Medicines & Healthcare products Regulatory Agency

MHRA

MHRA guidance on the health institution exemption (HIE) – IVDR and MDR (Northern Ireland)

January 2021

Preface

This guidance is only relevant for healthcare institutions in Northern Ireland. For information on the regulation of medical devices on the Great Britain market, please see our published guidance.

The Regulations for in vitro diagnostic medical devices (IVDs) and medical devices (MDs) will keep the exemption for manufacturing or modifying and using IVDs or MDs within the same health institution (also known as 'in house manufacture'). Health institutions wishing to apply the exemption in the Regulations will need to ensure that:

- *products meet the relevant General Safety and Performance Requirements*
- *there is an appropriate quality system in place*
- *there is a justification for applying the exemption*
- *technical documentation is in place; and*
- *some of this information is made publicly available*

The MHRA has worked with a range of stakeholders to develop this guidance for UK health institutions who wish to apply the exemption, including the UK Devolved Administrations.

There are still further provisions within the regulatory framework that have yet to be established (for example harmonised standards, common specifications, implementing acts and delegated acts). However, health institutions should not wait for these provisions before applying the requirements of the exemption.

Until or unless you start using the exemption in the Regulations, our existing advice on in house manufacture continues to apply until May 2021 (MDR) and May 2022 (IVDR) when they will fully apply in Northern Ireland. Current MHRA guidance on in house manufacture under the Directives can be found at:

- *General guidance on in house manufacture*
- *Clinical investigations and healthcare establishments*
- *IVD specific guidance - page 13 In-house manufacture of IVD medical devices*

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") does not apply to medical devices, IVDs or their accessories.

Contents

Introduction

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

In May 2017, new 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 2021 for medical devices and May 2022 for IVDs although health institutions may choose to apply the new requirements at any time before then.

This guidance is aimed at Northern Ireland-based 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 a high 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 IVD Regulations (IVDR) and MD Regulations (MDR) define a health institution as 'an organisation whose primary purpose is the care or treatment of patients or the promotion of public health[3]. This includes organisations supporting the health care system and/or addressing patient needs but who may not treat or care for patients directly eg. laboratories, local authorities and public health institutes.

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', (or their accessories) 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

Where this action is not explicit in a manufacturer's intended purpose or instructions for use manufacturing a device by a health institution could include:

- the putting together of a device from raw materials or component parts
- the complete rebuilding an existing device
- making a new device from used devices
- fully refurbishing a device
- device software development
- assigning a medical purpose to a product that is not CE marked as a device[4]
- putting together combinations of devices and other equipment
- 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

Modification

The new regulations introduce the concept of modification.

Where this action is not explicit in a manufacturer's intended purpose or instructions for use, modifying a device could include:

- significant deviations from the instructions for use that alter the function, performance or purpose of the device
- using an existing device for a purpose not intended by the manufacturer
- modifying a device for a new purpose

[3] MDR Article 2(36) IVDR Article 2(29)

[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

- use of sample types, accessories or components or combining devices not specified by the manufacturer.

Use of a device outside of the manufacturer's instructions (also called off-label use) may also be a modification 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
- 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 does not constitute a 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 (e.g. numbers of products, downloads, patients, episodes of use) and the methods of production (e.g. 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 which provide a cleaning, decontamination, repair or maintenance service (other than for single use devices) and which follow manufacturers' instructions are not manufacturing or modifying a device and do not need to apply the requirements of this exemption.

Health institutions which provide a cleaning, decontamination, repair or maintenance service (other than for single use devices) and which ***do not*** follow manufacturer's instructions are potentially modifying the device would therefore 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 or CE UKNI[6] marked medical devices into a system or procedure pack[7] may not be considered manufacturing or modification. Provided this is done in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers[8], 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 device CE mark or CE UKNI mark

Products used on humans for research purposes, where there is no intended medical purpose, are considered to be research tools and should not be CE marked or CE UKNI marked under MDR or IVDR. '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.

It should be noted that it is possible for these products to be CE marked or CE UKNI marked under other Directives or Regulations[9]. If a research tool is to be manufactured, consideration should be given from a best practice standpoint to meet some of the exemption requirements such as having an appropriate quality management system in place, meeting general safety and performance requirements etc. Obtaining a favourable ethics opinion for research may also be required.

If there is intention for the product to have a medical application, then the product is no longer a research tool, but falls within the definition of a medical device. Products that are not CE marked or CE UKNI marked as a device can be used within health

[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] BEIS Guidance on using the UKNI mark https://www.gov.uk/guidance/using-the-ukni-marking-from-1-january-2021

[7] MDR Article 2 (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;
MDR Article 2 (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;

[8] MDR Article 22 Systems and Procedure Packs

[9] Other legislation includes Measuring Instrument Directive (2014/32/EU) or Electromagnetic compatibility Directive (2014/30/EU). See also https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

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 or repurpose products labelled for ‘research-use’ or otherwise products that are not CE marked or CE UKNI marked as devices, and then use the product for patient management or in a manner that may influence patient care decisions will need
to apply the requirements of the exemption.

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.

“Custom-made” devices[10]

Requirements for “custom-made” medical devices continue in the MDR[11]. The concept of a “custom-made” medical device applies only to MDR and not IVDR. Detailed guidance on the regulation of “custom-made” medical devices is beyond the scope of this document.

For some products made or modified and used within a health institution and which are put into service but not placed into market, the health institution will need to decide for themselves whether to apply the requirements for “custom-made” medical devices or the requirements of the health institution exemption.

Table 1. Regulatory compliance options for health institutions under the MDR

MDR requirements	**Full MDR compliance**	**“Custom-made” medical device compliance if placed on the market**	**Health institution exemption compliance**
Quality System	As set out in Article 10.9	As set out in Article 10.9	Needs to be appropriate
Comply with relevant GSPR	Yes	Yes	Yes

[10] MDR Article 2(3) ‘custom-made device’ means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.
However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;

[11] MDR Annex XIII Procedure for custom made devices

Applies to medical devices put into service	Yes	Yes	Yes
Applies to medical devices placed on the market	Yes	Yes	No
Written prescription by an authorised prescriber	Not required	Required	Not required
Clinical evaluation report	Yes	Yes	Yes
Justification	Not required	Not required	Required
Manufacturing scale	Any	Not mass produced	Not on an industrial scale
Patient	Patient group or individual patient	Individual patient	Patient group or individual patient
Statement concerning "custom-made" medical devices	No	Yes	No
Person Responsible for Regulatory Compliance	Required	Required	Not required
Unique Device Identifier (UDI)	Required	Not required	Not required
Notified Body	Class I (sterile), I (measuring), IIa, IIb and III	Class III implantable devices only	Not required
Demonstrate compliance	CE mark	Statement	Publicly available declaration
Technical Documentation	Annex II and III	Annex XIII requirements	Required
Information available to MHRA	On request	On request	On request
Registration with MHRA	Required for Class I devices	Required	Not required
Post market activities	As set out in articles 83-92	Vigilance reporting requirements	Review experience

Periodic Safety Update Report	Required	Required	Not required

Transfer of devices[12]

A transfer refers to any type of legal transfer including a loan or gift. 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. Documentation sharing between original and transfer health institutions will facilitate this process.

At least some of the evidence to support the declaration of the receiving health institution will be based on local validation for the use of the device and knowledge of device validation that has been carried out by the manufacturing health institution.

Some devices made, distributed 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 a further exemption by the second health institute. Examples include implanted devices, fitted prostheses, assistive technology devices (e.g. mobility or support devices) issued to patients or patient-transfer devices.

Devices manufactured by a health institution and provided on loan to another health institution are being transferred to another legal entity. The arrangement should be subject to a written agreement which defines the device management requirements, responsibilities and liabilities. Delivery receipt and pre-use procedures for loan devices should be the same as those for purchased devices, unless otherwise specified in this written agreement.

If the device itself has been manufactured or modified according to this exemption, then a further exemption is not required for the transfer of patient samples or patient data between legal entities (e.g. for pathology testing).

Control of subcontractors

Where the health institution uses another party in the making of the device as per manufacturer's instructions, 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 need to have, as part of their quality management system, 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 in the IVDR/MDR.

[12] MDR/IVDR Article 5.5 (a) the devices are not transferred to another legal entity;

The justification[13]

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 (e.g. market surveys/literature reviews) for the availability on the market of equivalent CE marked or CE UKNI marked devices[14]. The justification should also include evidence that the device is more appropriate under the specific circumstances than any apparently equivalent CE marked or CE UKNI marked devices.

Critical features might include:

- patient needs
- device functionality
- device performance
- device reliability
- result turn-around times or order lead time
- systems compatibility

Cost of available equivalent devices would not generally be considered to be a valid justification.

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

Quality Management Systems (QMS)[15]

QMS for manufacturing or modification

One of the requirements for applying the exemption is that manufacture and use of the devices occur under appropriate quality management systems.

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[13] MDR Article 5.5c/ IVDR Article 5.5d the health institution justifies in its documentation 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
MDR Article 5.5d/ IVDR Article 5.5e the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

[14] Definition of equivalence for medical devices (equivalence for IVDs is not yet 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.

[15] MDR/IVDR Article 5.5b manufacture and use of the devices occur under appropriate quality management systems,

The minimum requirement for qualifying QMS 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.

Article 10.9 of MDR and 10.8 of the IVDR list component aspects that should be considered by a QMS for manufacture.

EN ISO 13485[16] is considered 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.

QMS for 'use'

The MHRA is not aware of a QMS that specifically covers the use of devices in healthcare. Health Institutions should be aware of guidance and other regulation relevant to the safe use of devices:

- Managing Medical Devices - Guidance for healthcare and social services organisations
- Management of In Vitro Diagnostic Medical Devices
- Provision and Use of Work Equipment Regulations 1998
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

QMS & ISO 15189[17]

A requirement for IVDs is that the laboratory of the health institution is compliant with standard EN ISO 15189. Although health institution laboratories may wish to have additional quality management systems, EN ISO 15189 is considered 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[18]. UKAS assessors may ask for details of IVDs that are exempted within the health institution.

[16] EN ISO 13485:2016 "Medical devices -- Quality management systems -- Requirements for regulatory purposes"
[17] IVDR Article 5.5c the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation;
[18] EN ISO 15189:2012 "Medical laboratories -- Requirements for quality and competence"

Inspections and enforcement

The MHRA may require that such health institutions submit to the MHRA any further relevant information about such devices which have been manufactured and used in Northern Ireland.

The MHRA will have the right to restrict the manufacture and use of any specific type of such devices and will be able to inspect the activities of the health institutions.

Information publicly available[19]

In order to apply the exemption, the Regulations require the health institution to make some information publicly available. At present, there is no centralised registration system for exempted devices. Health institutions may wish to use the form in the appendix as a basis for making information publicly available locally.

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 relevant general requirements set out in IVDR and MDR 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.

Where a requirement does not apply to a device 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[20] continue to apply in Northern Ireland. Devices that are in conformity with a harmonised standard are 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.

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[19] IVDR Article 5.5f MDR Article 5.5e
the health institution draws up a declaration which it shall make publicly available, including:
(i) the name and address of the manufacturing health institution,
(ii) the details necessary to identify the devices,
(iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor;

[20] 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

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

For some devices, Common Specifications[21] will be adopted as Implementing Acts which have the same presumption of conformity with corresponding GSPR as a harmonised standard.

Documentation requirements[22] for all medical devices and class D IVDs

There are specific requirements for the documentation of all medical devices and class D IVDs[23]**.** 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 the 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, 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.

Manufacturing process[24]

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

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

[22] IVDR Article 5.5g as regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met. Member States may apply this provision also to class A, B or C devices in accordance with the rules set out in Annex VIII;
MDR Article 5.5f the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met.

[23] 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)

[24] MDR Article 5.5g the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f),
IVDR Article 5.5h the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (g);

Surveillance[25]

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 (e.g. 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).

The MHRA expects that health institutions continue to report all adverse incidents associated with devices whether CE marked or CE UKNI marked or exempted.

Adverse events should be report via Northern Ireland Adverse Incident Centre.

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.

Distance Sales [26]

A device used outside of the Northern Ireland in the context of a commercial activity for the provision of a diagnostic or therapeutic service on behalf of patients located in Northern Ireland, must comply with the requirements of the Regulations.

Health institutions based in Great Britain (England, Wales and Scotland) will not be able to apply the exemption to devices that are used in diagnostic or therapeutic services offered to the Northern Ireland.

Transition arrangements

The IVDR and MDR came into force on the 25th May 2017 and will fully apply in Northern Ireland from 26th May 2022 for IVDR or 26th May 2021 for MDR. Until these dates, health institutions can choose to apply either the current exemption in the IVDD or MDD or the new exemption (this guidance) in the IVDR or MDR. By the end of the transition periods for the Regulations, all Northern Ireland health institutions should have moved to the provisions of the IVDR or MDR.

[25] IVDR Article 5.5i / MDR Article 5.5h the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.
[26] MDR/IVDR Article 6 Distance sales

Devices that are made or modified under the exemption for the IVDD or 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
- Clinical investigations and healthcare establishments
- IVD specific guidance - page 13 In-house manufacture of IVD medical devices

Appendix

Form

Although the regulations specify what information should be made publicly available[27], there is no specific requirement on how information should be made publicly available. In the absence of a central registration system, health institutions should make local decisions. This form is provided to assist with this decision making and 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 and Notified Body Operations Group.

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.

[27] MDR Article 5.5e/IVDR Article 5.5 f
the health institution draws up a declaration which it shall make publicly available, including:

(i) the name and address of the manufacturing health institution,
(ii) the details necessary to identify the devices,
(iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor;

PART A – Declaration

(can 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 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

(can 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	