

UK MEDICAL DEVICES NOTIFIED BODY GROUP

UK POSITION PAPER (Nov 1997 plus Annex IV)

**The Responsibilities of the Notified Body
Under Medical Device Directive 93/42/EEC**

1. Scope

To define the responsibilities of the Notified Body when undertaking certification to Annexes II, III, IV, V and VI, and then to indicate the level of competency required by the assessment team.

2. Background

These outline responsibilities are those directly required of the Notified Body by the directive disregarding any current national practice. They were agreed by joint meetings of the UK Competent Authority, UK manufacturers (ABHI) and delegates representing all UK Notified Bodies.

3. Requirements of the Notified Body

3.1 General

3.1.1 To check the manufacturer has followed his declared procedures and those required by the directive. The manufacturer through the EC Declaration of Conformity takes the ultimate responsibility for device safety and product liability. The Notified Body has a responsibility to monitor the manufacturer's system for producing the Declaration of Conformity for all Classes of device except Class 1 (non sterile/non measuring).

3.1.2 To agree the device classification with the manufacturer and whether the application is within the scope of the directive. The manufacturer will be asked to submit a classification of his device or device category at the application stage for consideration by the Notified Body. The final responsibility for classification remains with the manufacturer.

3.1.3 To refer to the Competent Authority instances where previously agreed clinical trial protocols have not been followed.

3.1.4 To check the correct use of the CE mark.

- 3.1.5 To ensure the manufacturer has informed the Notified Body of any significant changes to its products, processes or QA systems since the last audit.
- 3.1.6 To check the manufacturer's procedure for reviewing experience in the post-production phase.

Note: 3.1.1, 3.1.5 and 3.1.6 do not normally apply for certification under Annex III and IV.

3.2 Annex II

- 3.2.1 To audit the quality systems to the requirements of Annex II using the current EN 46001 as a basis for the audit (EN 46001:1996 as of 6/97) plus regulatory requirements of 93/42/EEC. There is no requirement in the Directive for the Annex II assessment to be different depending on whether Class IIa or IIb devices are involved.
- 3.2.2 If sterilisation or sterility are involved to include a technical evaluation by a suitably competent person.
- 3.2.3 To assess that the procedures for process control, inspection and testing are appropriate for that type of device and are in conformity with those indicated in the technical documentation.
- 3.2.4 To assess the procedures for controlling, monitoring and verifying the design of the device and its compliance with the requirements of the directive. To assess the capability of the manufacturer to use and interpret in the design process the essential requirements and the relevant standards for all product technologies used by the manufacturer. This includes checking the procedures for producing the Declaration of Conformity, and checking the content of the Declarations themselves on a sample basis to gain confidence that they are in the correct format and properly specify the products to which they apply. There is no requirement to check technical files for every device, but some should be checked on a sample basis as part of the audit of the design process (including use of clinical data, risk analysis and other technical assessments) in order to gain confidence that the products meet the ERs.
- 3.2.5 For Class 3 devices to undertake an EC Design Examination. The objective is to confirm that the product conforms to the relevant provisions of the Directive by verifying the items listed below.
 - the conclusions of the risk analysis;
 - that the applicable essential requirements have been addressed;

- that relevant standards have been applied or that the solutions adopted, in the absence of standards, meet the essential requirements;
 - the conclusions of the clinical data.
 - The Notified Body may require further tests or other data during this procedure.
- 3.2.6 - For Class III devices only, the Notified Body must also approve changes which could affect the product's conformity with the Essential Requirements or the conditions of use.

3.3 Annex III

- 3.3.1 To verify that the device is in conformity with the technical documentation.
- 3.3.2 To agree with the manufacturer which standards or protocols are applicable and which tests are required to verify compliance with the Essential Requirements.
- 3.3.3 To test or inspect to verify the solutions satisfy the Essential Requirements:
- using standards referred to in Article 5 where it is agreed that these apply;
 - or using other standards or protocols designed by the manufacturer where it is agreed that these verify compliance with the Essential Requirements.
- 3.3.4 To verify conclusions drawn from clinical data, risk analysis and other technical assessments.
- 3.3.5 To issue, if relevant an EC type-examination certificate with five-year validity.
- 3.3.6 When a manufacturer informs the Notified Body that a device previously granted an EC type Examination Certificate has undergone a significant change, to reassess the device prior to the manufacturer placing the changed device on the market.

3.4 Annex IV

- 3.4.1 To verify that the type is in conformity with the technical documentation.

- 3.4.2 Prepare a plan to ensure sufficient and consistent application of tests and inspections.
- 3.4.3 To test each product or, where the batch size exceeds 50 and the manufacturer does not choose otherwise, random samples taken from a homogeneous batch according to the sampling plan described in Annex IV.
- 3.4.4 If relevant, to prepare an Annex IV verification certificate specific to the product and limited to the batch or samples subjected to the verification process.
- 3.4.5 To ensure that the identification number of the Notified Body appears adjacent to the CE mark.
- 3.4.6 To take measures to prevent non-conforming samples or batches from being placed on the market.
- 3.4.7 For products supplied sterile¹, to ensure that the appropriate parts of Annex V have been applied.
- 3.4.8 As a non-statutory duty, the Notified Body may wish to examine the declaration of conformity, the technical documentation and the undertakings of the manufacturer.

3.5 Annex V

- 3.5.1 To audit the quality systems to the requirements of Annex V using the current EN 46002 as a basis for the audit (EN 46002:1996 as of 6/97) plus the regulatory requirements of 93.42.
- 3.5.2 For Class 2b and 3 devices, to check the validity of the EC Type Examination Certification and that production conforms to the type certificated. There is no responsibility to check the validity of the design solution, test reports, clinical data etc. This is the responsibility of the Notified Body that undertakes the EC Type Examination.
- 3.5.3 For Class 2a devices, to check procedures for controlling technical documentation and production conformity. Although there is no requirement to check all technical files for Class IIa devices, their content should be checked on a sample basis to gain confidence that the manufacturer is following the appropriate procedures and the Declarations are in the correct format. This should be checked on a sample basis for every product technology used by the manufacturer.
- 3.5.4 As for 3.2.2.
- 3.5.5 As for 3.2.3.

¹ The Annex IV conformity route is of limited application for sterile products.

3.6 Annex VI

- 3.6.1 To audit the quality system to the requirements of Annex VI using ISO 9003:1994 as a basis for the audit (when an EN 46003 is issued the current version will be the basis for the audit).
- 3.6.2 Unless 100% testing is carried out, to check that production is homogenous enough to allow sample inspection/testing. To check that final testing/inspection demonstrates continuing conformance to the EC Type Examination certificate or the relevant technical documentation.
- 3.6.3 To check the validity of the EC Type Examination certificate or technical documentation including user instructions and labelling.

4. **Competency Criteria for Assessment Teams**

4.1 Annex II

4.1.1 The assessment team shall include experience in:

- EN 46000 and the directive;
- the assessment of medical device manufacturers;
- the technology involved – including relevant harmonised standards.

4.1.2 For sterile devices the assessment team shall include a suitably competent assessor/expert.

4.1.3 The assessment team shall include a member with knowledge of the design criteria and solutions and harmonised standards appropriate to the device under assessment.

4.1.4 For Class 3 devices relevant experience of design reviews will be necessary.

4.2 Annex III and IV

4.2.1 The Notified Body must possess the relevant product specific expertise and competence and have access to the appropriate testing and inspection capability.

4.3 Annex V and VI

4.3.1 As for 4.1.1 and 4.1.2.