on manufacturers' premises. They shall ensure that the outcome of the evaluation, notified to the manufacture after the inspection, includes a reasoned evaluation;
- iv. The Notified Body shall have documented procedures for dealing with notifications from manufacturers of proposed changes in their certified quality systems or the product-range covered. They shall ensure that manufacturers are informed as to whether the modified quality system will meet the requirements of the relevant directive. This decision shall include a reasoned evaluation.

### b) Design dossier

- i. The Notified Body shall have procedures, sufficient expertise and facilities for the examination of design dossiers, relating to active implantable medical devices or class

III medical devices. Appropriately qualified personnel shall carry out examination of design dossiers.

- ii. For dossiers covering devices which incorporate a medicinal product acting in a manner ancillary to that of the device, the Notified Body shall have procedures to identify such devices and, in consideration of the application, enable consultation with the relevant authority for medicinal products. The Notified Body shall ensure its final decision is communicated to the authority consulted. A description of the consultation process is given in MED DEV 2.1/3.
  - iii. The Notified Body shall have procedures for the production of EC design examination certificates. The certificates should include their conditions of validity, the data needed for identification of the approved design, and (where appropriate) a description of the intended use of the product.
  - iv. The Notified Body shall have procedures for checking the significance of changes to the design dossier notified by the manufacturer: this shall include an evaluation of whether appropriate changes have been made to the manufacturer's quality system. Approval shall be given in the form of an addendum to the EC design-examination certificate.
- c) Surveillance
- i. The Notified Body shall have procedures, which define how and when surveillance inspections and evaluations of manufacturers' quality systems are to be carried out and how unannounced visits to manufacturers are to be conducted. Manufacturers shall be supplied with evaluation reports following all inspections.
- d) Administration procedures
- i. The Notified Body shall have facilities for communicating all relevant information on approvals of quality systems issued, refused, suspended or withdrawn to the Competent Authority and other Notified Bodies on request.

### **A3. Annex 3 of AIMDD & Annex III of MDD**

#### a) Type examination

- i. The Notified Body must carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of the Directive. All relevant and critical parameters shall be verified by the Notified Body or subcontractor under its responsibility.
- ii. Notified Bodies and/or their subcontractors shall have suitable facilities and procedures to examine and evaluate the documentation, to verify that the type has been manufactured in accordance with the documentation, and for performing the

appropriate inspections and tests to verify compliance with the essential requirements, including risk analysis, of the relevant directive.

- iii. The Notified Body shall make provision to issue an EC type-examination certificate to the manufacturer where the type meets the provisions of the relevant directive. It shall contain the name and address of the manufacturer, the conclusions of the control, the conditions under which the certificate is valid and the information necessary for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate.
  - iv. For devices which incorporate a medicinal product acting in a manner ancillary to that of the device, the Notified Body shall have procedures to identify such devices and, in consideration of the application, enable consultation with the relevant authority for medicinal products. The Notified Body shall ensure its final decision is communicated to the authority consulted
  - v. The Notified Body shall have documented procedures for reviewing changes to the approved product. When the change is considered to be satisfactory, they shall issue to the manufacturer a supplement to the initial EC type-examination certificate.
- b) Administration procedures
- i. The Notified Body shall have facilities for communicating all relevant information on EC type-examination certificates and supplements issued, refused, suspended or withdrawn to the Competent Authority and other Notified Bodies when requested.

#### **A4. Annex 4 of AIMDD and Annex IV of MDD**

- i. The Notified Body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Directive. Relevant and critical parameters shall be tested by the Notified Body or under its responsibility.
- ii. Notified Bodies and/or their subcontractors shall have available suitable facilities and procedures for examination and testing of products to verify that they conform to the requirements of the relevant directive.
- iii. The Notified Body shall make provision for examining and testing products on a statistical sampling basis for each homogeneously produced batch or, in addition for the medical devices directive on an individual product basis, and draw up a written certificate of conformity relating to the tests carried out
- iv. The Notified Body shall have procedures to ensure that any rejected product or batch of products is prevented from being placed on the market and in the case of frequent rejection of batches to suspend statistical verification.

#### **A5. Annex 5 of AIMDD and Annex V-VI of MDD**

a) Quality system

- i. Notified Bodies have to approve the quality system for the manufacture and final inspection of the products concerned. The quality system must ensure that the medical devices conform to the type described in the EC type-examination certificate or the technical documentation, respectively. Based on relevant technical documentation Notified Bodies shall review the elements, requirements and provisions adopted by the manufacturer including those in relation to fulfilling the essential requirements including the risk analysis. The documentation samples shall be chosen to reflect the risks associated with the intended use for the device, the complexity of the manufacturing technologies, the range of devices produced and any available post market surveillance data;
- ii. Notified Bodies shall ensure that personnel (whether directly employed or subcontracted) carrying out quality assurance audits are appropriately trained and experienced in the application of relevant harmonised standards.
- iii. Notified Bodies and/or their subcontractors shall have appropriate facilities for conducting quality systems audits on manufacturers' premises. They shall ensure that the outcome of the evaluation, notified to the manufacture after the inspection, includes a reasoned evaluation.
- iv. The Notified Body shall have documented procedures for dealing with notifications from manufacturers of proposed changes in their certified quality systems. They shall ensure that manufacturers are advised as to whether the modified quality system would meet the requirements of the relevant directive. This decision shall include a reasoned evaluation.

b) Surveillance

- i. The Notified Body shall have procedures, which define how and when surveillance audits and evaluations of manufacturers' quality systems are to be carried out and how unannounced visits to manufacturers are to be conducted. Manufacturers shall be supplied with evaluation reports following all audits.

c) Administration procedures

- i. The Notified Body shall have facilities for communicating all relevant information on approvals of quality systems issued, refused, suspended or withdrawn to the Competent Authority and other Notified Bodies on request.

**Certif-Document** <sup>(13)</sup>:

**96/03 rev 4 Procedure for designation of conformity assessment bodies(CABs) under mutual recognition agreements (MRAs) with non member countries.**

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<sup>(13)</sup> (Certif.Documents are working documents of the Senior Officials Group for Standardisation, chaired by the European Commission - DG ENTERPRISE -Directorate G. They can be request at CEC-DG ENTR/G/1 - tel.+32-2-295 13 04)



**APPENDIX - C**

**LIST OF GUIDANCES DOCUMENTS ON MEDICAL DEVICES**

*"" see last Updated Guidance in web site Unit G/4""*

**APPENDIX - D**

**Council directive 93/42/EC in relation to Medical Devices.**

**Harmonized standards**

Collated list of harmonised standards available at the following web address:  
<http://www.europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/>

OJ C 245 of 23 August 1996

OJ C 149 of May 17 1997

OJ C 338 of November 8 1997

OJ C 362 of December 6 1997

OJ C 144 of May 9 1998

OJ C 268 of August 27 1998

OJ C 181 of June 26 1999

OJ C 277 of August 10 1999

OJ C 288 October 9 1999

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**Attachments 1 to 4 : See on separate documents**