

Guidance on legislation

# Guidance on the In Vitro Diagnostic Medical Devices Directive 98/79/EC

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## 1 Introduction

This document outlines the current controls 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 98/79/EC (referred to in this document as ‘the Directive’).

It should be read in conjunction with vigilance guidance for IVDs and advice for notified bodies on self tests (available on the MHRA’s website).

## 2 Scope of the directive

### 2.1 What is an in vitro diagnostic medical device?

The Directive (see also Regulation 2) 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.’

This definition needs to be read in conjunction with the definition of a medical device in the Directive (see also Regulation 2):

‘Medical device’ means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories, including software intended by the manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application which –

(a) intended by the manufacturer to be used for human beings for the purpose of:

- (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
- (ii) diagnosis, monitoring, treatment, alleviation, or compensation for an injury or handicap,
- (iii) investigation, replacement or modification of the anatomy or of a physiological process,
- (iv) control of conception; and

(b) which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.’

### 2.2 Specimen receptacles

‘Specimen receptacles’ are devices, whether vacuum-type or not, specifically intended by the manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination. Specimen receptacles are considered to be IVDs and therefore fall within the scope of the Directive and the Regulations.

### 2.3 Products for general laboratory use

Products for general laboratory use are not IVDs unless, in view of their characteristics, they are intended specifically by their manufacturer to be used for in vitro diagnostic examination of samples derived from the human body for the purposes outlined in the definition of an IVD.

## 2.4 Accessories to IVDs

'Accessory' means 'an article which, whilst not being an in vitro diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose.' (Article 1.2(c) of the Directive and Regulation 32(1)).

Accessories on their own will not provide diagnostic information and it is this that will differentiate them from devices. Some reagents for example can be both accessories and IVDs dependent on their stated intended purpose. Examples of accessories are bar code scanners, microtome blades and general media such as saline for running instruments.

For the purposes of the Directive and Regulations accessories are treated as IVDs in their own right.

However, 'invasive sampling devices' or those which are directly applied to the human body for the purpose of obtaining a specimen are not considered to be accessories to IVDs. Generally, such devices will be regulated by Directive 93/42/EEC. However, where a diagnostic device incorporates an invasive element and a diagnostic element and is sold as a single integrated unit (rather than two separate products within the same pack) the MHRA's view is that such a device will generally be treated as an IVD, rather than a general device regulated by Directive 93/42/EEC.

## 2.5 Devices for performance evaluation

A 'device for performance evaluation' means a 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. These are used alongside established methods of diagnosis to make sure the results provided by the test say with regards to sensitivity and specificity are appropriate in terms of clinical need. Instruments, apparatus, appliances, materials or other articles which are intended to be used for research purposes without any medical objective are not regarded as devices for performance evaluation.

Devices for performance evaluation are not subject to the normal conformity assessment/CE marking procedures (which are detailed below), but manufacturers must draw up the statement and follow the procedure set out in Annex VIII of the Directive and must also register with the competent authority (see below under 'Registration' for further information).

## 2.6 Certified reference material

Although internationally certified reference material and those materials used for external quality assurance schemes are not covered by the legislation, calibrators and control materials needed to establish or verify performance of devices are IVDs

## 2.7 Exemption for health institutions

Article 1.5 of the Directive (see Regulation 33) excludes from its scope devices 'manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having being transferred to another legal entity.'

The MHRA's view is that the exemption above will apply where a health institution manufactures an IVD in-house and then uses that IVD on the premises of manufacture (or on premises in the immediate vicinity) provided that the use of the IVD is intrinsic to the operation of the health institution, and not for some extraneous purpose that does not form part of the health functions of the institution. If these conditions are satisfied, it is irrelevant that a diagnostic service is being provided to a different legal entity – the exemption will still apply.

This is a complex issue; the appendix has a series of examples illustrating how the exemption can be applied.

## 2.8 Trade fairs etc

IVDs which are not in compliance with the regulatory requirements may be shown at trade fairs, exhibitions, demonstrations, scientific or technical gatherings etc. provided that such devices are not used on specimens taken from the participants and a visible sign clearly indicates that the device cannot be marketed or put into service until it complies with the requirements of the Directive.

## 3 The conformity assessment process

In general terms, a manufacturer wishing to place their products on the market under this Directive must:

- assign his devices to one of the relevant risk categories defined in the Directive;
- ensure that the device meets the 'essential requirements' specified in Annex I of the Directive;
- follow the appropriate conformity assessment procedure;
- if appropriate (depending on the risk category of the device), ensure that an independent certification body (called a 'notified body') is involved in the conformity assessment procedure.

As stated earlier, manufacturers of IVDs that are not placed on the market but which are put into service and used in the context of the manufacturer's professional activity must also follow the appropriate conformity assessment procedure.

Definitions and further detail are provided below.

### 3.1 Definition of a manufacturer

The manufacturer is defined in the Directive (see also Regulation 2) as:

- a) the 'person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party;' or
- b) a person who 'assembles, packages, processes, fully refurbishes and/or labels one or more ready made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name.' This does not apply to a person who assembles or adapts devices already on the market to their intended purpose for an individual patient.

### 3.2 Notified body (NB)

A 'notified body' is a third party independent certification organisation which the competent authority designates to carry out certain tasks in respect of the conformity assessment procedures described in the annexes to the Directive. A notified body must be qualified to perform all the functions set out in any Annex for which it is designated. The tasks which a notified body can carry out may be restricted by the competent authority. The activities of notified bodies are regularly monitored.

Manufacturers are free to apply to any notified body in the EU designated to carry out the desired conformity assessment procedure, regardless of which Member State that notified body is designated in.

Manufacturers are required to inform their notified body (NB) of changes to their product ranges and quality system. In cases where design or type examination has been carried out by the notified body the manufacturer is required to notify them of changes to the design, as well as any information they have on changes to the pathogen and markers of infection to be tested. All such changes need to be approved by the notified body prior to implementation.

### 3.3 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.

### 3.4 Level of regulatory control

The majority of IVDs do not require the intervention of a notified body in the conformity assessment process. However, for some IVDs (the correct performance of which is perceived to be essential to health), involvement of a notified body will be required.

For the purposes of the conformity assessment procedures, the Directive groups IVDs into four categories.

### 3.5 The four categories of IVDs

These categories are, in order of increasing perceived risk:

- general IVDs, i.e. all IVDs other than those covered by Annex II and IVDs for self-testing such as blood gas analysers, therapeutic monitoring reagents and tissue processors;
- IVDs for self-testing (a device intended by the manufacturer to be able to be used by lay persons in a home environment) excluding self-test devices covered in Annex II;
- IVDs in Annex II List B of the Directive: Which, amongst others, includes reagents products for rubella, toxoplasmosis and phenylketonuria as well as devices for self testing for blood sugar;
- IVDs in Annex II List A of the Directive: Which includes reagents and products for HIV I and II, Hepatitis B, C and D, and reagent products for determining ABO systems and anti-kell including those used to test donated blood plus tests for screening vCJD.

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 duly substantiated request for the change to the Commission for consideration and amendment by the Directive's Regulatory Committee. This procedure was adopted for vCJD screening assays to be placed into annex II List A.

### 3.6 The conformity assessment routes

In order to demonstrate compliance with the essential requirements of the Directive, the manufacturer must follow the conformity assessment procedure appropriate for the category of IVD concerned. Conformity assessment routes are detailed in Regulation 40 (Article 9 of the Directive), which cross-refers to the relevant Annexes. The conformity assessment routes are outlined below.

### 3.7 General IVDs

The manufacturer must fulfil the applicable obligations imposed by sections 1 to 5 of Annex III and must declare and ensure that the device meets the provisions of the Directive which apply. No notified body involvement is required.

### 3.8 Self-test IVDs not covered in Annex II

The manufacturer, in addition to complying with the requirements for general IVDs, must, before a declaration of conformity can be made, lodge an application with a notified body for the examination of the design of the device (section 6 of Annex III). 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 detailed below.

### 3.9 Annex II IVDs

For Annex II List B devices, the manufacturer must follow the applicable obligations imposed either by Annex IV, or by Annexes V and VI, or alternatively by Annexes V and VII and must declare and ensure that the device meets the provisions of the Directive which apply. For List A devices, the manufacturer must follow either Annex IV, or alternatively Annexes V and VII (i.e. it cannot follow Annexes V and VI). All Annex II IVDs require the intervention of a notified body before a declaration of conformity with the Directive can be made.

### 3.10 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.

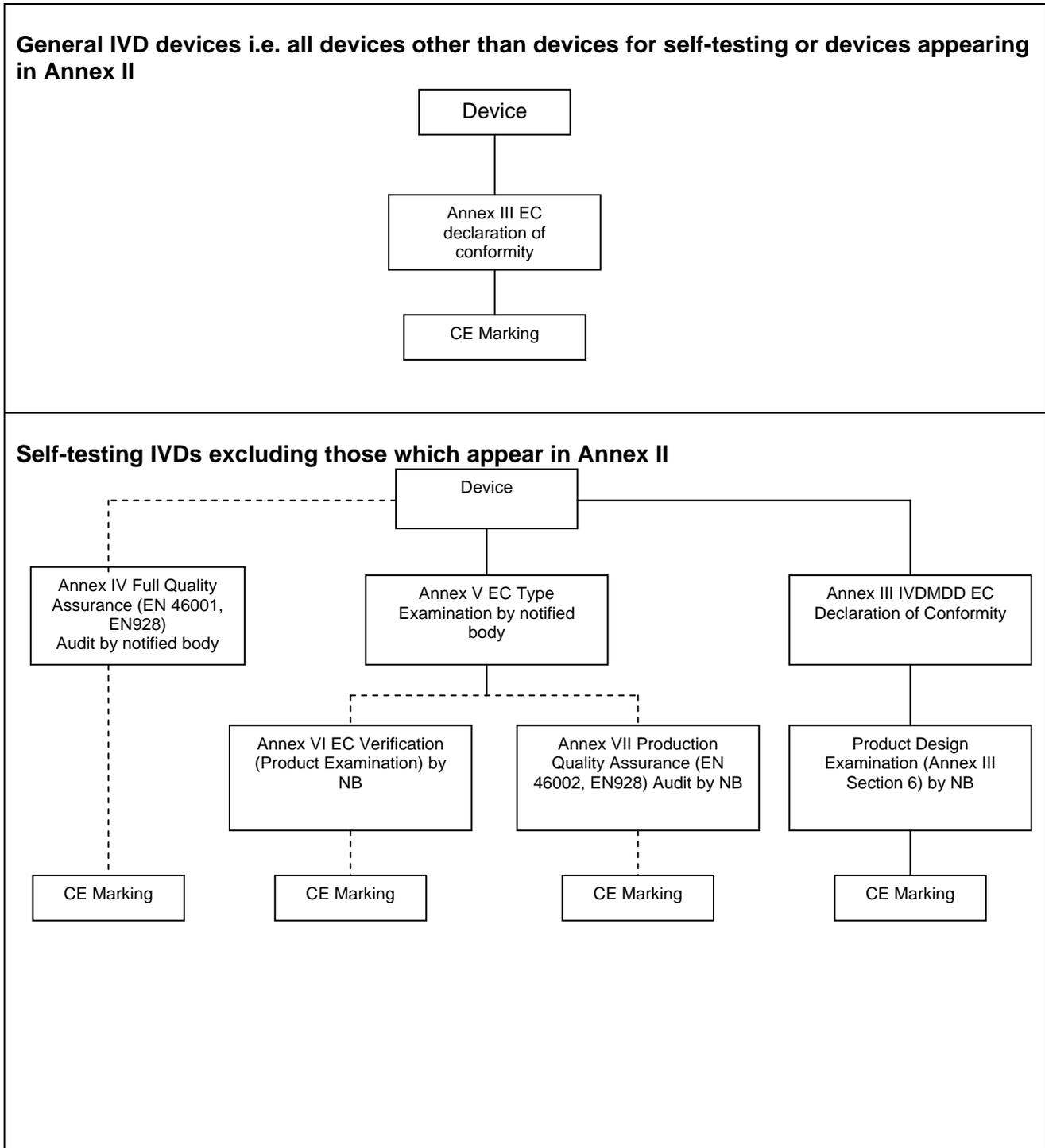
A notified body will:

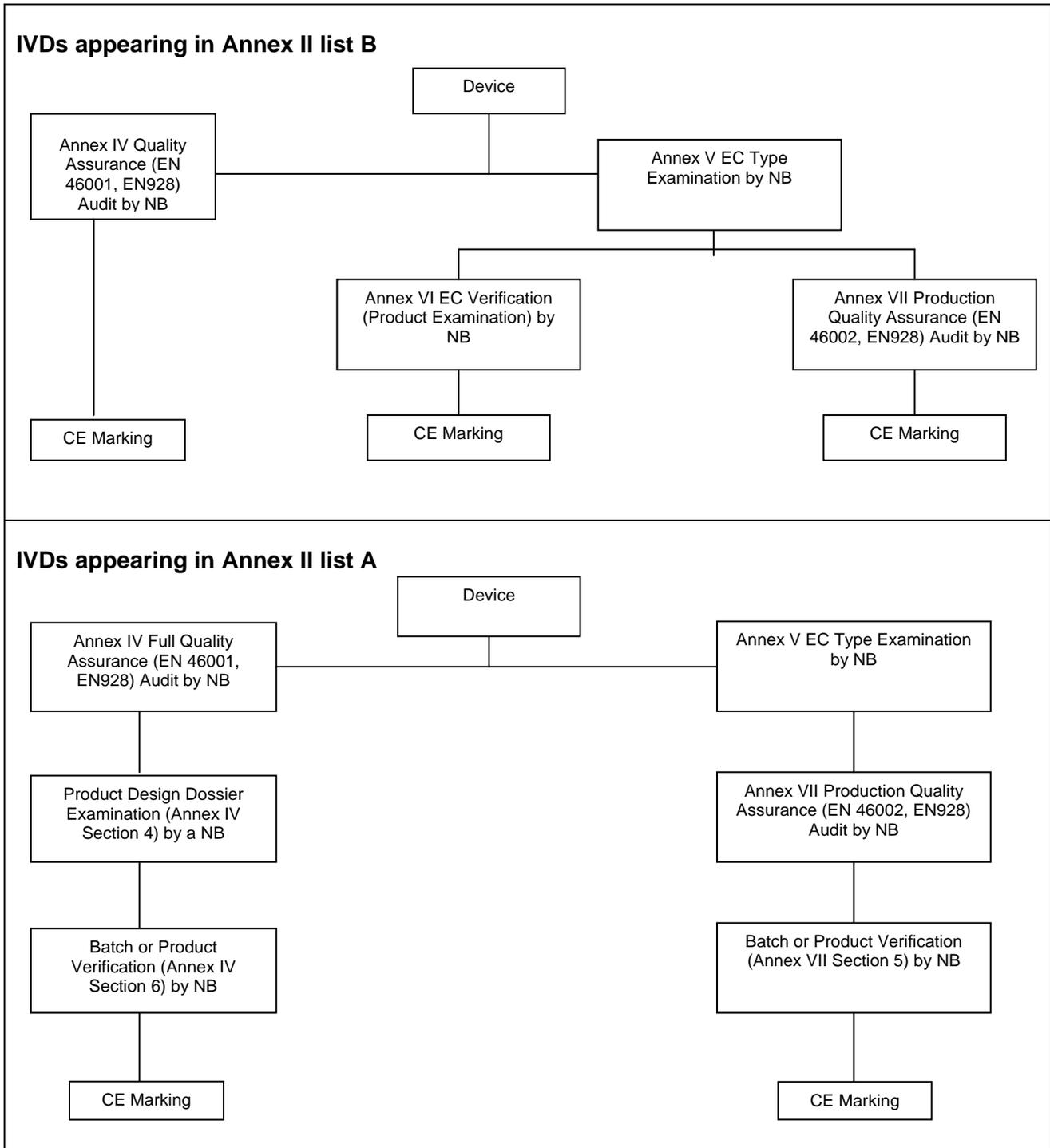
- **either** carry out an audit of the full quality assurance system and review the product design dossier
- **or** carry out type examination plus audit of the production quality assurance system.

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.

**3.11 Conformity assessment procedure flow charts**

The conformity assessment routes are summarised below.





It is for the manufacturer to determine how best to demonstrate conformity. The use of harmonised standards or common technical specifications (CTS) (see below) can be helpful.

### 3.12 Documentation

The declaration of conformity, the technical documentation and the decision, reports and certificates of notified bodies must be kept available for inspection for a period of five years after manufacture of the last device.

### 3.13 Harmonised standards

European standards that have been [harmonised under the IVD Directive](#) may be used to show conformity with the relevant essential requirements. Compliance with an appropriate harmonised European standard gives a presumption of conformity with the essential requirements to which the standard relates. The use of harmonised standards is not mandatory and other standards exist that are not harmonised and which may be used to assist in showing conformity. However, unlike harmonised standards they offer no presumption of conformity.

### 3.14 Common technical specifications (CTS)

For the devices in List A (and where necessary in list B) of Annex II of the Directive, 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 from the 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.

A CTS exists for vCJD assays for blood grouping and another CTS for the other list of Annex II list A devices. Copies of the CTS in question can be obtained from the European Commission at [http://ec.europa.eu/health/medical-devices/documents/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/index_en.htm) (original 2002 CTS plus 2009 update and 2011 vCJD table) [http://ec.europa.eu/health/medical-devices/documents/guidelines/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm) MEDDEV 2.14/4 vCJD CTS guidance

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

### 3.15 CE marking

IVDs must bear the CE marking when they are placed on the market. Devices for performance evaluation do not need to be CE marked.

A manufacturer must not apply the CE marking unless he has fulfilled the applicable obligations of the Directive. The CE mark is therefore seen as a declaration by the manufacturer that the product meets all of the appropriate provisions of the relevant legislation, including those relating to safety. A device bearing a CE marking can be freely marketed anywhere in the EU without further control, except that competent authorities can take action to prevent the supply of a device in certain circumstances. We have further information on the CE marking on our website.

### 3.16 Affixing the CE marking

The CE marking must be affixed in a visible, legible and indelible form on the device (where practicable and appropriate) and on the instructions for use. It must also appear on the sales packaging. The relevant notified body number (where one has been used) should accompany the CE marking.

### 3.17 IVDs not placed on the market

The conformity assessment procedures apply not only to IVDs that are placed on the market, but also to any person who manufactures IVDs and, without placing them on the market, 'puts them into service and uses them within the context of his professional activity.' (Article 9.13 of the Directive). Thus, for example, a person who manufactures an IVD and then uses it to provide diagnostic services without placing that device on the market would generally need to comply with the appropriate conformity assessment procedure in respect of that device. A good example is a commercial pregnancy testing service provider who produces his own reagents for use in-house.

## 4 Other regulatory requirements

### 4.1 Language used in labelling and instructions for use

The Directive allows Member States to stipulate in their implementing legislation that the information needed to use an IVD (labelling and instructions) is in their official language. In the UK, Regulation 35(2) requires this information to be in English if the device may reach a final user in the UK, unless the MHRA has authorised the use of another Community language(s). If the device is a device for self-testing, the instructions for use and label must include a translation into the official language of any member state of the community in which the device reaches a final user.

### 4.2 Registration

Pursuant to Regulation 44, a manufacturer with a registered place of business in the UK who places a relevant device on the market (remember that for these purposes, market means the EU market) or who makes available a device for performance evaluation under his own name must register with the MHRA.

In addition, a person with a registered places of business in the UK who (a) places a relevant device on the UK market, or (b) who makes a device available for performance evaluation, on behalf of a manufacturer who does not have a registered place of business in the Community or in a state which is party to an Association Agreement, must register with the MHRA (see also 'Authorised Representatives' below).

Registration will not be required if the IVD was first placed on the market in another Member State (or if applicable in a state which is a party to an Association Agreement) and the manufacturer or his authorised representative has already registered with the Competent Authorities of that state (although note the transitional arrangements which apply pending the setting up of the European database, as to which see later).

Further guidance for registration in the UK is given on our website.

### 4.3 Authorised representative

Manufacturers who do not have a registered place of business in the EU (or in a state which is party to an association agreement) must designate an authorised representative to perform certain obligations (e.g. to make certain documentation available on request) and may designate an authorised representative to perform other substantive obligations (see Regulation 60(1) of the Regulations).

Additionally, such a manufacturer must also designate an authorised representative as the person responsible for marketing the IVD in the EU and for registering that device with the appropriate competent authority (see Regulation 60(2)).

### 4.4 European databank – Eudamed

The aim of Eudamed is to strengthen market surveillance and transparency in the field of medical devices by providing Member State competent authorities fast access to information on manufacturers and authorised representatives, on devices, certificates, vigilance and on clinical investigation data, as well as to contribute to a uniform application of the Directives, in particular in relation to registration requirements.

Further information relating to the information contained on Eudamed is available on the [European Commission website](#).

## 4.5 Post-market surveillance and vigilance procedures

The conformity assessment procedures include obligations with regard to experience gained in the post-production phase, including implementation of any necessary corrective actions.

Manufacturers must maintain a 'vigilance system' to notify the regulatory authorities of incidents that might lead to or might have led to death or serious health consequences, or to a systematic recall of a device.

More details are given on our website.

## 4.6 Reporting obligations of the member states

In outline, member states have obligations under the Directive to inform the European Commission and other member states where an IVD has been withdrawn, prohibited or restricted because it may compromise the health and safety of patients, users or others and/or where an incident has been reported as part of the vigilance procedure.

In addition, there are some additional 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 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 Regulations also impose certain requirements on persons who provide an HIV testing service. These regulations are in the process of being repealed and from April 2014 it will no longer be illegal to sell or advertise an HIV test kit in the UK. It is expected that CE marked kits will be on the market later in 2014.

### **The Radioactive Material (Road transport) (Great Britain) Regulations 2002**

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**

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

### **Further information**

In Vitro Diagnostic Medical Devices Directive 98/79/EC [http://ec.europa.eu/health/medical-devices/regulatory-framework/legislation/index\\_en.htm](http://ec.europa.eu/health/medical-devices/regulatory-framework/legislation/index_en.htm)

UK Regulations <http://www.legislation.gov.uk/>

## Appendix: In-house manufacture of IVD medical devices

Devices which are manufactured by health institutions and used only on their own patients ('in-house manufacture') are exempt from the requirements of the Medical Devices Regulations 2002 (as amended).

This appendix relates specifically to in-house manufacture of in vitro diagnostics but should be read in conjunction with the general guidance that we have on the subject (available on our website).

### Background

The IVD Directive applies not only to devices that are placed on the market, but also to devices that are put into service and used in the context of a professional activity, without being placed on the market (article 9.13 of the Directive). This provision covers the test kits manufactured and used by commercial or other testing service providers, which they use in-house but do not place on the market.

However, article 1.5 of the Directive exempts 'health institutions' from the provisions of the Directive in certain circumstances:

*'This Directive shall not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity.'*

A good example is a commercial pregnancy testing service provider who produces his own reagents for use in-house.

### Advice

The MHRA's view is that the exemption above will apply where a health institution manufactures an IVD in-house and then uses that IVD on the premises of manufacture (or on premises in the immediate vicinity) provided that the use of the IVD is intrinsic to the operation of the health institution, and not for some extraneous purpose that does not form part of the health functions of the institution. If these conditions are satisfied, it is irrelevant that a diagnostic service is being provided to a different legal entity – the exemption will still apply.

### What is a 'health institution'?

The MHRA's view is that a health institution is a body whose primary purpose is the care and/or promotion of public health. Bodies that clearly qualify as health institutions are NHS trusts and bodies such as the National Blood Authority. Similarly, the MHRA considers that private hospitals and bodies which provide private health care (for example, BUPA) can be treated as health institutions, provided that the primary purpose of those bodies is the care and/or promotion of public health.

On the other hand, free-standing laboratories that provide diagnostic services, (which are not part of a body that has as its purpose the care and/or promotion of public health) do not, in the MHRA's view, qualify as health institutions. Similarly, were a clinic to be established purely to provide diagnostic services, which did not have as its overall purpose the provision of health care (i.e. care and treatment of patients) or the promotion of public health, the MHRA would not consider such a clinic to be a 'health institution.' This means that the exemption will not apply to such bodies even if they would otherwise fall within the exemption.

In general, the MHRA's view is that a health institution will be a single legal entity (e.g. a trust, rather than an individual hospital) although there may be exceptional circumstances where it is appropriate to treat two different legal entities as a single health institution. Whether two legal entities can be treated as a single institution will depend on their precise circumstances. It is not sufficient that they both have as their primary purpose the care and/or promotion of public health.

There must be some close association and common identity, as well as shared premises and facilities, such that they can genuinely be considered as a single institution. For example, a hospital may be considered a single health institution, even though the premises are shared by an NHS trust and a research laboratory run by the university which operates the hospital's medical school or medical research department. The laboratory may manufacture an IVD which is then used by the NHS trust staff, but such use could be treated as being use within the same health institution.

### **What qualifies the health institutions for the exemption?**

There are two distinct circumstances in which the exemption will apply:

1. a device is manufactured and used within the same health institution, on the premises of manufacture
2. a device is manufactured and used within the same health institution, on premises in the immediate vicinity (provided the device has not been transferred to another legal entity).

As set out above, concern has centered on the use of devices which have been manufactured in-house (i.e. the circumstances covered by article 9.13) and which are not transferred to another body.

Where a health institution manufactures a device and transfers it to a different health institution, the exemption does not apply because the device is not manufactured and used within the same health institution. This means that in most cases, where a device is transferred by a health institution to a different legal entity, the exemption does not apply.

The MHRA's interpretation is best illustrated by a series of examples:

#### **Example 1**

##### **A health institution manufactures an IVD in-house and uses that IVD on the premises of manufacture, or on premises in the immediate vicinity.**

Provided that the use of the IVD by the health institution is intrinsic to its operation and not for some extraneous purpose that does not form part of its health functions, the MHRA considers that the exemption will apply. Our revised view is that this is regardless of the identity of the entity to which the diagnostic service is being provided. This would cover an NHS trust hospital providing a routine or specialist diagnostic service to a hospital within a different NHS trust (e.g. the Supra Regional Assay Service); or a body such as the National Blood Authority or the Health Protection Agency providing specialist testing services within its remit to other bodies.

However, the MHRA considers that the use by a health institution of a device for an extraneous purpose (e.g. an NHS hospital setting up commercial, diagnostic service available to privately paying patients, which was not part of its NHS functions) is not use 'within' the institution and therefore the exemption does not apply.

#### **Example 2**

##### **A health institution manufactures an IVD in-house, but then transfers that IVD to a different part of the same health institution located on a different site which is not in the immediate vicinity.**

The exemption does not apply, because although the IVD is manufactured and used within the same health institution, the use of the IVD is not on the premises of manufacture or on premises in the immediate vicinity.

#### **Example 3**

##### **A health institution manufactures an IVD in-house, but then transfers it to a different legal entity, which is based on the same premises.**

In general, the exemption does not apply because the device is not manufactured and used within the same health institution. However, if the two separate legal entities can be treated as one health institution and the legal entity which uses the IVD does so on the premises of manufacture (assuming that the use of the IVD is part and parcel of the operation of that health institution), then

the exemption does apply. An example might be the manufacture of an IVD by a university laboratory on trust hospital premises (as part of a joint health partnership), which is then used by the hospital to test NHS patients.

However, the MHRA does not consider that the exemption would apply if a commercial manufacturer set up on hospital premises and manufactured IVDs which were then used by the hospital - the MHRA would not regard the hospital and manufacturer together as a 'health institution'.

#### **Example 4**

**A health institution manufactures an IVD in-house, but then transfers it to a different legal entity, which is based on nearby premises.**

In the example above, the university research laboratory and hospital are on different premises, albeit nearby. The exemption does not apply.

#### **What about modification of IVDs bought from a third party?**

The MHRA's view is that the regulatory requirements apply whenever a device has been modified to such an extent that it can be considered as a new device. If it is appropriate to treat the modified device as a new device, then the modifier is in the same position as if he had manufactured a device from scratch for the purposes of the regulatory requirements - i.e. if he is placing the device on the market, or falls within article 9.13, he will need to follow the appropriate regulatory procedure. Health institutions will get the benefit of the exemption in the normal way. There are no hard and fast rules about when a modified device should be treated as a new device and every situation will need to be looked at individually. The question is whether the device has been subject to important changes which modify its original performance. The MHRA can give advice in individual cases.

Similarly, the MHRA considers that where a person or body uses a device bought from a third party, in the context of his professional activity, in a way which makes important changes to its original purpose, that person will need to comply with article 9.13 unless the health institution exemption applies.