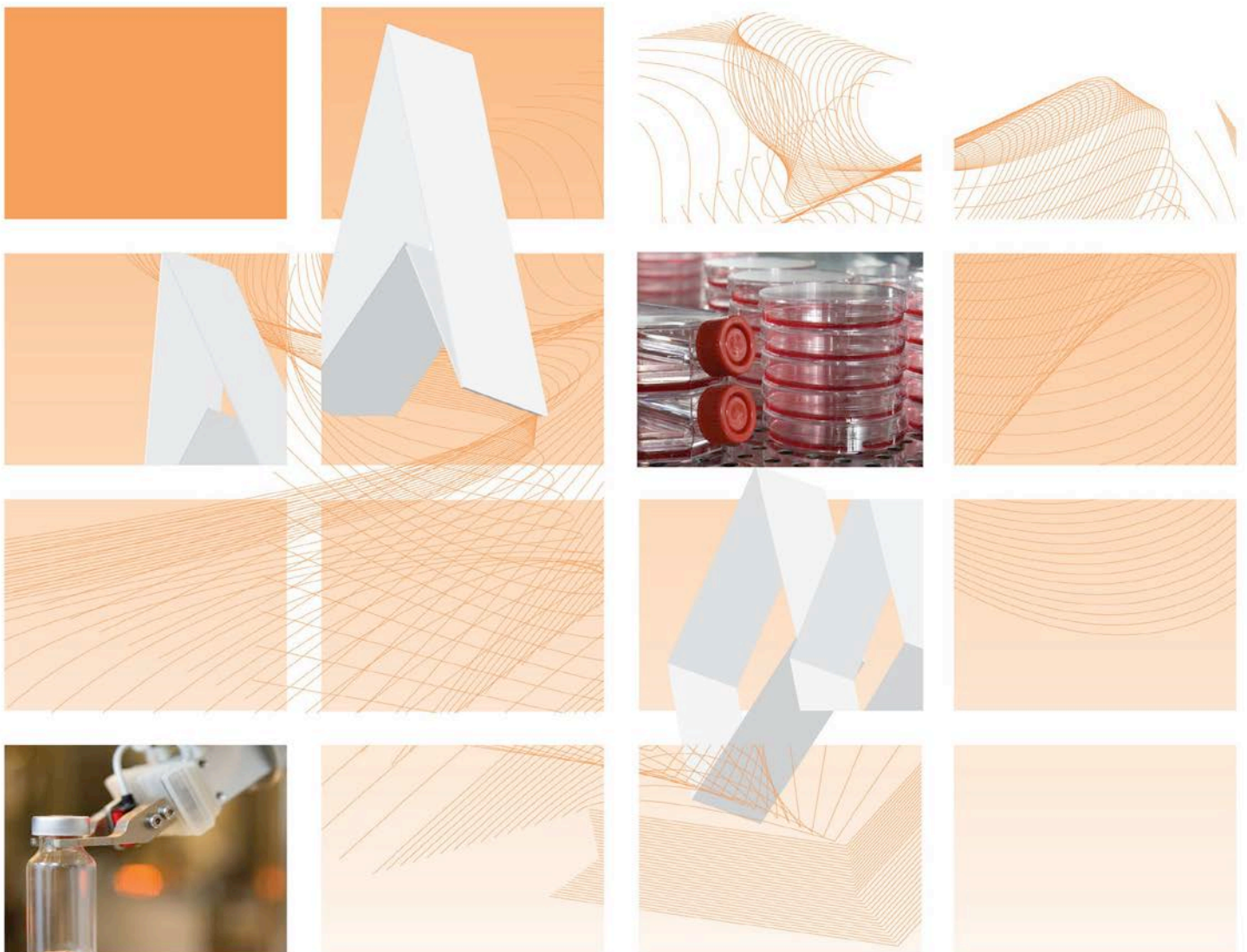




UK Standards for Microbiology Investigations

European Directive on In Vitro Diagnostic Medical Devices
(98/79/EC)



Issued by the Standards Unit, Microbiology Services, PHE

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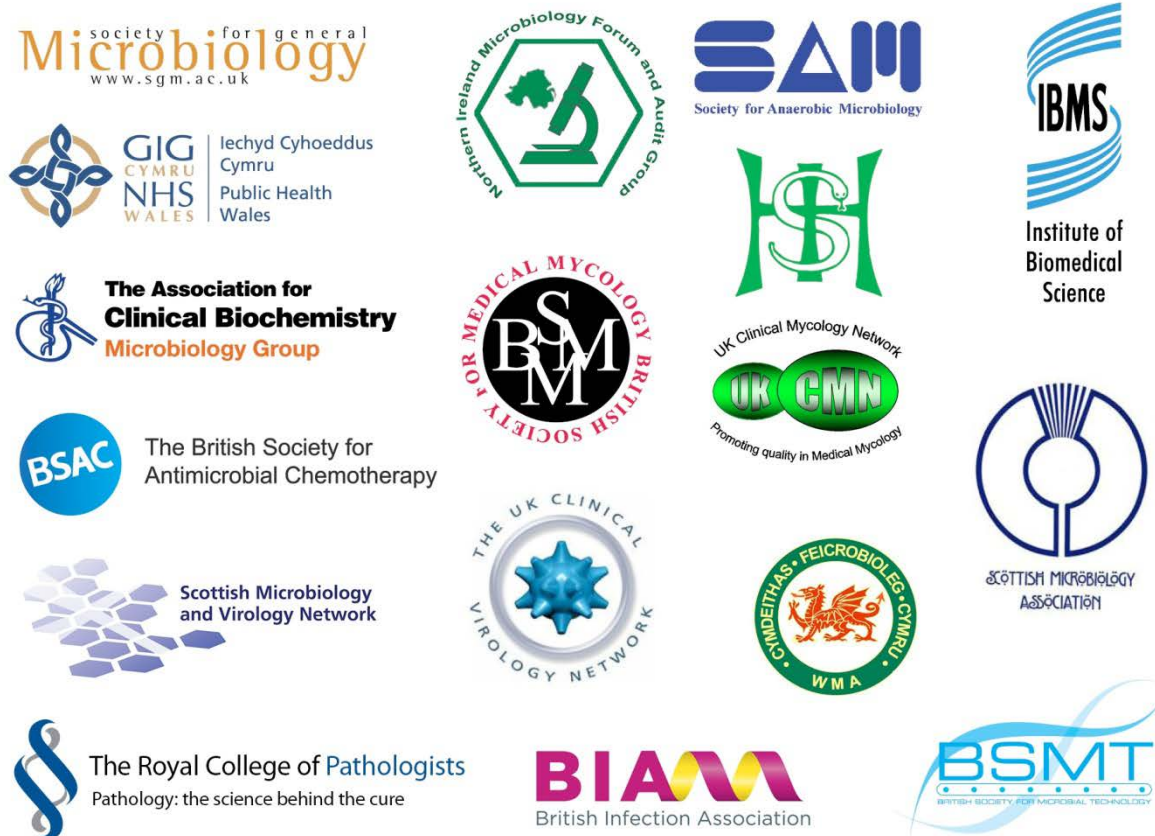
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For full details on our accreditation visit: www.nice.org.uk/accreditation.

Amendment Table

Each SMI method has an individual record of amendments. The current amendments are listed on this page. The amendment history is available from standards@phe.gov.uk.

New or revised documents should be controlled within the laboratory in accordance with the local quality management system.

Amendment No/Date.	8/09.10.13
Issue no. discarded.	4.2
Insert Issue no.	4.3
Section(s) involved	Amendment
Whole document.	<p>Document has been transferred to a new template to reflect the Health Protection Agency's transition to Public Health England.</p> <p>Front page has been redesigned.</p> <p>Status page has been renamed as Scope and Purpose and updated as appropriate.</p> <p>Professional body logos have been reviewed and updated.</p> <p>Standard safety references have been reviewed and updated.</p> <p>Scientific content remains unchanged.</p>

Amendment No/Date.	7/11.11.11
Issue no. discarded.	4.1
Insert Issue no.	4.2
Section(s) involved	Amendment
Whole document.	<p>Q 3 formerly QSOP 33.</p> <p>Document presented in a new format.</p>
References.	Some references updated.

UK Standards for Microbiology Investigations[#]: Scope and Purpose

Users of SMIs

- SMIs are primarily intended as a general resource for practising professionals operating in the field of laboratory medicine and infection specialties in the UK.
- SMIs provide clinicians with information about the available test repertoire and the standard of laboratory services they should expect for the investigation of infection in their patients, as well as providing information that aids the electronic ordering of appropriate tests.
- SMIs provide commissioners of healthcare services with the appropriateness and standard of microbiology investigations they should be seeking as part of the clinical and public health care package for their population.

Background to SMIs

SMIs comprise a collection of recommended algorithms and procedures covering all stages of the investigative process in microbiology from the pre-analytical (clinical syndrome) stage to the analytical (laboratory testing) and post analytical (result interpretation and reporting) stages.

Syndromic algorithms are supported by more detailed documents containing advice on the investigation of specific diseases and infections. Guidance notes cover the clinical background, differential diagnosis, and appropriate investigation of particular clinical conditions. Quality guidance notes describe laboratory processes which underpin quality, for example assay validation.

Standardisation of the diagnostic process through the application of SMIs helps to assure the equivalence of investigation strategies in different laboratories across the UK and is essential for public health surveillance, research and development activities.

Equal Partnership Working

SMIs are developed in equal partnership with PHE, NHS, Royal College of Pathologists and professional societies.

The list of participating societies may be found at <http://www.hpa.org.uk/SMI/Partnerships>. Inclusion of a logo in an SMI indicates participation of the society in equal partnership and support for the objectives and process of preparing SMIs. Nominees of professional societies are members of the Steering Committee and Working Groups which develop SMIs. The views of nominees cannot be rigorously representative of the members of their nominating organisations nor the corporate views of their organisations. Nominees act as a conduit for two way reporting and dialogue. Representative views are sought through the consultation process.

SMIs are developed, reviewed and updated through a wide consultation process.

[#] Microbiology is used as a generic term to include the two GMC-recognised specialties of Medical Microbiology (which includes Bacteriology, Mycology and Parasitology) and Medical Virology.

Quality Assurance

NICE has accredited the process used by the SMI Working Groups to produce SMIs. The accreditation is applicable to all guidance produced since October 2009. The process for the development of SMIs is certified to ISO 9001:2008.

SMIs represent a good standard of practice to which all clinical and public health microbiology laboratories in the UK are expected to work. SMIs are NICE accredited and represent neither minimum standards of practice nor the highest level of complex laboratory investigation possible. In using SMIs, laboratories should take account of local requirements and undertake additional investigations where appropriate. SMIs help laboratories to meet accreditation requirements by promoting high quality practices which are auditable. SMIs also provide a reference point for method development.

The performance of SMIs depends on competent staff and appropriate quality reagents and equipment. Laboratories should ensure that all commercial and in-house tests have been validated and shown to be fit for purpose. Laboratories should participate in external quality assessment schemes and undertake relevant internal quality control procedures.

Patient and Public Involvement

The SMI Working Groups are committed to patient and public involvement in the development of SMIs. By involving the public, health professionals, scientists and voluntary organisations the resulting SMI will be robust and meet the needs of the user. An opportunity is given to members of the public to contribute to consultations through our open access website.

Information Governance and Equality

PHE is a Caldicott compliant organisation. It seeks to take every possible precaution to prevent unauthorised disclosure of patient details and to ensure that patient-related records are kept under secure conditions.

The development of SMIs are subject to PHE Equality objectives http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317133470313. The SMI Working Groups are committed to achieving the equality objectives by effective consultation with members of the public, partners, stakeholders and specialist interest groups.

Legal Statement

Whilst every care has been taken in the preparation of SMIs, PHE and any supporting organisation, shall, to the greatest extent possible under any applicable law, exclude liability for all losses, costs, claims, damages or expenses arising out of or connected with the use of an SMI or any information contained therein. If alterations are made to an SMI, it must be made clear where and by whom such changes have been made.

The evidence base and microbial taxonomy for the SMI is as complete as possible at the time of issue. Any omissions and new material will be considered at the next review. These standards can only be superseded by revisions of the standard, legislative action, or by NICE accredited guidance.

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Suggested Citation for this Document

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Scope of Document

This SMI describes the items covered by the European Directive on *in vitro* diagnostic medical devices (98/79/EC).

This SMI should be used in conjunction with other SMIs.

Introduction

This Quality Guidance defines items that fall within the scope of the IVD Directive and describes the implications of these items for laboratories¹. It includes definitions of *in vitro* diagnostic medical devices (IVDs) and other terms used within the IVD Directive, classification of IVDs, an introduction to the essential requirements, conformity assessment routes, Conformité Européene (CE) marking and registration of devices.

To comply with the IVD Directive, laboratories should:

- Decide if they are a manufacturer (section 2)
- Establish whether any items produced are IVDs (section 3)
- Decide which items fall within the scope of the Directive (section 4)
- Assess items against the list of essential requirements on a case by case basis. Not all of the essential requirements will apply to all IVDs (section 5)
- Verify whether the items manufactured need CE marking (section 6 and 7)
- Decide which group the items belong to (section 10)
- Select a suitable conformity assessment route (section 11)

1 What is the IVD Directive?

The In Vitro Diagnostic Medical Devices Directive (98/79/EC) was formally adopted at the General Affairs Council of Ministers on 5th October 1998 and was published in the Official Journal of European Communities on 7th December 1998. The Directive came into force on 7th June 2000 and is implemented into UK legislation via the In Vitro Diagnostic Medical Devices Regulations. The Statutory Instrument is 2002 No. 0618 ISBN 0110423178. Compliance with the IVD Directive became mandatory on 7th December 2003. Since that date, all *in vitro* diagnostic medical devices (IVDs) which have been placed on the market have had to affix the CE marking. Before the Directive was transposed into UK law, supply of IVDs was unregulated in the UK. There are many benefits in manufacturers being forced to meet an internationally agreed set of standards. Previously, it was the responsibility of users to ensure that they only used reagents which were fit for purpose. Whilst this responsibility has not diminished, the knowledge that all suppliers of reagents must meet the same standards reduces the risk of poor quality IVDs being placed on the market.

2 Who is the Manufacturer of the IVD?

A manufacturer is defined as “the natural or legal 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.”

Placing on the market means “the first making available in return for payment or free of charge of a device other than a device intended for performance evaluation with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished.”

3 Is the Item Produced an IVD?

An IVD is “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”

A key phrase in the above definition is “...intended by the manufacturer...for the purpose of...”.

This includes all diagnostic kits or microbiological growth media or accessories to those kits, such as specimen receptacles. However, it does not include individual components of kits, such as primer sets which on their own cannot be used without other components which the supplier does not provide and has no control over. Products for general laboratory use are not IVDs.

Calibration and control materials refer to “any substance, material or article intended by their manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended use of that device.” Calibrators and control materials which are used to validate specific assay runs are also included within the definition and so must affix the CE marking.

Specimen receptacles are covered by the IVD Directive and are defined as “those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.”

Accessories are covered by the IVD Directive. An accessory is defined as “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.”

IVDs may be placed on the market and/or put into service only if the manufacturer complies with the requirements of the IVD Directive.

Putting into service “means the stage at which an IVD has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose.”

Making available means “the transfer of the IVD by way of transfer of ownership or the passing of the IVD to the final consumer or user in a commercial transaction, for payment or free of charge regardless of the legal instrument on which the transfer is based (sale, loan, hire, lease, gift or any other type of commercial or legal instrument)”.

4 IVDs Excluded from the Requirements of the Directive

If an IVD is made within one legal entity for use in that same entity, then the requirements do not apply. This rule still applies even when the IVD is used on premises in the immediate vicinity as long as there has been no transfer to another legal entity.

Once an IVD is transferred to another legal entity the IVD is subject to the requirements of the IVD Directive.

Although materials used for external quality assessment schemes are not covered by the Directive, calibrators and control materials needed by the user to establish or verify performances of devices are *in vitro* diagnostic medical devices.

4.1 In House Assays

Article 1.5 of the Directive (see Appendix 1b) relates to the use of in house reagents. It has been the subject of much discussion because, although it specifically states that the Directive does not apply to in house reagents, initially the Medicines and Healthcare products Regulatory Agency (MHRA) interpreted it to mean that it does apply when in house reagents are used to test specimens obtained from another legal entity. This would have had serious repercussions. However, following extensive consultation with representatives of the Royal College of Pathologists, Public Health England (PHE) formerly HPA and a number of other pathology associations, the MHRA has now accepted that all in house assays fall outside the scope of the Directive, and the source of the specimens is immaterial.

The MHRA stipulates 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. Normal activities undertaken within a laboratory fulfil this requirement. However, if staff within a laboratory set up a small private facility to take on work from, for example, the private sector, then this would not be intrinsic to the operation of the health institution. In this situation, the Directive would apply to the use of in house assays.

MHRA have taken the view that 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.

Recitals 10 and 11 of the Directive (see Appendix 1c) make it clear that if use of an in house assay is part of a commercial transaction, then the Directive will apply. However, there is a clear distinction between commercial use of a reagent and the situation which occurs in many PHE laboratories whereby a charge is sometimes made to certain clients to recover costs, when use of the IVD is intrinsic to the operation of the health institution.

For further information on this area refer to the [MHRA in-house guidance](#).

5 Modification of Commercially Produced Kits

The MHRA have advised that if a device has been modified to such an extent that it can be considered as a new one, then the modifier is in the same position as if he had manufactured a device from scratch. In other words, if the modified device is only used in house, then the Directive does not apply. However, 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. MHRA can give advice in individual cases. Clearly, any modification of a commercial kit will affect the manufacturers liability and transfer some or all of it to the user. All IVD systems should be validated prior to use (Refer to [Q 1 - Commercial and in-house diagnostic tests: Evaluations and Validations](#)).

6 What are the Essential Requirements of an IVD?

The essential requirements are listed in annex I of the IVD Directive. These aim to ensure that the health and safety of patients and users are not compromised by the IVDs, and that these products are designed and manufactured to achieve the intended performance and purpose. The IVD must comply with the requirements before being CE marked and placed on the market.

The requirements are listed under the following headings:

- a) General
- b) Design and manufacturing
 - Chemical and physical properties
 - Infection and microbial contamination
 - Manufacturing and environmental properties
 - Devices which are instruments or apparatus with a measuring function
 - Protection against radiation
 - Medical devices connected to or equipped with an energy source
 - Devices for self-testing
 - Information supplied by the manufacturer

7 What does CE Marking Mean?

The term CE marking means that a manufacturer has satisfied the IVD Directive by ensuring that a product conforms to the relevant essential requirements and that it is fit for its intended purpose².

CE marking is also a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation including those that relate to safety and where required has been assessed in accordance with these. This may require assessment by a Notified Body – see Section 11.

When an IVD bears the CE marking it means that it can be freely marketed anywhere in the European Economic Area without further control, ie would not be required to comply with any national schemes when exported to other countries in the European Union.

8 Which IVDs Do Not Need CE Marking?

IVDs that are undergoing performance evaluation are exempt from CE marking. IVDs for performance evaluation means “any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analysis or in other appropriate environments outside his own premises.”

However, although IVDs for performance evaluation would not require third party conformity checks manufacturers still need to draw up their own statement of compliance. Such statements would be subject to control by the UK’s Competent Authority, the Medicines and Healthcare products Regulatory Agency (MHRA)³.

IVDs such as instruments, apparatus, materials or other articles that are intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation and do not require CE marking.

9 What Does the CE Marking Look Like?

The CE marking of conformity should be at least 5mm in size and should appear on the packaging and on the IVD itself where practicable. Instruction leaflets relevant to the IVD should also bear the CE marking.

The CE marking should look like the symbol below:



10 Classification of IVDs

The IVD Directive classifies devices according to the perceived level of risk. This classification of IVDs is based on who the IVD user may be or the effect that the IVD may have if it fails to perform as intended. Each group of IVDs is subject to a degree of regulatory control that reflects the perceived risk (see section 11). The four groups of IVDs are:

- **General** eg bacteriological culture media, cell cultures for virus isolation, specimen containers (see section 11.1)
- **Self-test** eg test kits used in a home environment – pregnancy testing excluding self-test devices covered in Annex II (see section 11.2)
- **Annex II, list A** eg reagents including related calibrators and controls for use in HIV, HTLV and hepatitis assays (see section 11.3.1)
- **Annex II, list B** eg reagents including related calibrators and controls for use in rubella, toxoplasma, cytomegalovirus and chlamydia assays (see section 11.3.2)

Under the Regulations, it is not part of the role of the MHRA to give decisions on whether a particular product is or is not a medical device. These are questions for the manufacturer to decide in conjunction with their lawyers or professional advisors. Any opinion or guidance issued by the MHRA as to whether a product is or is not a medical device has no legal consequences. An authoritative ruling can only be given by a court of law in properly constituted proceedings.

11 Which Conformity Assessment Route Should the Manufacturer Follow?

To demonstrate compliance with the essential requirements, the manufacturer must use an appropriate conformity assessment route (Appendix 2)⁴. The choice of route depends on the group that the IVD falls into. IVDs in the higher group pose more risk, and hence have the most stringent conformity assessment procedures.

11.1 General IVDs

See Appendix 3

The manufacturer self-declares conformity (Annex III of the IVD Directive) and compliance of the IVD with all the relevant essential requirements (Annex I). This means that the manufacturer is making a legal statement that the product meets the requirements of the IVD Directive. Notified bodies are not involved.

11.2 Self-test IVDs

Other than those covered by Annex II (see Appendix 4)

In addition to self-declaration the manufacturer has to submit details of the IVD design to an independent certification organisation called a Notified Body. Details of all UK Notified Bodies designated under the IVD directive can be found on the MHRA website at

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=733.

While a list of all EU Notified Bodies can be found at:

<http://ec.europa.eu>

The Notified Body will assess the design of the IVD in terms of its suitability for non-professional users. Manufacturers can choose to follow the route for higher risk items instead.

11.3 Annex II IVDs

The systems operated by the manufacturer have to be verified by a Notified Body.

11.3.1 Annex II list A IVDs

See Appendix 5

The Notified Body must verify each product or batch of product before the manufacturer may place them on the market and will undertake one of the following:

- Carry out an audit of the manufacturers full quality assurance system and review the product design dossier (Annex IV)
- Carry out type-examination plus some form of production audit or sample (Annex V and Annex VII)

List A IVDs must meet the requirements of Common Technical Specifications, where they are available, to establish their performance characteristics.

11.3.2 Annex II list B IVDs

See Appendix 6

The Notified Body will undertake one of the following:

- Carry out an audit of the manufacturers full quality assurance system (Annex IV)
- Carry out type-examination plus verification of each batch of product (Annex V and Annex VI)
- Carry out type-examination plus audit of the production quality assurance system (Annex V and Annex VII)

Common Technical Specifications may be developed to establish the performance characteristics of some of the IVDs in list B. List B IVDs will not require batch release by the Notified Body.

Where a Notified Body has been involved in conformity assessment of the IVD the identification number assigned to it must be applied below the CE marking.

12 What if a Reagent or Kit Falls Within the Scope of the Directive?

If it is thought that the Directive might apply to an assay produced by a laboratory, then it is recommended that the advice prior to taking any further action. It may be necessary to seek further clarification from MHRA.

If it is deemed that the Directive does apply, then continued supply of the reagent should be stopped as compliance with the Directive is a legal requirement. The decision as to whether or not to affix the CE marking on the reagent is likely to be

based on the availability of an alternative commercial reagent; the public health importance of the reagent; the cost and complexity of conformity; whether or not the reagent falls within Annex II; the amount of reagent supplied. All IVD systems should be validated prior to use (Refer to [Q 1 - Commercial and in-house diagnostic tests: Evaluations and Validations](#)).

13 Registration of Manufacturers and Devices

Manufacturers of IVDs, including devices for performance evaluation, have to register the following details by completing Registration Form RG3 with the MHRA:

- Name and address of registered place of business or authorised Representative
- Information relating to reagents, reagents products and calibration and control materials including any significant changes and discontinuation of placing on the market
- Indications relating to kits, instruments, apparatus, equipment or systems
- For annex II and self-test IVDs all data allowing for the identification of such devices, analytical and diagnostic parameters, the outcome of performance evaluations, certificates, and any significant changes and discontinuation of placing on the market
- Notification of new IVDs

Form RG3, along with Guidance note 18 'Guidance notes for the registration of persons responsible for placing IVD medical devices on the market' published by the MHRA, February 2006, can be obtained from the MHRA website: <http://www.mhra.gov.uk>.

Appendix 1: Definitions

a) Definition of an *in vitro* diagnostic medical device (IVD)

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

b) Article 1.5 of the Directive (concerning use of in house assays)

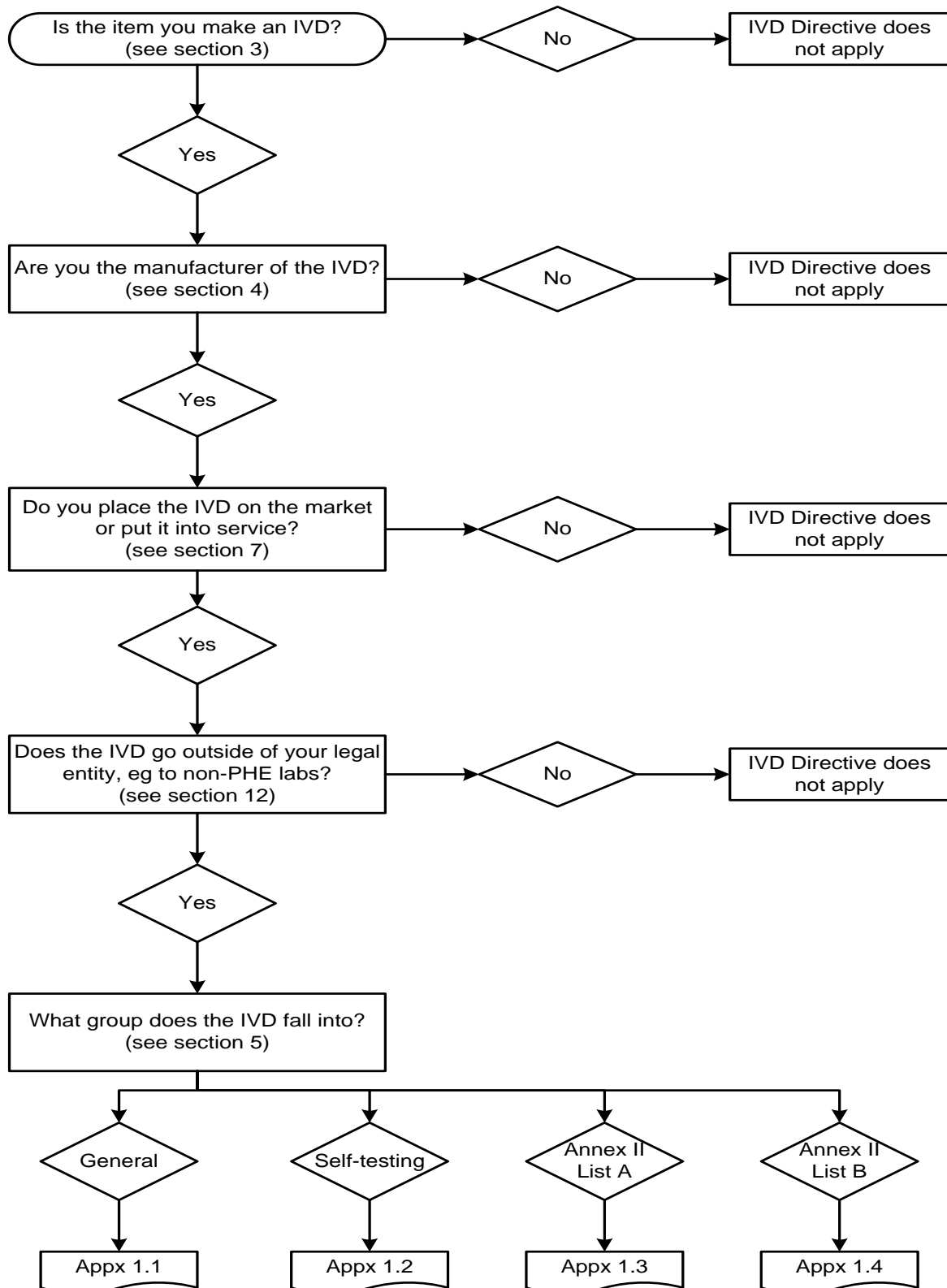
“This Directive shall not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity. This does not affect the right of Member State to subject such activities to appropriate protection requirements.”

c) Recitals 10 and 11 (relating to commercial use of reagents)

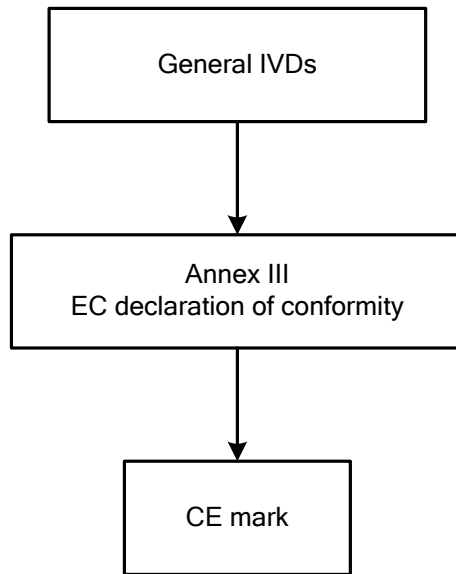
(10) Whereas, having regard to the principle of subsidiarity, reagents which are produced within health institution laboratories for use in that environment and are not subject to commercial transactions are not covered by this Directive;

(11) Whereas, however, devices that are manufactured and intended to be used in a professional and commercial context for purposes of medical analysis without being marketed are subject to this Directive;

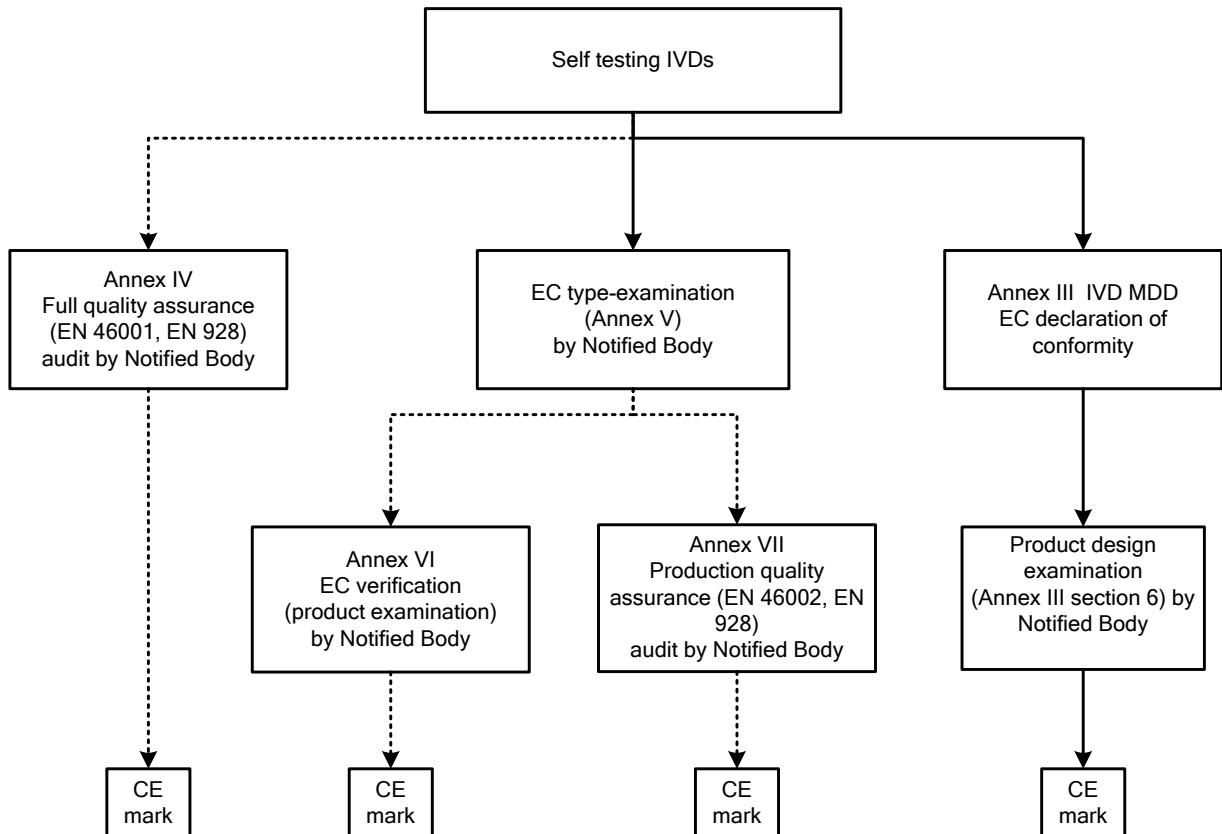
Appendix 2: Summary of the Process



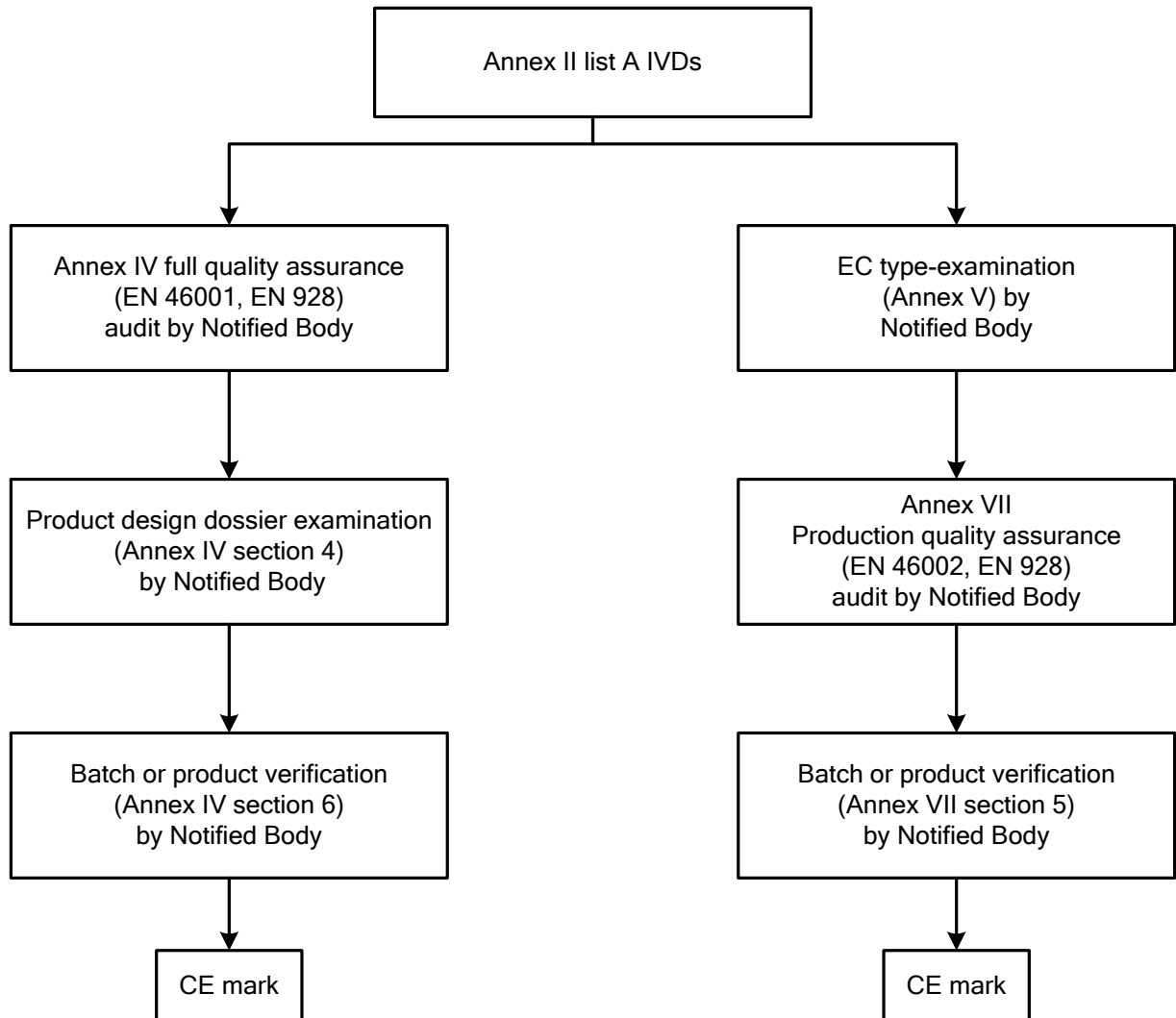
Appendix 3: Conformity Assessment for General IVDs



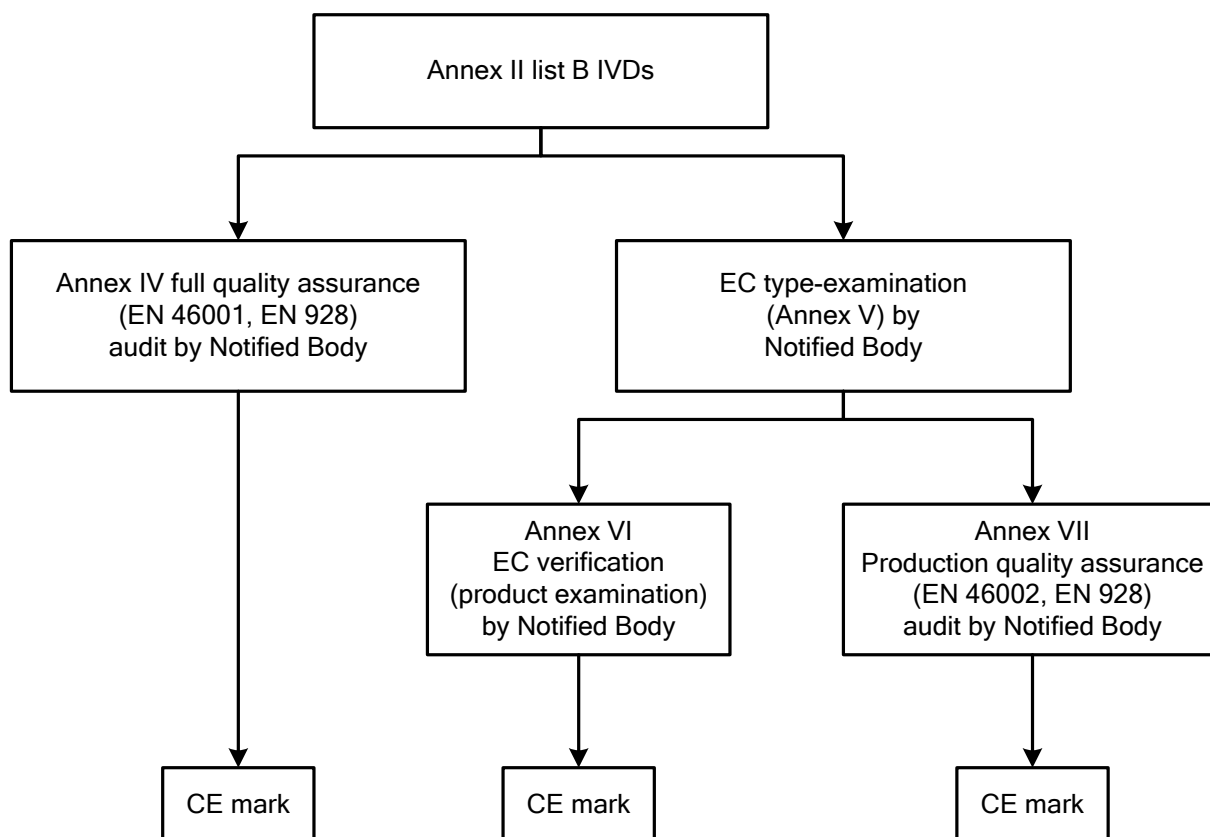
Appendix 4: Conformity Assessment for Self Testing IVDs



Appendix 5: Conformity Assessment for Annex II List A IVDs



Appendix 6: Conformity Assessment for Annex II List B IVDs



Appendix 7: Additional Sources of Information on IVDs

For further information on how the MHRA regulates the implementation of EC Medical Devices Directive into UK law, visit the MHRA website:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=48

For further details on the sale and supply of *in vitro* diagnostic medical devices see MHRA Bulletin 12, published February 2006:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=196

The EU Commission has published several guidance documents on IVD medical devices. Of Interest are the guidelines covering general laboratory equipment for research use only (guidance document 2.14/2) and for borderline issues (guidance document 2.14/1):

http://ec.europa.eu/enterprise/medical_devices/meddev/index.htm

References

1. Official Journal of the European Communities. Council Directive 98/79/EC: On *in vitro* diagnostic devices L331. 1998.
2. Medicines and Healthcare Products Regulatory Agency. MHRA Bulletin No 2 'The CE Mark'. 2006.
3. Medicines and Healthcare Products Regulatory Agency. EC Medical Devices Directives. Guidance Notes on the IVD Directive - Guidance note 19. 2006. p. 1-19.
4. Medicines and Healthcare Products Regulatory Agency. MHRA Bulletin 20 'Conformity assessment procedures under the in vitro diagnostic medical devices directive 98/79/EC'. 2000.