Medicines & Healthcare products Regulatory Agency

Guidance on legislation

Guidance on the regulation of In Vitro Diagnostic medical devices in Great Britain

July 2023

Contents

1 Introduction

This document outlines the current controls on the sale and supply of in vitro diagnostic (IVD) medical devices in Great Britain and explains the main features of the requirements for IVDs, set out in Part IV of the UK Medical Devices Regulations 2002 (as amended) (UK MDR 2002).

It should be read in conjunction with vigilance guidance for IVDs and advice for UK Approved Bodies on self-tests.

This guidance is specific to in vitro diagnostic devices placed on the market in Great Britain (England, Wales and Scotland). For guidance on the legislation applicable to in vitro diagnostic medical devices in Northern Ireland, please see our published guidance.

2 Scope of the UK MDR 2002

2.1 What is an in vitro diagnostic medical device?

The UK MDR 2002, Regulation 2 defines an IVD as:

> 'a medical device which
>
> a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and
> b) is 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:
> i. concerning a physiological or pathological state
> ii. concerning a congenital abnormality
> iii. to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or
> iv. to monitor therapeutic measures
>
> and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.'

This definition needs to be read in conjunction with the definition of a medical device in the UK MDR 2002 (Regulation 2):

> 'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its 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 of or compensation for an injury or handicap

iii. investigation, replacement or modification of the anatomy or of a physiological process, or
iv. control of conception; and

b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is 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 UK MDR 2002.

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.' (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 UK MDR 2002 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 Part II of the UK MDR 2002 as medical devices. 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.

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 their 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 procedures (which are detailed below), but manufacturers must draw up the statement of conformity (Part IV of the UK MDR 2002, Annex VIII [as modified by Part III of Schedule 2A to the UK MDR 2002]). These devices must be registered with the MHRA (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 (commonly referred to as in-house manufacturing)

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 been 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. This is a complex issue; the appendix has a series of examples illustrating how the exemption can be applied. If the device is transferred to another legal entity, you will be considered a manufacturer and the full regulations will apply.

The UK MDR 2002 may also apply for joint ventures between multiple establishments, even if there is a third establishment created to place the device on the market.

They do not apply if your institution has a specialist research and development laboratory that has been commissioned by another institution. This would usually be to manufacture a product for specific clinical or research purposes, which are not commercial objectives.

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 UK MDR 2002.

3 The conformity assessment process

In general terms, a manufacturer wishing to place their products on the market under the UK MDR 2002 must:

- assign their devices to one of the relevant risk categories
- ensure that the device meets the 'essential requirements' (Part IV of the UK MDR 2002, Annex I [as modified by Part III of Schedule 2A to the UK MDR 2002])

- follow the appropriate conformity assessment procedure
- if appropriate (depending on the risk category of the device), ensure that an independent certification body (called a 'UK approved 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 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 their own name, regardless of whether these operations are carried out by that person themselves or on their 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 their 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 UK approved body

A 'UK approved body' is a third-party independent certification organisation which the MHRA designates to carry out certain tasks in respect of the conformity assessment procedures in Great Britain (Part IV of the UK MDR 2002, [as modified by Part III of Schedule 2A to the UK MDR 2002]. A UK approved body must be qualified to perform all the functions for which it is designated. The tasks which a UK approved body can carry out may be restricted by the MHRA. The activities of UK approved bodies are regularly monitored.

Manufacturers are required to inform their UK approved body of changes to their product ranges and quality system. In cases where design or type examination has been carried out by the UK approved 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 UK approved body prior to implementation.

3.3 Essential requirements

IVDs must comply with the essential requirements before being placed on the market (Part IV of the UK MDR 2002, Annex I [as modified by Part III of Schedule 2A to the UK MDR 2002]). 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 their particular product. One way in which manufacturers can demonstrate that they have met essential requirements is to comply with the relevant designated standards to the UK MDR 2002.

3.4 Level of regulatory control

The majority of IVDs do not require the intervention of a UK approved 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 UK approved body will be required.

For the purposes of the conformity assessment procedures, IVDs are grouped 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 below
- 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 below
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List B (as modified by Part III of Schedule 2A to the UK MDR 2002): Which, amongst others, includes reagents products for rubella, toxoplasmosis and phenylketonuria as well as devices for self-testing for blood sugar
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List A (as modified by Part III of Schedule 2A to the UK MDR 2002): 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

It is possible that Annex II Lists A and B (Part IV of the UK MDR 2002, as modified by Part III of Schedule 2A) may be amended or extended in the future.

3.6 The conformity assessment routes

To demonstrate compliance with the essential requirements, the manufacturer must follow the conformity assessment procedure appropriate for the category of IVD concerned. Conformity assessment routes are detailed in Regulation 40 (Part IV of the UK MDR 2002, [as modified by Part III of Schedule 2A to the UK MDR 2002]. 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 (Part IV of the UK MDR 2002, Annex III [as modified by Part III of Schedule 2A to the UK MDR 2002]) and must declare and ensure that the device meets the provisions of the UK MDR 2002 which apply. No UK approved body involvement is required.

3.8 Self-test IVDs not covered in Part IV of the UK MDR 2002, Annex II (as modified by Part III of Schedule 2A to the UK MDR 2002)

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 UK approved body for the examination of the design of the device (Part IV of the Medical Devices

Regulations 2002, Annex III [as modified by Part III of Schedule 2A to the UK MDR 2002]). 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 Part IV of the UK MDR 2002, Annex II (as modified by Part III of Schedule 2A to the UK MDR 2002)

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 UK MDR 2002 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 UK approved body before a declaration of conformity with the IVDD can be made. The manufacturer must ensure that Annexes to Part IV are followed taking into account any amendments within Part III of Schedule 2A to the UK MDR 2002.

3.10 Classifications stated in Part IV of the UK MDR 2002, Annex II List B (as modified by Part III of Schedule 2A to the UK MDR 2002)

The UK approved 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 UK approved body will:

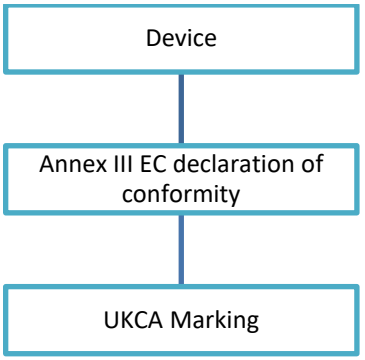
- **either** carry out an audit of the full quality assurance system and review the product design dossier
- **or** carry out type examination plus audit of the production quality assurance system

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

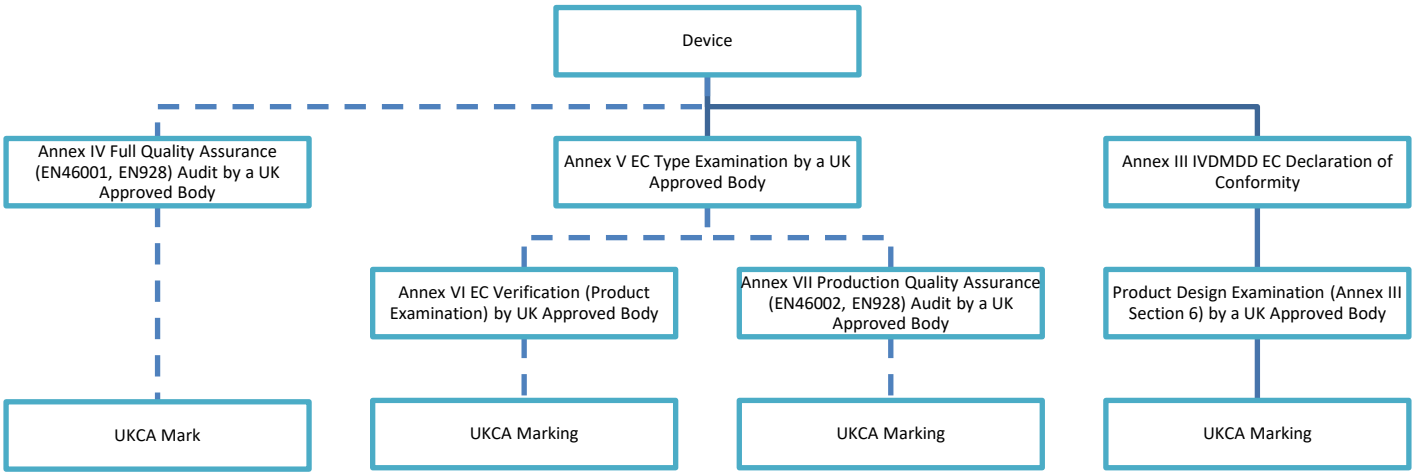
3.11 Conformity assessment procedure flow charts

The conformity assessment routes are summarised below.

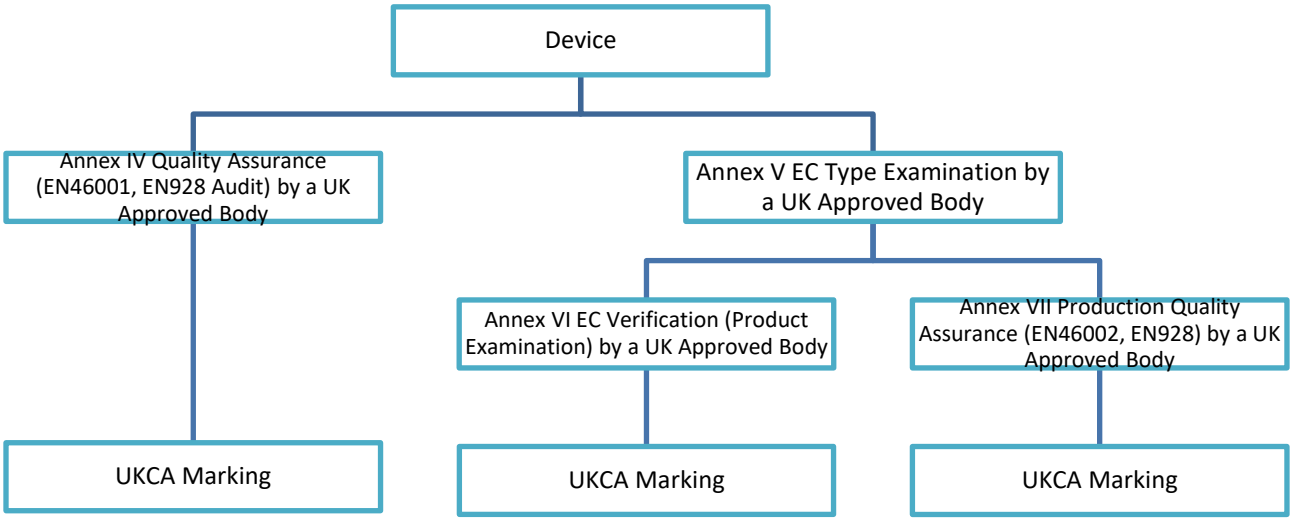
General IVD Devices (i.e., all devices other than devices for self-testing or Annex II devices)



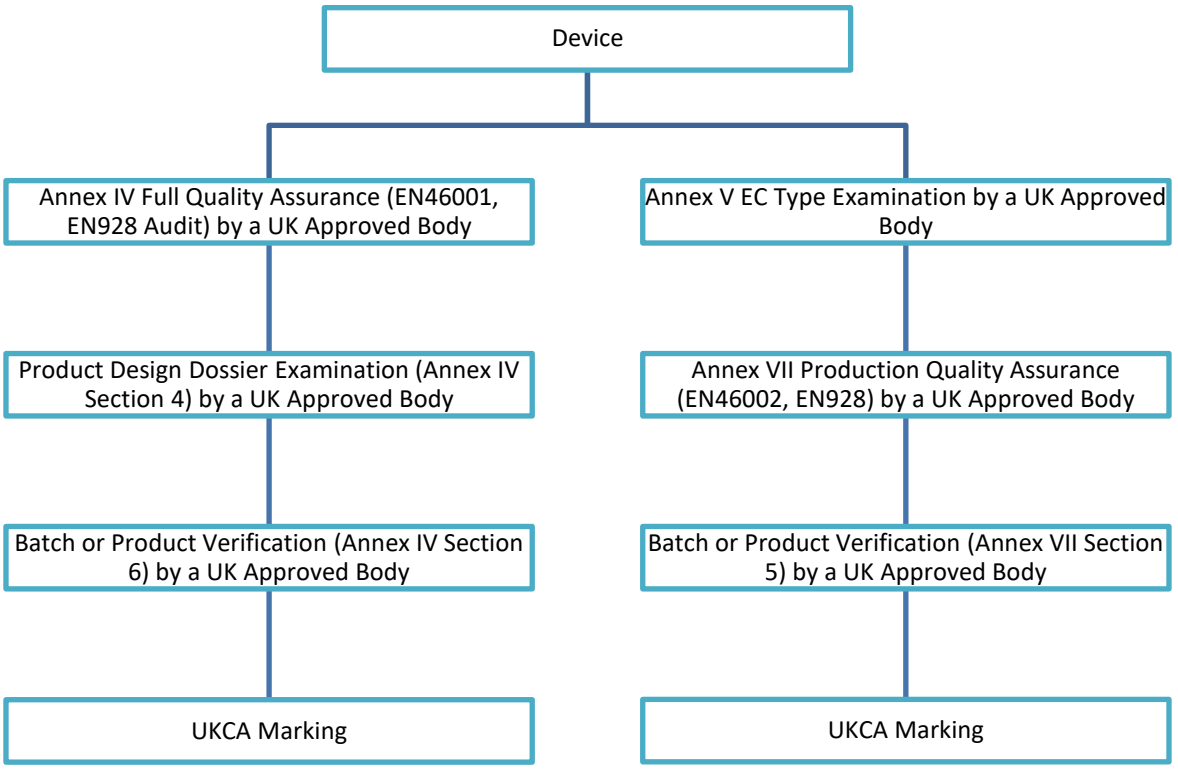
Self-testing IVDs excluding those in Annex II



IVDs appearing in Annex II List B



IVDs appearing in Annex II List A



Note

- Annexes as modified by Part III of Schedule 2A to the UK MDR 2002

It is for the manufacturer to determine how to demonstrate conformity. The use of designated 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 UK approved bodies must be kept available for inspection for a period of five years after manufacture of the last device.

3.13 Designated standards

Standards that have been designated under Part IV of the UK MDR 2002 may be used to show conformity with the relevant essential requirements. Compliance with an appropriate designated standard gives a presumption of conformity with the essential requirements to which the standard relates. The use of designated standards is not mandatory and other standards exist that are not designated, and which may be used to assist in showing conformity. However, unlike designated 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 (Part IV of the UK MDR 2002, Annex II [as modified by Part III of Schedule 2A to the UK MDR 2002]), common technical specifications are available to establish appropriate performance evaluation and re-evaluation criteria, batch release criteria, reference methods and reference materials. These specifications describe criteria for the performance evaluation and manufacturer's batch release for products encompassed within List A.

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 here (original 2002 CTS plus 2009 update and 2011 vCJD table) and here (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 UKCA marking

Manufacturers may use the UKCA mark on a voluntary basis until 30 June 2030. CE marked medical devices will continue to be accepted on the Great Britain market with the deadline for acceptance depending on the type of device and the legislation it complies with. The latest of these deadlines is 30 June 2030. Refer to the timelines for placement of CE marked medical devices on the Great Britain market. Devices for performance evaluation do not need to be UKCA marked.

A manufacturer must not apply the UKCA marking unless they have fulfilled the applicable obligations of the UK MDR 2002. The UKCA mark is therefore seen as a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation, including those relating to safety. A device bearing a UKCA mark can be marketed in Great Britain (England, Wales and Scotland), but is not recognised in the EU, EEA or Northern Ireland markets.

Devices placed on the market in the EU, EEA or Northern Ireland will still require CE marking, unless an exemption applies. A CE UKNI mark can be affixed for the purposes of Northern Ireland, but this device cannot circulate on the EU or EEA markets. You can read more about the Northern Ireland requirements here.

3.16 Affixing the UKCA marking

The UKCA 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 UK approved body number (where one has been used) should accompany the UKCA marking. For more information, please see the published guidance on using the UKCA 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 their professional activity.' 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. For example, a commercial pregnancy testing service provider who produces their own reagents for use in-house.

4 Other regulatory requirements

4.1 Language used in labelling and instructions for use

Regulation 35(2) requires the labelling and instructions for a device to be in English.

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 Great Britain market, or who makes available a device for performance evaluation under their own name must register the device(s) with the MHRA prior to it being placed on the market.

In addition, a person with a registered places of business in the UK who (a) places a relevant device on the Great Britain 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 United Kingdom must register the device(s) with the MHRA prior to it being placed on the market (see also 'UK Responsible Person' below).

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

4.3 UK Responsible Person

Manufacturers who do not have a registered place of business in the United Kingdom must designate a UK Responsible Person to perform certain obligations (e.g., to make certain documentation available on request) (Regulation 33A).

Additionally, such a manufacturer must also designate a UK Responsible Person as the person responsible for marketing the IVD in Great Britain and for registering that device the MHRA.

As well as registering the device with the MHRA, the UK Responsible Person must:

- ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
- keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA
- in response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device.
- where they have samples of the device or access to the device, comply with any request from the MHRA to provide such samples or access
- where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the MHRA to provide such samples or access, and communicate to the MHRA whether the manufacturer intends to comply with that request
- cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices
- immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed
- if the manufacturer acts contrary to its obligations under these Regulation:
    - terminate the legal relationship with the manufacturer; and
    - inform the MHRA and, if applicable, the relevant approved body of that termination

The name and address of the UK Responsible Person, where applicable, will also need to be included on product labelling where the UKCA mark has been affixed.

4.4 Post-market surveillance and vigilance procedures

The conformity assessment procedures include obligations regarding experience gained in the post-production phase, including implementation of any necessary corrective actions. Manufacturers must maintain a ‘vigilance system’ to notify MHRA 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 the MHRA website.

4.5 Additional legislation that may apply to IVDs

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 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.

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 UK MDR 2002.

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 UK MDR 2002 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. 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, Regulation 33 exempts 'health institutions' from the provisions of the UK MDR 2002 in certain circumstances:

> 'The requirements of this Part in respect of relevant devices apply in respect of in vitro diagnostic medical devices and accessories to such devices, except for products manufactured and used within the same health institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity.'

For example, a commercial pregnancy testing service provider who produces their 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 the device is transferred to another legal entity, you will be considered a manufacturer and the full regulations will apply.

The UK MDR 2002 may also apply for joint ventures between multiple establishments, even if there is a third establishment created to place the device on the market.

They do not apply if your institution has a specialist research and development laboratory that has been commissioned by another institution. This would usually be to manufacture a product for specific clinical or research purposes, which are not commercial objectives.

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.

Establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres are not considered to be health institutions and the exemption does not apply.

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 focused on the use of devices which have been manufactured inhouse (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. 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 they had manufactured a device from scratch for the purposes of the regulatory requirements - i.e., if he is placing the device on the market, 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 specific 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 their professional activity, in a way which makes important changes to its original purpose, that person will need to comply with the UK MDR 2002 unless the health institution exemption applies.