

CONFORMITY ASSESSMENT PROCEDURES UNDER THE IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE 98/79/EC

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INTRODUCTION

The Medical Devices Regulations 2002 which consolidates all the existing medical devices Regulations into a single piece of legislation, came into force on 13 June 2002.

This bulletin sets out in broad terms the conformity assessment routes which are available to manufacturers under the *In Vitro* Diagnostic Medical Devices Directive 98/79/EC to demonstrate that their devices meet the Essential Requirements. The CE mark may then be affixed to denote compliance. Directive 98/79/EC came into force via implementing regulations on 7th June 2000 with a transitional period until 7th December 2003, after which date manufacturers must comply with the legislation. IVDs which conform with existing national legislation already in the distribution chain at the end of the transitional period can continue to be supplied to the end user for a further two years (i.e. until 7 December 2005)

This bulletin is intended as general guidance only and should not be regarded as an authoritative statement of the law, or as having any legal status. Manufacturers and others should not rely solely on the information in this bulletin but should also consult with their lawyers and other professional advisers. The Medicines & Healthcare products Regulatory Agency (MHRA) does not accept any liability for any errors, omissions, misleading or other statements in this bulletin, whether negligent or otherwise.

DEFINITION

The Directive defines an *In Vitro* Diagnostic Medical Device (IVD) as:

`any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

concerning a physiological or pathological state, or

concerning a congenital abnormality, or

to determine the safety and compatibility with potential recipients, or

to monitor therapeutic measures'

LEVEL OF REGULATORY

The Directive groups IVDs into 4 categories so that the level

CONTROL

of regulatory control applied to an IVD will be proportionate to the degree of perceived risk based on the effect if the IVD fails to perform as intended or who the device user may be.

THE FOUR CATEGORIES

These categories are, in order of increasing perceived risk: general IVDs

IVDs for self-testing i.e. test kits used in a home environment (excluding self-test devices covered in Annex II)

IVDs in Annex II List B of the Directive: e.g. test kits for rubella, chlamydia, CMV, PSA or the major tissue typing groups

IVDs in Annex II List A of the Directive: e.g. test kits for HIV, hepatitis B, C, or D, HTLV and the major blood groups.

DEVICES FOR PERFORMANCE EVALUATION

Device for performance evaluation means “any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises”. Devices for performance evaluation will not carry the CE mark. However the manufacturer must draw up the statement and follow the procedures set out in Annex VIII of the Directive before such devices may be used.

AMENDMENT OR EXTENSION OF ANNEX II LISTS A AND B

There is provision in the Directive under Article 14 for Annex II Lists A and B to be amended or extended in the future. This requires a Member State to submit a substantiated request for the change to the Commission for consideration and amendment by the Directive’s Regulatory Committee.

THE CONFORMITY ASSESSEMENT ROUTES

In order to demonstrate compliance with the Essential Requirements the manufacturer must use a conformity assessment route appropriate for the category of device concerned. Conformity assessment routes are detailed in Article 9 and the relevant Annexes of the Directive, and are outlined below.

GENERAL IVDS

The manufacturer declares conformity with the provisions of the Directive, including compliance of the product with all the relevant Essential Requirements. This means that the manufacturer is making a legal statement that his product meets the requirements of the Directive. No Notified Body involvement is required.

SELF-TEST IVDS NOT COVERED IN ANNEX II

The manufacturer, prior to drawing up the declaration of conformity with the provisions of the Directive as for general IVDs, must in addition, lodge an application with a Notified Body for the examination of the design of the device. This will include aspects affecting its suitability for non-professional users.



Alternatively the manufacturer may follow the conformity assessment routes for higher risk products as below.

ANNEX II IVDS

For the higher risk devices the manufacturer's systems will have to be verified by a Notified Body before a declaration of conformity with the Directive can be made.

ANNEX II LIST B IVDS

The Notified Body will *either* carry out an audit of the full quality assurance system *or* carry out type examination plus verification of each batch or product *or* carry out type examination plus audit of the production quality assurance system.

ANNEX II LIST A IVDS

A Notified Body will *either* carry out an audit of the full quality assurance system and review the product design dossier

or carry out type examination plus audit of the production quality assurance system.

In addition, for Annex II list A IVDs, the Notified Body must verify each product or batch of product before the manufacturer may place them on the market.

CONFORMITY ASSESSMENT CHARTS

The charts at Annex A of this bulletin show schematically how the conformity assessment routes operate and indicate the Annexes and Quality Systems Standards which are relevant to each route.



FURTHER INFORMATION

Copies of guidance documents and other bulletins in the series, which go into more detail on specific areas of interest such as CE Marking and Notified Bodies, and may be of use but are not all specific to the *In Vitro* Diagnostic Medical Devices Directive, can be obtained from our website :

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