

Draft guidance on the health institution exemption (HIE) – IVDR and MDR

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the new Regulations for Member States is May 2022 (IVDR) and May 2020 (MDR) we are actively working on producing the draft guidance so that health institutions here have sufficient time to consider the new requirements before the end of any relevant transition period.

The draft guidance is not complete.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*

- 1 [https://www.gov.uk/government/publications/in-house-manufacture-of-](https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices)
2 [medical-devices/in-house-manufacture-of-medical-devices](https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices)
3 • *Clinical investigations and healthcare establishments*
4 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/381068/Clinical_investigations_and_healthcare_establishments.pdf)
5 [381068/Clinical_investigations_and_healthcare_establishments.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/381068/Clinical_investigations_and_healthcare_establishments.pdf)
6 • *IVD specific guidance - page 13 In-house manufacture of IVD medical devices*
7 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376918/Guidance_on_the_In_Vitro_Diagnostic_Medical_Devices_Directive.pdf)
8 [376918/Guidance_on_the_In_Vitro_Diagnostic_Medical_Devices_Directive.p](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376918/Guidance_on_the_In_Vitro_Diagnostic_Medical_Devices_Directive.pdf)
9 [df](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376918/Guidance_on_the_In_Vitro_Diagnostic_Medical_Devices_Directive.pdf)

10
11 *This guidance will apply only to products which are covered by the definition of a*
12 *medical device or in vitro diagnostic medical device or their accessories. MHRA*
13 *guidance on the supply of unlicensed medicinal products (“specials”) - see MHRA*
14 *guidance at*
15 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/37350](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf)
16 [5/The_supply_of_unlicensed_medicinal_products_specials.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf) *- does not apply to*
17 *medical devices, IVDs or their accessories.*

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20
21 This is a draft document for consultation following discussion with key stakeholders. It
22 represents various thoughts and ideas on the interpretation of the exemption for health
23 institutions under the MDR and IVDR and should not be taken as MHRA policy.

24
25 This draft document does not represent the final views of MHRA or its stakeholders.

26
27
28 A quick note on format
29 This draft guidance document is likely to be published online and so will need to be
30 formatted for web viewing (not pdf or Word)

31

1	Contents	
2	Preface	1
3	Introduction	4
4	Definitions and Scope	5
5	Manufacturing	5
6	Cleaning, decontamination, repair or maintenance	6
7	Systems and procedure packs	7
8	Research use products with no CE mark	7
9	Performance studies and clinical investigations	8
10	Custom-made devices	8
11	Transfer of devices	9
12	Control of subcontractors	10
13	The justification	10
14	Quality Management Systems	11
15	Inspections and enforcement	12
16	Information publicly available	12
17	General Safety and Performance Requirements (GSPR)	12
18	Documentation requirements for all medical devices and class D IVDs	13
19	Manufacturing process	14
20	Surveillance	14
21	Governance	15
22	Distance Sales	15
23	Transition arrangements	16
24	Guidance for completion of the form	17
25	Part A Declaration	17
26	Part B Listing of exempt devices	17
27	Part C device details	17
28	Glossary	18
29	Appendix simple form	19
30		
31		

1 Introduction

2 Under the current Directives¹, medical devices (MDs) and in vitro diagnostic medical
3 devices (IVDs) that are used in the same health institution as they are made, are
4 exempt from all of the requirements of the IVD and MD Directives.

5
6 In May 2017, new EU Regulations² were published which include a specific exemption
7 for IVDs and MDs that are used in the same health institution as they are made *or*
8 *modified* but with some specific requirements. These requirements are set out in
9 Article 5 paragraph 5 in both Regulations. The date of application for the new
10 Regulations is May 2020 for medical devices and May 2022 for IVDs although health
11 institutions may wish to apply the new requirements at any time before then.

12
13 This guidance is aimed at health institutions wishing to apply the exemption.

14
15 IVDs and MDs that are used in the same health institution as they are made or
16 modified are considered to have been 'put into service' and must meet all of the
17 relevant general safety and performance requirements that are set out in Annex I of
18 both Regulations. The use of exempted devices must be justified, the manufacture
19 and use of the devices must be covered by a quality management system and some
20 information about the device must be publicly available.

21
22 These new requirements are intended to provide the highest level of health protection
23 for patients whilst allowing health institutions to address the specific needs of target
24 patient groups which cannot be met at the appropriate level of performance by an
25 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>

1 Definitions and Scope

2 The new IVD and MD Regulations³ define a health institution as ‘an organisation
3 whose primary purpose is the care or treatment of patients or the promotion of public
4 health’. This includes hospitals, laboratories, local authorities and public health
5 institutes supporting the health care system and/or addressing patient needs, but may
6 not treat or care for patients directly.

8 QUESTION A

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

- 11
- 12 a) Collaborations led by a health institutions to provide healthcare? Yes/no
13 b) Collaborations led by a health institutions for product development with/without
14 commercial intent? Yes/no
15 c) Free standing commercial laboratories? Yes/no

16
17 Any other examples?
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22

23 Establishments primarily claiming to pursue health interests or healthy lifestyles, such
24 as gyms, spas, wellness and fitness centres are not considered to be health
25 institutions and the exemption does not apply.
26

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

30 Manufacturing

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

- 32
- 33 • the putting together of a device from raw materials or component parts, or
 - 34 • the complete rebuilding an existing device, or
 - 35 • making a new device from used devices, or
 - 36 • fully refurbishing a device, or
 - 37 • device software development, or
 - 38 • using a product for a medical purpose that is not CE marked as a device⁴, or
 - 39 • putting together combinations of devices and other equipment, or
 - 40 • significant deviations from the instructions for use that alter the function,
41 performance or purpose of the device, or
 - 42 • using an existing device for a different purpose to that intended by the
43 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>

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

3

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

11

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

15

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

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

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

25

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

30

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

36

37 **Cleaning, decontamination, repair or maintenance**

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

41

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

45

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

49

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

4
5 MHRA advice in the re-use and reprocessing of single use devices continues to apply⁵
6 and devices designated as 'single-use' must not be reused.

7
8 Items that are used to replace a part or component of a device and that significantly
9 change the performance or safety characteristics or the intended purpose of the device
10 shall be considered to be modification of the device and the requirements of the
11 exemption apply.

12
13 Items used to replace a part or component of a device and that do not significantly
14 change the performance or safety characteristics or the intended purpose of the device
15 are not considered devices and no exemption is needed.

16

17 **Systems and procedure packs**

18 Combining CE marked medical devices into a system or procedure pack⁶ is not
19 considered manufacturing or modification. Health institutions who put together
20 systems or procedure packs that are used within the same health institution do not
21 need to apply the exemption.

22

23 **Research use products with no CE mark**

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

29

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

32

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

36

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

40

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;

1 **Performance studies and clinical investigations**

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

5
6 Where the device for performance study or clinical investigation is intended to be made
7 or modified and used only within the same health institution after the end of the
8 investigation/study and there is no commercial intent, the requirements of the
9 exemption will apply.

10
11 Where the study is being carried out on behalf of a third party or where the study is
12 intended to support CE marking of the device or where there is a commercial intent
13 then the requirements of the Regulations apply. In some circumstances, the health
14 institution will need to apply to MHRA for an assessment before starting the clinical
15 investigation or performance evaluation.

16
17 **QUESTION B**

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

20
21 b) Is this approach proportionate and desirable? Yes/no

22
23 c) What is an appropriate QMS for use in a clinical investigation/performance study?
24 Please specify.

25
26
27 d) Should clinical investigations/performance studies:
28 Be registered with MHRA? Yes/no
29 Comply with relevant GSPR? Yes/no
30 Have the same level of justification? Yes/no

31
32 e) Do general principles apply to performance studies (IVDR Article 57) and 'other
33 clinical investigations' (MDR Article 82) when applying the exemption?

34 IVDR Article 57 – yes/no

35 MDR Article 82 – yes/no

36
37 f) Any other comments?
38
39
40
41

42 **Custom-made devices**

43 Requirements for custom-made medical devices continue in the new MDR. For some
44 products made or modified and used within a health institution and which are not
45 placed on the market, the health institution will need to decide for themselves whether
46 to apply the requirements for custom-made devices or the requirements of the health
47 institution exemption.
48

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

1
2 The concept of a custom-made device applies only to MDR and not IVDR. Detailed
3 guidance on the regulation of custom-made devices is beyond the scope of this
4 document.
5

6 **Transfer of devices**

7 To transfer a device between health institutions each health institution will need to
8 apply the exemption separately with each applying the requirements of the exemption
9 including making a separate declaration. At least some of the evidence to support the
10 declaration will be based on local validation for the manufacture or modification and
11 use of the device.
12

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

4
5 Some devices made and used within a health institution have been issued to an
6 individual patient and are essential to the continuity of patient care. These devices can
7 be transferred between legal entities without the need for an exemption. Examples
8 include implanted devices, fitted prostheses, assistive technology devices issued to
9 patients or patient-transfer devices.

10
11 An exemption is not required for the transfer of patient samples or patient data
12 between legal entities (eg for pathology testing) provided the device itself is not
13 transferred.

14

15 **Control of subcontractors**

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

22

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

29

30 **The justification**

31 The health institution's justification for applying the exemption must be that the target
32 patient group's specific needs cannot be met or cannot be met at the appropriate level
33 of performance by an equivalent device available on the market. The justification
34 should include evidence (eg market surveys/literature reviews) for the availability on
35 the market of equivalent CE marked devices⁷. The justification should also include
36 evidence that the device is more appropriate under the specific circumstances than
37 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.

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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 13485⁸, 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"

1
2 A requirement for IVDs is that the laboratory of the health institution is compliant with
3 standard EN ISO 15189. Although health institutions may need to have additional
4 quality management systems, ISO 15189 is considered in the UK to be an ‘appropriate
5 quality management system’ (Article 5 para 5 b) for IVDs. The UK operates an
6 accreditation process via UKAS who can accredit medical laboratories to ISO 15189⁹.
7 UKAS assessors may ask for details of IVDs that are exempted within the health
8 institution.

9 **Inspections and enforcement**

10 MHRA may choose to request information and may inspect institutions as part of its
11 enforcement powers.
12

13 **Information publicly available**

14 In order to apply the exemption, the Regulations require the health institution to make
15 some information publicly available. A form has been designed to help decide what
16 information should be made public.
17
18

19 **QUESTION E**

- 20 a) Should there be a register of health institutions applying this exemption? Yes/no
21
22 b) Should parts A and B of the form be made publicly available centrally? Yes/no
23
24 c) Should part C of the form also be made publicly available? Yes/no
25
26 d) Should MHRA consider the need to carry out market surveillance activities of
27 registered exemptions? Yes/no
28
29 e) Any other comments

32 **General Safety and Performance Requirements (GSPR)**

33 Health institutions seeking to apply this exemption to a device will need to demonstrate
34 that exempted devices meet all the general requirements set out in Annex I Chapter I
35 and the relevant requirements for performance, design and manufacture set out in
36 Annex I Chapter II and the information requirements set out in Annex I Chapter III –
37 ‘relevance’ is to be determined by the health institution.
38

39 Devices for performance evaluation or clinical investigation will not be able to
40 demonstrate that they meet the requirements that are to be established by the study,
41 but they should be able to demonstrate that they meet all the other relevant
42 requirements.
43

⁹ EN ISO 15189:2012 “Medical laboratories -- Requirements for quality and competence”

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

4
5 Harmonised standards are European standards that have been mandated by the
6 European Commission and published in the Official Journal of the European Union.
7 Devices that are in conformity with a harmonised standard shall be presumed to be in
8 conformity with those requirements of the Regulations listed in the standard. For
9 example, the risk management standard EN ISO 14971:2012 “Medical devices -
10 Application of risk management to medical devices” has been harmonised to both
11 IVDD and MDD. Annex Z of a harmonised standard maps the clauses of the standard
12 to the corresponding essential requirement of the Directive. It is anticipated that the
13 same format will be used for standards harmonised to IVDR and MDR.

14
15 Health institutions may wish to use harmonised standards to demonstrate conformity
16 with corresponding GSPR.

17
18 For some devices, Common Specifications will be adopted as Implementing Acts by
19 the European Commission which have the same presumption of conformity with
20 corresponding GSPR as a harmonised standard.

21
22 List of current IVDD harmonised standards

23 [https://ec.europa.eu/growth/single-market/european-standards/harmonised-
24 standards/iv-diagnostic-medical-devices_en](https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en)

25
26 List of current MDD harmonised standards

27 [https://ec.europa.eu/growth/single-market/european-standards/harmonised-
28 standards/medical-devices_en](https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en)

29
30 Current Common Technical Specifications for IVDs

31 http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en
32

33 **Documentation requirements for all medical devices and class D IVDs**

34 There are specific requirements for the documentation of all medical devices and class
35 D IVDs¹⁰. To apply the exemption, the health institution should prepare documentation
36 that describes:

- 37
38 i. the intended purpose of the device;
39 ii. the manufacturing facility;
40 iii. the manufacturing process;
41 iv. the design and performance data of the devices in relation to its intended
42 purpose.

43
44 The documentation should be sufficiently detailed to enable MHRA to ascertain that
45 all of the relevant general safety and performance requirements are met. Health
46 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)

1 readily searchable and unequivocal way. The documentation could include the
2 evidence or it could provide references to the location of the evidence. An appropriate
3 format for documentation is described in detail in Annex II of the MDR/IVDR.
4

5 **QUESTION F**

6 a) Can these requirements be applied in emergency situations? – eg development of
7 an assay for an emergent epidemic such as SARS or MERS?

8 Yes/no
9

10 b) If not what is the alternative route?
11
12
13
14

15 **QUESTION G**

16 a) Should this additional documentation requirement also apply to IVDs in class A, B
17 or C? yes/no
18

19 b) If so, what is the robust, risk-based rationale and where can people go for guidance
20 on IVD classification?
21
22
23

24 **Manufacturing process**

25 During manufacturing or modification of the device, health institutions should make
26 sure that they follow the process set out in their technical documentation.
27

28 **Surveillance**

29 Regardless of the class of the device manufactured under this exemption, the health
30 institution should have a surveillance system in place which gathers experience in the
31 clinical use of the device. This experience should be reviewed and if necessary
32 corrective and preventative actions taken to safeguard the safety of patients, users or
33 others (eg change the way the device is made or used, review results from previous
34 uses of the device, suspend further use of the device either permanently or temporarily
35 or other relevant corrective action).
36

37 **QUESTION H**

38 Should MHRA reserve the right to impose review and reporting requirements for all
39 serious incidents plus trend reporting of other incidents in the future? Yes/no
40

41 MHRA expect that health institutions continue to report all adverse incidents
42 associated with devices whether CE marked or exempted.

43 Health institutions in England and Wales should report to MHRA via yellowcard
44 (<https://yellowcard.mhra.gov.uk/>)

45 Welsh incidents should also be copied to Welsh Surgical Materials Testing
46 Laboratory (<http://www.wales.nhs.uk/sites3/page.cfm?orgid=465&pid=56203>)
47

1 Health institutions in Scotland should report via Health Facilities Scotland Incident
2 Reporting and Investigation Centre ([http://www.hfs.scot.nhs.uk/services/incident-
3 reporting-and-investigation-centre-iric-1/how-to-report-an-adverse-incident/](http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric-1/how-to-report-an-adverse-incident/))
4

5 Health institutions in Northern Ireland should report via Northern Ireland Adverse
6 Incident Centre (<https://www.health-ni.gov.uk/articles/reporting-adverse-incident>)
7

8 **Governance**

9 All devices that are manufactured or modified and used within the health institution
10 including where modification and use of the device is also considered to be 'off label
11 use' should be included in the declaration. Good practice for health institutions
12 includes referral to a medical device management committee (or other similar
13 structure) prior to making the declaration.
14

15 Health institutions should appoint the most appropriate competent and senior
16 person(s) with relevant expertise to sign the declaration and take responsibility for
17 regulatory compliance of exempted devices including the supervision and control of
18 manufacturing, and surveillance over the lifetime of the device. (See Article 16 for
19 guidance on responsibilities)
20
21

22 **QUESTION I**

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

29 **QUESTION J**

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

34
35 b) If not should this be justified?

36 **Distance Sales**

37 A device used outside of the UK in the context of a commercial activity for the provision
38 of a diagnostic or therapeutic service must comply with the requirements of the
39 Regulations.
40

41 Health institutions based in countries elsewhere in the EU will need to follow local
42 requirements.
43

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

1 Transition arrangements

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

7
8 Devices that are made under the exemption for the IVDD/MDD that are put into service
9 before the end of the transition period can continue to be used until expiry or until a
10 significant change in the device.

11
12 Until or unless the health institution starts using the exemption in the new Regulations,
13 our existing advice on in house manufacture continues to apply. Current MHRA
14 guidance on in house manufacture under the Directives can be found at:

- 15 • General guidance on in house manufacture
- 16 • [https://www.gov.uk/government/publications/in-house-manufacture-of-medical-](https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices)
17 [devices/in-house-manufacture-of-medical-devices](https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices)
- 18 • Clinical investigations and healthcare establishments
- 19 • [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/38](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/381068/Clinical_investigations_and_healthcare_establishments.pdf)
20 [1068/Clinical_investigations_and_healthcare_establishments.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/381068/Clinical_investigations_and_healthcare_establishments.pdf)
- 21 • IVD specific guidance - page 13 In-house manufacture of IVD medical devices
- 22 • [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/37](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376918/Guidance_on_the_In_Vitro_Diagnostic_Medical_Devices_Directive.pdf)
23 [6918/Guidance_on_the_In_Vitro_Diagnostic_Medical_Devices_Directive.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376918/Guidance_on_the_In_Vitro_Diagnostic_Medical_Devices_Directive.pdf)

25 QUESTION K

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

27 [http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVit](http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/UCM536965.pdf)
28 [roDiagnostics/LaboratoryDevelopedTests/UCM536965.pdf](http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LaboratoryDevelopedTests/UCM536965.pdf)



FDA LDT discussion
paper.pdf

29
30
31
32

1 **Guidance for completion of the form**

2
3 The form is in three parts:

4 Part A is the declaration

5 Part B is the listing of the exempt devices

6 Part C provides more details of the exempt devices

7
8 Parts A and B include the information that must be made publicly available.

9 Part C includes the information that does not need to be made publicly available, but
10 should be submitted on request by the MHRA.

11 12 **Part A Declaration**

13 *Information about the manufacturing or modifying health institution*

14 The name of the legal entity of the health institution

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

17 18 **Part B Listing of exempt devices**

19 Devices can be grouped together using a coding system.

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

23 **NOTE**

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

27
28
29 Updates to part B also need an updated declaration at part A.

30 **Part C device details**

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

34
35 If using the GSPR checklist, please include a copy in part C. Otherwise provide a list
36 of the GSPR that have been met with a description of the solutions for each and the
37 GSPR that have not met with a justification for each.

1 **Glossary**

2

3 To include all relevant definitions from Article 2 MDR/IVDR

4 Consider including new definitions for:

- 5 • Modification
- 6 • Off label use
- 7 • legal entity,
- 8 • equivalent device (for IVDs) and
- 9 • industrial scale

10

11 **QUESTION M**

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

13

14

15

1 **Appendix simple form**

2

PART A – Declaration

3

(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	

4

5

6

DECLARATION	
<p>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).</p> <p>These devices are manufactured in accordance with our Technical Documentation.</p> <p>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.</p>	<p>.....</p> <p>Signed on behalf of the organisation</p> <p>Name Date</p>

7

8

9

10

11

1
2
3
4

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)

5
6
7

1
2
3

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	

5
6

1

Part C (continued)

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

3 (including justification of any requirements not applicable)

4

5 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	

6

7