

THE NOTIFIED BODY

BULLETIN No. 6

COMPETENT AUTHORITY(UK)
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INTRODUCTION

This bulletin explains the role of Notified Bodies in the EC-wide system of medical device regulation introduced under the medical devices Directives.

MEDICAL DEVICES DIRECTIVES

There are three European Directives concerning medical devices:

The Medical Devices Directive(93/42/EEC): as amended in Directives 2000/70 and 2 DIRECTIVES 001/104 on medical devices incorporating stable derivatives of human blood or human plasma

The Active Implantable Medical Devices Directive (90/385/EEC)

The In *Vitro* Diagnostic Medical Devices Directive (98/79/EC)

These have been implemented into UK legislation by the Medical Devices Regulations 2002, which consolidates all the existing medical devices Regulations into a single piece of legislation and which came into force on 13 June 2002. The main purpose of these Regulations is to bring about the completion of the single market by introducing harmonised and statutorily based controls to regulate the safety and performance of devices throughout the European Union. The Directives replace any existing national systems in Member States and include provisions for mandatory CE marking of products within their scope, except for certain specific exclusions.

Before a manufacturer can affix the CE marking (see Bulletin 2), allowing free circulation of products throughout the EC, a device will have to comply with the requirements of the relevant Directive, and in particular to essential requirements on health and safety.

CONFORMITY ASSESSMENT

The methods manufacturers use to demonstrate that devices comply with these requirements will vary depending on which Directive applies and on whether a device is classed as low, medium or high risk. These methods, known as conformity assessment procedures, are set out in the annexes to the Directives and are discussed more fully in Bulletins 4 and 20.

The organisation that will check whether the appropriate conformity assessment procedures have been followed for medium and high risk devices, and for low risk medical devices marketed in a sterile condition or with a measuring function, is known as a Notified Body. Where a Notified Body is involved in the CE marking the CE mark will be accompanied by the Notified Body's identification number.

WHAT IS A NOTIFIED BODY?

A Notified Body is a certification organisation which the national authority (the Competent Authority) of a Member State designates to carry out one or more of the conformity assessment

procedures described in the annexes of the Directives. The Medicines & Healthcare products Regulatory Agency is the UK Competent Authority under the three **Medical Devices Directives**.

A Notified Body must be qualified to perform all the functions set out in any annex for which it is designated. The designation may be restricted to specified types of devices and/or Annexes.

SELECTION OF NOTIFIED BODIES

All three Directives contain the criteria against which the Competent Authority must assess whether certification organisations are sufficiently qualified to act as Notified Bodies. A Competent Authority may designate as a Notified Body only organisations that come under its own jurisdiction. The Competent Authority notifies those bodies it selects as being suitable to the European Commission.

The selection criteria are designed to ensure the impartiality and expertise of prospective Notified Bodies. After a Notified Body is appointed the Competent Authority periodically audits it to ensure the expected criteria are still being met. Notified Body status may be withdrawn if these criteria are no longer met.

ROLE OF SUBCONTRACTORS

A Notified Body will not necessarily have to carry out every part of the testing

SUBCONTRACTORS

and/or auditing with its own staff or facilities. Some aspects may be undertaken by subcontractors such as testing laboratories or other specialists.

In all such cases the Notified Body must retain the final and overall responsibility. The Notified Body must be competent to evaluate the results of tests and audits even if it does not physically carry them out. The Notified Body also has responsibility for ensuring the competence of its subcontractors.

WHAT WILL A NOTIFIED BODY DO?

A Notified Body's tasks will vary depending on the classification of the products concerned and the conformity assessment route a manufacturer has chosen. See also Bulletins 4 and 20.

Typical activities that can be undertaken by a Notified Body include:

Full Quality Assurance - The Notified Body will carry out an assessment of the manufacturer's quality system, including design. They will sample across the range of products and processes to ensure that the requirements are being met.

Examination of the Design - The Notified Body will assess the full design dossier relating to each type of product to ensure that they meet the requirements.

Type Examination - The notified Body will assess the full technical information relating to each type of product and carry out appropriate testing of a representative sample of production to ensure that it meets the requirements.

Verification - The Notified Body will either test every unit or every batch of product to ensure that they are meeting the requirements before the manufacturer can place them onto the market.

Production and Product Quality Assurance - The Notified Body will carry out an assessment of either the manufacturer's quality system covering production and inspection (Production QA) or final inspection (Product QA). They will sample across the range of products to ensure that relevant technical files are available as well as ensuring that the relevant processes being undertaken meet the requirements.

DO I HAVE TO APPLY TO A UK NOTIFIED BODY?

No. Manufacturers are free to apply to any Notified Body in the EC capable of carrying out the desired conformity assessment procedure, regardless of which Member State that Notified Body is established in.

The Directives allow devices to be sold anywhere in the EC once they have been shown to comply with the requirements of the Directives.

This means that Member States may be accepting products assessed by foreign Notified Bodies onto their national market. It therefore makes no sense to demand that national manufacturers go to a national Notified Body. This would not only be contrary to EC law but also against the principles of the Single Market.

UK NOTIFIED BODIES

The following are the current UK Notified Bodies as at June 2004:

- AMTAC - MDD and IVDMDD (ID No.0473)
- British Standards Institution(BSI) - AIMDD & MDD (ID No.0086)
- Intertek Testing Services(ITS) - MDD (ID No. 0359)
- Lloyds Register Quality Assurance (LRQA) - MDD & IVDMDD (ID No.0088)
- Satra Quality Assurance Ltd - MDD (ID No.0321)
- SGS United Kingdom Ltd - MDD (ID No.0120)
- Underwriters Laboratory (UK) - MDD & IVDMDD (ID No.0843)

Further information including contact details and the tasks that these Notified Bodies can undertake can be found on the MHRA website under Key Topics, headed UK Notified Bodies under the Medical Devices Directive:

<http://www.mhra.gov.uk>

Information on Notified Bodies in all the Member States can be found at the following web address:

<http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified-bodies>

GUIDELINES FOR NOTIFIED BODIES

The Medicines & Healthcare products Regulatory Agency has produced guidance notes for Notified Bodies under the Medical Devices Directives which can be found in Publications/Regulatory on our website at:
<http://www.mhra.gov.uk>

FURTHER INFORMATION

These bulletins briefly describe aspects of the regulatory system. The reader should consult the appropriate Directive and the Regulations which implement the Directives into United Kingdom law, for all the provisions that may be relevant.

Further information can be obtained from:-

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