

COMPETENT AUTHORITY (UK)

BULLETIN No. 12
SALE AND SUPPLY OF IN VITRO
DIAGNOSTIC MEDICAL DEVICES (IVDS)

Updated February 2006

INTRODUCTION

This information bulletin outlines the current controls in the UK on the sale and supply of in vitro diagnostic (IVD) medical devices and explains the main features of the In Vitro Diagnostic Medical Devices Directive which came into force on 7 June 2000

THE IVD DIRECTIVE

The *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) was 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 came into force on 13 June 2002. Part IV of these Regulations cover legislative controls dealing specifically with the safety, quality and performance of *in vitro* diagnostic medical devices (IVDs). The Directive is the third of three New Approach Directives aimed at creating a single market and reducing technical barriers to trade for medical devices. It will introduce common regulatory requirements for IVDs across Europe, bringing them in line with other medical devices.

TRANSPOSITION OF THE IVD DIRECTIVE 2000 INTO UK LAW

The UK implementing regulations came into full force on 7 December 2003. It is now mandatory to comply with the legislation. To allow for this change, IVDs that were in the distribution chain could continue to be supplied for two years until 7 December 2005)

FEATURES OF THE DIRECTIVE

Structure

The Directive lays down harmonising rules designed to ensure the safety and performance of IVDs. The format of the Directive is similar to that of the two previous Directives. It consists of a number of Articles which cover definitions, scope, free movement, standards and vigilance. These are followed by annexes covering essential requirements, conformity assessment procedures and criteria for designation of Notified Bodies.

Definition of an IVD

The Directive defines an 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."

Risk category

The Directive groups IVDs into four categories according to the risks associated with relative dangers to public health and/or patient treatment by an IVD failing to perform as intended :

- general
- self-testing
- Annex II List B – which amongst others includes test kits for rubella, toxoplasmosis and phenylketonuria test kits as well as self test kits for blood glucose
- Annex II List A – which includes test kits for HIV, HTLV and Hepatitis and some blood grouping products, including those used to test donated blood

Level of control

The level of control applied is proportionate to the risk associated with relative dangers to public health and/or patient treatment by the IVD failing to perform as intended. For general IVDs the manufacturer self-declares conformity with the relevant essential requirements of the Directive. For self-test devices, in addition to the self-declaration, there will be a requirement for the manufacturer to submit details of the device design to an independent certification organisation known as a Notified Body. The Notified Body will assess the design of the device in terms of its suitability for non-professional users. Alternatively, manufacturers can opt to follow the routes for higher risk products. For the highest risk products, i.e. those listed in Annex II, the manufacturer's systems will have to be verified by a Notified Body. The Notified Body will undertake either an audit of the manufacturer's full quality assurance system (for Annex II List A products this will also include a design dossier review) or carry out type-testing and some form of production audit or sample examination. For products in List A of Annex II (and where appropriate List B) "common technical specifications" (CTSS) will be developed to establish the performance characteristics of the device. Manufacturers will be able to use CTSS to demonstrate conformity with the Directive. In addition, products in List A of Annex II will require batch release by the Notified Body.

Essential requirements

The Directive also includes essential requirements with which IVDs must comply before being placed on the market. The essential requirements aim to ensure that the products do not compromise the health and safety of patients and users, and are designed and manufactured to achieve the performance specified by the manufacturer for the stated medical purpose. Not all the essential requirements will apply to all devices and it is up to the manufacturer of the device to assess which are appropriate for his particular product. One way in which manufacturers can demonstrate that they have met essential requirements is to comply with the relevant national standards that transpose harmonised standards

COMMON TECHNICAL SPECIFICATIONS

For the devices in List A of Annex II of the Directive and, where necessary, the devices of Annex II List B, the Directive introduces the concept of common technical specifications. These are to establish appropriate performance evaluation and re-evaluation criteria, batch release criteria,

reference methods and reference materials. A committee of representatives of Member States, scientific experts and manufacturers has drawn up a specification which describes criteria for the performance evaluation and manufacturer's batch release for products encompassed within List A. This specification has been formally adopted prior to being published in the Official Journal of the European Communities. In the meantime, Notified Bodies and Trade Associations have copies of the draft document. As a general rule, manufacturers are required to comply with the common technical specifications. If for duly justified reasons they do not comply with them they must adopt solutions of a level at least equivalent to them

CE mark

The CE mark denotes that the product conforms with the requirements of the Directive. Under the Directive, all IVDs must be CE marked before they may be placed on the market.

In addition, there are some legal requirements of which IVD manufacturers should be aware:

The Health and Safety at Work Act 1974

The Health and Safety at Work Act 1974 imposes a general duty on any person who designs, manufacturers, imports or supplies any article for use at work (which includes IVDs) to make sure that the article is safe and without risks to health as far as is reasonably practicable. The Act includes a requirement for appropriate testing and examination, and the provision of adequate information about the use of the article

The General Product Safety Regulations 1994

The General Product Safety Regulations 1994 impose safety requirements on any consumer product for which there are no specific provisions in European law governing all aspects of the safety of the product. Therefore, until such time as the proposed IVD Regulations come into force, the General Product Safety Regulations apply to IVDs. Under these Regulations, IVDs may not be placed on the market unless they are safe. The Regulations also impose a requirement on producers to provide information to consumers. Requirements are also imposed on distributors.

The HIV Testing Kits and Services Regulations 1992

These Regulations make it illegal to sell or supply an HIV testing kit unless it is accompanied by a notice which indicates that the kit must not be sold or supplied to a member of the public. It must also include appropriate warnings about the interpretation of results.

The Radioactive Material (Road transport) (Great Britain) Regulations 1996 (SI 1996 No 1350)

IVDs which contain radioactive substances must comply with the requirements of these Regulations which are enforced by the Health and Safety Executive.

Packaging Requirements for the Royal Mail System

Infectious substances (including those which are known or thought likely to contain pathogens in risk groups 2 or 3) which are put into the Royal Mail system must comply with IATA Packaging Instruction 602. Discussions are ongoing as to what packaging is necessary for diagnostic samples. Until a decision is made current Royal Mail Guidelines should be followed for these substances

For further information ring the Royal Mail Customer Services Helpline on: 0845 740740.

FURTHER INFORMATION

Copies of the *In Vitro* Diagnostic Medical Devices Directive 98/79/EC are available quoting reference L331/1, date of publication 7 December 1998,

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