Draft guidance on the health institution exemption (HIE) – IVDR and MDR

Draft version 0.2 (December 2017) includes comment by IVDR and MDR external strategy groups received by 11th December 2017

To be reviewed for publication as a draft for informal consultation

Preface

The new EU Regulations for in vitro diagnostic medical devices (IVDs) and medical devices (MDs) will continue the exemption for manufacturing or modifying and using IVDs or MDs within the same health institution in Member States (also known as 'in house manufacture'). Health institutions wishing to apply the exemption in the new Regulations will need to ensure that products meet the relevant General Safety and Performance Requirements. In addition, health institutions will need to have

- *an appropriate quality system in place;*
- *a justification for applying the exemption;*
- *technical documentation in place.*

Some of this information will need to be publicly available.

MHRA are working towards a proportionate solution to applying such an exemption in the UK. We have worked with a range of stakeholders to develop a simple process with associated guidance that UK health institutions could use to apply the exemption. We have also worked with all the UK Devolved Administrations with the shared intent that the guidance can be used across the UK.

Although the formal transition to the new Regulations for Member States is May 2022 (IVDR) and May 2020 (MDR) we are actively working on producing the draft guidance so that health institutions here have sufficient time to consider the new requirements before the end of any relevant transition period.

The draft guidance is not complete. There are still further provisions within the new regulatory framework that have yet to be established (for example harmonised standards, implementing acts and delegated acts). For these areas, it is not always possible for us to suggest a position at this stage. In addition, there are elements of the guidance where we need more information to establish a UK position. These are marked in the text and we welcome further input from all stakeholders.

Until or unless you start using the exemption in the new Regulations, our existing advice on in house manufacture continues to apply. Current MHRA guidance on in house manufacture under the Directives can be found at:

- *General guidance in in house manufacture*

https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices

- *Clinical investigations and healthcare establishments https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/381068/Clinical_investigations_and_healthcare_establishments.pdf*
- *IVD specific guidance - page 13 In-house manufacture of IVD medical devices https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376918/Guidance_on_the_In_Vitro_Diagnostic_Medical_Devices_Directive.pdf*

This guidance will apply only to products which are covered by the definition of a medical device or in vitro diagnostic medical device or their accessories. MHRA guidance on the supply of unlicensed medicinal products ("specials") - see MHRA guidance at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf *- does not apply to medical devices, IVDs or their accessories.*

This is a draft document for consultation following discussion with key stakeholders. It represents various thoughts and ideas on the interpretation of the exemption for health institutions under the MDR and IVDR and should not be taken as MHRA policy.

This draft document does not represent the final views of MHRA or its stakeholders.

A quick note on format

This draft guidance document is likely to be published online and so will need to be formatted for web viewing (not pdf or Word)

Contents

Introduction

Under the current Directives[1], medical devices (MDs) and in vitro diagnostic medical devices (IVDs) that are used in the same health institution as they are made, are exempt from all of the requirements of the IVD and MD Directives.

In May 2017, new EU Regulations[2] were published which include a specific exemption for IVDs and MDs that are used in the same health institution as they are made *or modified* but with some specific requirements. These requirements are set out in Article 5 paragraph 5 in both Regulations. The date of application for the new Regulations is May 2020 for medical devices and May 2022 for IVDs although health institutions may wish to apply the new requirements at any time before then.

This guidance is aimed at health institutions wishing to apply the exemption.

IVDs and MDs that are used in the same health institution as they are made or modified are considered to have been 'put into service' and must meet all of the relevant general safety and performance requirements that are set out in Annex I of both Regulations. The use of exempted devices must be justified, the manufacture and use of the devices must be covered by a quality management system and some information about the device must be publicly available.

These new requirements are intended to provide the highest level of health protection for patients whilst allowing health institutions to address the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent device available on the market.

[1] Medical Device Directive 93/42/EEC and IVD Directive 98/79/EC

[2] Official Journal of the European Union L117 Volume 60 5 May 2017

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC

Definitions and Scope

The new IVD and MD Regulations[3] define a health institution as 'an organisation whose primary purpose is the care or treatment of patients or the promotion of public health'. This includes hospitals, laboratories, local authorities and public health institutes supporting the health care system and/or addressing patient needs, but may not treat or care for patients directly.

QUESTION A
Some examples of what we consider to be health institutions are obvious eg NHS Trusts/ NHS Boards, but what about the following?

a) Collaborations led by a health institutions to provide healthcare? Yes/no
b) Collaborations led by a health institutions for product development with/without commercial intent? Yes/no
c) Free standing commercial laboratories? Yes/no

Any other examples?

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 this document, we are referring to either 'medical devices' or 'in-vitro diagnostic medical devices', each defined in the respective Regulations. We will use the term 'device(s)' to refer to both, and the abbreviations MD or IVD to differentiate.

Manufacturing

Manufacturing or modifying a device by a health institution could include:

- the putting together of a device from raw materials or component parts, or
- the complete rebuilding an existing device, or
- making a new device from used devices, or
- fully refurbishing a device, or
- device software development, or
- using a product for a medical purpose that is not CE marked as a device[4], or
- putting together combinations of devices and other equipment, or
- significant deviations from the instructions for use that alter the function, performance or purpose of the device, or
- using an existing device for a different purpose to that intended by the manufacturer, or
- modifying a device for a new purpose, function or performance

[3] Article 5 IVDR/MDR
[4] MHRA Guidance on Off-label use of a medical device published 18 December 2014 https://www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device

and where this action is not explicit in a manufacturer's intended purpose or instructions for use.

The new regulations introduce the concept of modification. Modifying a device includes significant deviations from the instructions for use that alter the function, performance or purpose of the device. Modification could include using an existing device for a purpose not intended by the manufacturer, modifying a device for a new purpose, use of sample types, accessories or components or combining devices not specified by the manufacturer. Therefore, off-label use may also be a modification or manufacture and the exemption requirements would apply.

The modification and use of the device should be verified against the original device when used as intended by the manufacturer to demonstrate and document whether the function, performance or purpose has been altered.

The requirements of the exemption do not apply to devices designed and intended by the manufacturer to be:

- assembled, built or installed from modules or component parts, or
- used together in combinations with other devices or equipment, or
- configured by the user of the device

and where this is explicit in the device manufacturer's intended purpose or instructions for use. This could include some medical electrical systems, rehabilitation engineering units and pathology systems. These devices will need to be CE marked in the usual way.

The MDR and IVDR include provisions for manufacturers around systematic misuse and reasonably foreseeable misuse. Modification of a device that is subject to the requirements of the exemption including appropriate clinical investigation/performance study does not constitute foreseeable or systematic misuse.

The exemption does not apply to devices that are manufactured on an "industrial scale". Health institutions should determine whether their activities are on an industrial scale considering the magnitude (eg numbers of products, downloads, patients, episodes of use) and the methods of production (eg standardised, serial or batched production).

Cleaning, decontamination, repair or maintenance

Cleaning, decontamination, repair or maintenance of a device (other than single use devices) in line with the manufacturer's instructions are not considered modification or manufacturing.

Health institutions who provide a cleaning, decontamination, repair or maintenance service to other legal entities may be placing devices on the market and may need to comply fully with the Regulations.

Health institutions who provide a cleaning, decontamination, repair or maintenance service (other than for single use devices) and who follow manufacturers' instructions do not need to apply the requirements of this exemption.

Health institutions who provide a cleaning, decontamination, repair or maintenance service (other than for single use devices) and who do not follow manufacturer's instructions will need to apply the requirements of this exemption.

MHRA advice in the re-use and reprocessing of single use devices continues to apply[5] and devices designated as 'single-use' must not be reused.

Items that are used to replace a part or component of a device and that significantly change the performance or safety characteristics or the intended purpose of the device shall be considered to be modification of the device and the requirements of the exemption apply.

Items used to replace a part or component of a device and that do not significantly change the performance or safety characteristics or the intended purpose of the device are not considered devices and no exemption is needed.

Systems and procedure packs

Combining CE marked medical devices into a system or procedure pack[6] is not considered manufacturing or modification. Health institutions who put together systems or procedure packs that are used within the same health institution do not need to apply the exemption.

Research use products with no CE mark

Products labelled or designated only for 'research use' do not have a medical purpose; are not intended for clinical use and should not be CE marked under IVDR or MDR. 'Research use' products are specifically excluded from the IVDR and although are not explicitly excluded from MDR, they do not have a medical purpose and are therefore considered as excluded from the MDR.

Products without a CE mark can be used within health institutions provided they are not put into service for clinical use.

Products without a CE mark can be used within health institutions as part of a clinical investigation or performance study where the purpose of the clinical investigation or performance study is to establish clinical evidence for the use of the product.

Health institutions who procure products labelled for 'research-use' or otherwise without a CE mark and then use the product for patient management will need to apply the requirements of the exemption.

[5] MHRA Guidance for healthcare professionals on using single-use medical devices https://www.gov.uk/government/publications/single-use-medical-devices-implications-and-consequences-of-re-use

[6] MDR definitions are (10) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;
(11) 'system' means a combination of products, either packaged together or not, which are intended to be inter- connected or combined to achieve a specific medical purpose;

Performance studies and clinical investigations

Devices made or modified and used in performance studies or clinical investigations are subject to the requirements of the Regulation unless the requirements of the exemption apply.

Where the device for performance study or clinical investigation is intended to be made or modified and used only within the same health institution after the end of the investigation/study and there is no commercial intent, the requirements of the exemption will apply.

Where the study is being carried out on behalf of a third party or where the study is intended to support CE marking of the device or where there is a commercial intent then the requirements of the Regulations apply. In some circumstances, the health institution will need to apply to MHRA for an assessment before starting the clinical investigation or performance evaluation.

QUESTION B
a) Is this a right approach to the regulation of devices in clinical investigations and performance studies? Yes/no

b) Is this approach proportionate and desirable? Yes/no

c) What is an appropriate QMS for use in a clinical investigation/performance study? Please specify.

d) Should clinical investigations/performance studies:
Be registered with MHRA? Yes/no
Comply with relevant GSPR? Yes/no
Have the same level of justification? Yes/no

e) Do general principles apply to performance studies (IVDR Article 57) and 'other clinical investigations' (MDR Article 82) when applying the exemption?
IVDR Article 57 – yes/no
MDR Article 82 – yes/no

f) Any other comments?

Custom-made devices

Requirements for custom-made medical devices continue in the new MDR. For some products made or modified and used within a health institution and which are not placed on the market, the health institution will need to decide for themselves whether to apply the requirements for custom-made devices or the requirements of the health institution exemption.

MDR requirement	Health institution exemption	Custom-made medical device
Comply with relevant GSPR	Yes	Yes
Applies to medical devices put into service	Yes	Yes
Applies to medical devices placed on the market	No	Yes
Written prescription	Not required	Required, by an authorised prescriber
Justification	Required	Not required
Scale	Not on an industrial scale	Not mass produced
Patient	Patient group or individual patient	Individual patient
Exemptions	General exemption with specific requirements	Specific exemptions apply
Person Responsible for Regulatory Compliance	Not required	Required
Quality System	Needs to be appropriate	As set out in Article 10.9
Demonstrate compliance	Publicly available declaration	Statement
Documentation	Required	Annex XIII requirements
Information available to MHRA	On request	On request
Registration with MHRA	Not required	Not required
Notified Body	None	Class III only
Post market	Review experience	Vigilance reporting requirements
Periodic Safety Update Report	Not required	Required

The concept of a custom-made device applies only to MDR and not IVDR. Detailed guidance on the regulation of custom-made devices is beyond the scope of this document.

Transfer of devices

To transfer a device between health institutions each health institution will need to apply the exemption separately with each applying the requirements of the exemption including making a separate declaration. At least some of the evidence to support the declaration will be based on local validation for the manufacture or modification and use of the device.

The requirements of the exemption apply to devices being developed in collaborations led by health institutions provided the same declaration can be made for all of the sites involved.

Some devices made and used within a health institution have been issued to an individual patient and are essential to the continuity of patient care. These devices can be transferred between legal entities without the need for an exemption. Examples include implanted devices, fitted prostheses, assistive technology devices issued to patients or patient-transfer devices**.**

An exemption is not required for the transfer of patient samples or patient data between legal entities (eg for pathology testing) provided the device itself is not transferred.

Control of subcontractors

Where the health institution uses another party in the making of the device, they will need to have sufficient responsibility and control for the work of the other party that the requirements of the exemption can be applied to the device. Control might include specifications for subcontractor quality systems, regular audit, supply chain control and mandatory notification of relevant changes. Without sufficient responsibility and control for the work of the other party, then the exemption will cease to apply.

When manufacturing or modifying and using devices with open-source or cloud-based components (including software and hardware) health institutions should ensure that they have sufficient responsibility and control throughout the lifetime of the device. The health institution should consider whether they have sufficient information about the safety, quality and performance of the component to meet the relevant requirements of Annex I on the IVDR/MDR.

The justification

The health institution's justification for applying the exemption must be that the target patient group's specific needs cannot be met or cannot be met at the appropriate level of performance by an equivalent device available on the market. The justification should include evidence (eg market surveys/literature reviews) for the availability on the market of equivalent CE marked devices[7]. The justification should also include evidence that the device is more appropriate under the specific circumstances than any apparently equivalent CE marked devices.

[7] Definition of equivalence for medical devices (equivalence for IVDs still needs to be defined) Annex XIV para 3 MDR

Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;

Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

Critical features might include:

- patient needs (including invasive sample taking)
- device performance
- device reliability
- device requirements
- turn-around times
- systems compatibility

The extent/detail of the justification should be proportionate to the risk class of the device.

QUESTION C
Please could you provide other examples that we can use to help health institutions understand what is needed?

QUESTION D
a) Should the health institution regularly monitor the market and test similar devices for equivalence? yes/no

b) Should the health institution stop making or modifying and using the device once an equivalent CE marked product is made available? Yes/no

c) any other comments

Quality Management Systems

One of the requirements for applying the exemption is that manufacture and use of the devices occur under appropriate quality management systems. EN ISO 13485[8], is an appropriate quality management system for manufacture of devices in all health institutions. The quality management system can cover the whole health institution or just those parts of the health institution manufacturing or modifying the device. Additional sector-specific quality management systems may also apply.

For advice on appropriate quality management systems for use of the device see MHRA - Managing Medical Devices - Guidance for healthcare and social services organisations - April 2014

The minimum requirement for qualifying Quality Management Systems is a standard appropriate for the scope of products to be covered by the exemption. Essential elements of an appropriate standard include selection of devices, management, use and record keeping for the lifetime of the device. Additional elements include design, manufacturing, performance review and the need to conform to applicable laws (including IVDR or MDR) and harmonised to the IVDR/ MDR.

For more guidance and advice on device quality systems, Health institutions may wish to refer to Article 10 paragraph 8 (IVDR)/ paragraph 9 (MDR).

[8] EN ISO 13485:2016 “Medical devices -- Quality management systems -- Requirements for regulatory purposes”

A requirement for IVDs is that the laboratory of the health institution is compliant with standard EN ISO 15189. Although health institutions may need to have additional quality management systems, ISO 15189 is considered in the UK to be an 'appropriate quality management system' (Article 5 para 5 b) for IVDs. The UK operates an accreditation process via UKAS who can accredit medical laboratories to ISO 15189[9].

UKAS assessors may ask for details of IVDs that are exempted within the health institution.

Inspections and enforcement

MHRA may choose to request information and may inspect institutions as part of its enforcement powers.

Information publicly available

In order to apply the exemption, the Regulations require the health institution to make some information publicly available. A form has been designed to help decide what information should be made public.

QUESTION E

a) Should there be a register of health institutions applying this exemption? Yes/no

b) Should parts A and B of the form be made publicly available centrally? Yes/no

c) Should part C of the form also be made publicly available? Yes/no

d) Should MHRA consider the need to carry out market surveillance activities of registered exemptions? Yes/no

e) Any other comments

General Safety and Performance Requirements (GSPR)

Health institutions seeking to apply this exemption to a device will need to demonstrate that exempted devices meet all the general requirements set out in Annex I Chapter I and the relevant requirements for performance, design and manufacture set out in Annex I Chapter II and the information requirements set out in Annex I Chapter III – 'relevance' is to be determined by the health institution.

Devices for performance evaluation or clinical investigation will not be able to demonstrate that they meet the requirements that are to be established by the study, but they should be able to demonstrate that they meet all the other relevant requirements.

[9] EN ISO 15189:2012 "Medical laboratories -- Requirements for quality and competence"

Where a requirement does not apply to a device then there should be a reasoned justification. For example, devices which do not incorporate materials of biological origin do not need to demonstrate compliance with that requirement

Harmonised standards are European standards that have been mandated by the European Commission and published in the Official Journal of the European Union. Devices that are in conformity with a harmonised standard shall be presumed to be in conformity with those requirements of the Regulations listed in the standard. For example, the risk management standard EN ISO 14971:2012 “Medical devices - Application of risk management to medical devices” has been harmonised to both IVDD and MDD. Annex Z of a harmonised standard maps the clauses of the standard to the corresponding essential requirement of the Directive. It is anticipated that the same format will be used for standards harmonised to IVDR and MDR.

Health institutions may wish to use harmonised standards to demonstrate conformity with corresponding GSPR.

For some devices, Common Specifications will be adopted as Implementing Acts by the European Commission which have the same presumption of conformity with corresponding GSPR as a harmonised standard.

List of current IVDD harmonised standards
https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en

List of current MDD harmonised standards
https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

Current Common Technical Specifications for IVDs
http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

Documentation requirements for all medical devices and class D IVDs

There are specific requirements for the documentation of all medical devices and class D IVDs[10]**.** To apply the exemption, the health institution should prepare documentation that describes:

i. the intended purpose of the device;
ii. the manufacturing facility;
iii. the manufacturing process;
iv. the design and performance data of the devices in relation to its intended purpose.

The documentation should be sufficiently detailed to enable MHRA to ascertain that all of the relevant general safety and performance requirements are met. Health institutions should be able to present all the relevant information in a clear, organised,

[10] Class D includes tests intended for screening the blood supply (eg for infectious disease agents including blood borne viruses, prion disease and certain blood groups) plus tests intended for life threatening diseases with a high risk of propagation (eg influenza, Lassa, Marburg and Ebola)

readily searchable and unequivocal way. The documentation could include the evidence or it could provide references to the location of the evidence. An appropriate format for documentation is described in detail in Annex II of the MDR/IVDR.

QUESTION F
a) Can these requirements be applied in emergency situations? – eg development of an assay for an emergent epidemic such as SARS or MERS?
Yes/no

b) If not what is the alternative route?

QUESTION G
a) Should this additional documentation requirement also apply to IVDs in class A, B or C? yes/no

b) If so, what is the robust, risk-based rationale and where can people go for guidance on IVD classification?

Manufacturing process

During manufacturing or modification of the device, health institutions should make sure that they follow the process set out in their technical documentation.

Surveillance

Regardless of the class of the device manufactured under this exemption, the health institution should have a surveillance system in place which gathers experience in the clinical use of the device. This experience should be reviewed and if necessary corrective and preventative actions taken to safeguard the safety of patients, users or others (eg change the way the device is made or used, review results from previous uses of the device, suspend further use of the device either permanently or temporarily or other relevant corrective action).

QUESTION H
Should MHRA reserve the right to impose review and reporting requirements for all serious incidents plus trend reporting of other incidents in the future? Yes/no

MHRA expect that health institutions continue to report all adverse incidents associated with devices whether CE marked or exempted.
Health institutions in England and Wales should report to MHRA via yellowcard (https://yellowcard.mhra.gov.uk/)
Welsh incidents should also be copied to Welsh Surgical Materials Testing Laboratory (http://www.wales.nhs.uk/sites3/page.cfm?orgid=465&pid=56203)

Health institutions in Scotland should report via Health Facilities Scotland Incident Reporting and Investigation Centre (http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric-1/how-to-report-an-adverse-incident/)

Health institutions in Northern Ireland should report via Northern Ireland Adverse Incident Centre (https://www.health-ni.gov.uk/articles/reporting-adverse-incident)

Governance

All devices that are manufactured or modified and used within the health institution including where modification and use of the device is also considered to be 'off label use' should be included in the declaration. Good practice for health institutions includes referral to a medical device management committee (or other similar structure) prior to making the declaration.

Health institutions should appoint the most appropriate competent and senior person(s) with relevant expertise to sign the declaration and take responsibility for regulatory compliance of exempted devices including the supervision and control of manufacturing, and surveillance over the lifetime of the device. (See Article 16 for guidance on responsibilities)

QUESTION I
Although not a requirement in the Regulations, should MHRA require health institutions to employ/subcontract/have access to competent regulatory advisers in lieu of a Person Responsible for Regulatory Compliance? (ref Article 15 IVDR and MDR)? Yes/no

QUESTION J
a) Although not a requirement in the Regulations, should MHRA require or recommend health institutions to submit higher risk classification devices to a conformity assessment route using a Notified Body or other suitably qualified independent body? Yes/no

b) If not should this be justified?

Distance Sales

A device used outside of the UK in the context of a commercial activity for the provision of a diagnostic or therapeutic service must comply with the requirements of the Regulations.

Health institutions based in countries elsewhere in the EU will need to follow local requirements.

Health institutions based in countries outside the EU must comply with the requirements of the Regulations.

Transition arrangements

The IVDR and MDR came into force on the 25th May 2017 with transition periods of 5 and 3 years respectively. From 25th May 2017, health institutions can choose to apply the current exemption in the IVDD/MDD or the new exemption in the IVDR/MDR (this guidance). By the end of the transition period, all UK health institutions should have moved to the provisions of the IVDR/MDR.

Devices that are made under the exemption for the IVDD/MDD that are put into service before the end of the transition period can continue to be used until expiry or until a significant change in the device.

Until or unless the health institution starts using the exemption in the new Regulations, our existing advice on in house manufacture continues to apply. Current MHRA guidance on in house manufacture under the Directives can be found at:

- General guidance on in house manufacture
- https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices
- Clinical investigations and healthcare establishments
- https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/381068/Clinical_investigations_and_healthcare_establishments.pdf
- IVD specific guidance - page 13 In-house manufacture of IVD medical devices
- https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376918/Guidance_on_the_In_Vitro_Diagnostic_Medical_Devices_Directive.pdf

QUESTION K

Is there any cross over with FDA deliberations on Laboratory Developed Tests?

http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/UCM536965.pdf

FDA LDT discussion paper.pdf

Guidance for completion of the form

The form is in three parts:

- Part A is the declaration
- Part B is the listing of the exempt devices
- Part C provides more details of the exempt devices

Parts A and B include the information that must be made publicly available.
Part C includes the information that does not need to be made publicly available, but should be submitted on request by the MHRA.

Part A Declaration

Information about the manufacturing or modifying health institution

The name of the legal entity of the health institution

The name and contact details of the person within the health institution who can be contacted for further information.

Part B Listing of exempt devices

Devices can be grouped together using a coding system.

Coding systems which may be suitable include the Global Medical Device Nomenclature codes (https://www.gmdnagency.org/) and Notified Body Operations Group (https://ec.europa.eu/info/law/better-regulation/initiatives/c-2017-7779_en).

NOTE

We are seeking health institutions willing to model the different coding systems to help determine the most appropriate approach. Please let us know if you are interested in taking part.

Updates to part B also need an updated declaration at part A.

Part C device details

A new part C will be needed for each device or group of devices. For example, devices with similar documentation, intended purpose, justification and GSPR could be grouped together on a single part C.

If using the GSPR checklist, please include a copy in part C. Otherwise provide a list of the GSPR that have been met with a description of the solutions for each and the GSPR that have not met with a justification for each.

Glossary

To include all relevant definitions from Article 2 MDR/IVDR
Consider including new definitions for:

- Modification
- Off label use
- legal entity,
- equivalent device (for IVDs) and
- industrial scale

QUESTION M
Please list any additional terms that you would like to be included in a glossary.

Appendix simple form

PART A – Declaration

(to be made publicly available by the health institution)

INFORMATION ABOUT THE MANUFACTURING HEALTH INSTITUTION	
Name	
Address	
Name of contact	
Job Title	
Department	
Contact telephone number	
Contact e-mail	

DECLARATION	
Devices listed in part B are manufactured or modified and used by this health institution and meet the relevant General Safety and Performance Requirement set out in Annex I of the regulations on IVD (2017/746)/ MD (2017/745). **These devices are manufactured in accordance with our Technical Documentation.** **Further information concerning the use of exempt device will be provided to the MHRA upon request. I understand that MHRA may need to inspect these activities.**	…… Signed on behalf of the organisation Name Date

PART B – Listing of exempt devices

(to be made publicly available by the health institution)

Device	Coding system	Code
		(for longer lists, extend this table as required)

Part C – Device Details

Complete new part C for each row in part B

Code and coding system (as used in part B)	
Reference to Technical Documentation	
MD for clinical investigation or IVD for performance study?	
Intended purpose of device	
Justification for applying the exemption	
quality management system accreditation/provisions	

Part C (continued)

Statement of compliance with the General Safety & Performance Requirements of the IVDR/MDR

(including justification of any requirements not applicable)

GSPR checklist

Requirement	IVDR	MDR	Reference to documentation or if the requirement is not applicable, state why
GENERAL REQUIREMENTS	x	x	
Performance characteristics	x		
Chemical, physical and biological properties	x	x	
Infection and microbial contamination	x	x	
Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.		x	
Devices incorporating materials of biological origin	x	x	
Construction of devices and interaction with their environment	x	x	
Devices with a diagnostic or measuring function		x	
Devices with a measuring function	x		
Protection against radiation	x	x	
Electronic programmable systems	x	x	
Active devices and devices connected to them		x	
Particular requirements for active implantable devices		x	
Devices connected to or equipped with an energy source	x		
Protection against mechanical and thermal risks	x	x	
Protection against the risks posed to the patient or user by devices supplying energy or substances		x	
Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons		x	
Protection against the risks posed by devices intended for self-testing or near-patient testing	x		
Label and instructions for use	x	x	