Guidance Document

Medical Device Regulations (2017/745)

Application of the health institution exemption (HIE) to Rehabilitation Engineering

June 2020

Ref: RSM0001

Revision History

Version	Date	Changes
1.0	17/6/20	Initial document release.

About RESMaG

We are a voluntary group formed to support healthcare science and other professionals working in Rehabilitation Engineering in England, Scotland, Wales and Northern Ireland. More information is available online at https://resmag.org.uk.

Foreword

These guidelines have been produced by RESMaG to assist Rehabilitation Engineering services apply the Medical Device Regulations (MDR 2017/745), specifically the health institution exemption (HIE), according to Article 5.5.

This document provides an interpretation of the Medicines and Healthcare products Regulatory Agency (MHRA)'s draft guidance for medical devices manufactured or modified and used within health institutions. The MHRA draft guidance was published for consultation which ran from January 2018 to March 2019. It is recommended that reference should be made to the MHRA website to access the latest version of the official guidance.

The work to produce this guidance involved input and review from several RESMaG members who represent a range of Rehabilitation Engineering services in the NHS and private sector.

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Disclaimer

This guidance is based on an interpretation of the relevant EU regulation and the MHRA draft guidance on the health institution exemption. It is not, and should not be read as, a statement of the definitive legal position on any matter. The use of this guidance and any outcomes arising from its use are the sole responsibility of the person or organisation making use of the document and no liability is accepted for its use.

Contents

Background

The MDR stipulates that medical devices manufactured and put into service within a health institution will be subject to full conformity assessment (i.e. will require CE marking) unless the requirements of Article 5.5 are met. Provided that the manufacture and use of a device takes place within the same health institution (i.e. the device is not 'placed on the market'), then the requirements of Article 5.5 can be applied. MHRA have referred to the application of Article 5.5 as the 'health institution exemption' (HIE).

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

- the putting together of raw materials or component parts, or
- the complete rebuilding of an existing device, or
- making a new device from used devices, or
- fully refurbishing a device, or
- developing software that is either incorporated into a physical medical device or is a medical device in its own right, or
- assigning a medical purpose to a product that is not CE marked as a device, 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 from that intended by the manufacturer, or
- modifying a device for a new purpose, function or performance;

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

The date of the full application of the MDR and the health institution requirements has been delayed due to the EU postponement announced in April 2020. Taking into account the UK's exit from the EU at the end of 2020, it is anticipated that UK legislation will follow the MDR and have an application date of 26 May 2021.

How to use this guidance?

This guidance is for health institutions (HI) to determine the necessary actions to ensure compliance to the MDR.

Table 1 outlines a set of questions to determine if the health institution exemption (HIE) applies to a particular activity. Table 2 provides guidance on how to apply the HIE to Rehabilitation Engineering services and provision, according to the MDR's Article 5.5.

The document presents guidance for six examples of Rehabilitation Engineering activity.

Table 1 – Questions to decide if the HIE (Article 5.5) applies

				Article 5.5 applies when all answers are:
1	Are you working in a health institution?	YES	go to Q2	YES
		NO	HIE cannot be applied[1]	
2	Does the activity involve a medical device or an accessory for a medical device (both referred to as a medical device)?	YES	go to Q3	YES
		NO	MDR does not apply[2]	
3	Are you putting the medical device into use within the same health institution (legal entity)?	YES	go to Q4	YES
		NO	full MDR will have to be applied[3]	
4	Are the target patient group's specific needs met or met at the appropriate level of performance by an equivalent medical device available on the market?	YES	consider use of equivalent device	NO
		NO	document reasons and go to Q5	
5	Is this manufacturing activity under the request of a professional for the use of a particular named patient (i.e. custom-made device)?	YES	need to decide if custom-made requirements of MDR (Annex XIII) or HIE would be best applied	YES or NO
		NO	HIE may be applicable; go to Q6	
6	Are you manufacturing / modifying /repairing/using a CE marked device explicitly in line with the manufacturer's intended purpose and instructions for use (IFU)?	YES	HIE is not required: the work can proceed	NO
		NO	go to Q7	
7	Assess and document the deviations. Do they significantly alter the function, safety or performance or intended purpose of the device?	YES	HIE must be applied	YES
		NO	HIE is not required: the work can proceed. It is good practice to document the deviations.	

[1] The full MDR or other regulations may have to be applied

[2] Other regulations may apply

[3] If transferred to another health institution, each health institution may need to apply the exemption separately (refer to the MHRA guidance for further details)

Table 2 – Article 5.5 and application to RE Services

MDR Requirement		Application to RE services
Annex 1	General Safety and Performance Requirements (GSPR) Devices shall achieve the performance intended by their manufacturer and shall be safe and effective	This is a fundamental requirement of the MDR for all medical devices and also applies to the manufacture and use of devices within the same health institution. Annex 1 contains over 200 individual requirements. The use of a standardised checklist tool would be an appropriate method to document the assessment process of these requirements. Justification should be provided where a requirement does not apply. This checklist may form part of the technical documentation with reference to the relevant section of the Quality Management System (QMS) or part of the technical documentation that satisfies each requirement. See https://www.ipem.ac.uk/ScientificJournalsPublications/FreePublications.aspx for a useful Excel based app.
Article 5.5a)	Devices are not transferred to another legal entity	Devices manufactured and issued to an individual patient who may reside in another region different to the service provider would not be considered in breach of this requirement because the patient's care would still remain with the providing health institution. If the patient moves out of area, the responsibility of the device is taken by the new provider which may require application of the health institution exemption. There is recognition by MHRA that assistive technology devices are essential for continuity of patient care and that "devices can be transferred between legal entities without the need for a further exemption by the second health institution". If a device is transferred to another health institution and requires modification/manufacturing, each health institution will need to apply the exemption separately including making a separate declaration. Documentation sharing between original and transfer health institutions will facilitate this process.
Article 5.5b)	Manufacture and use of the devices occur under appropriate quality management systems	The HI should have in place an appropriate QMS (e.g. a QMS mapped to ISO 13485 is considered best practice). Refer to Article 10.9 which provides further details regarding a QMS. Certification by an external body is not a current requirement.
Article 5.5c)	Justify 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	Technical documentation should contain justification which may include: patient needs, device performance, reliability, turnaround times, compatibility reasons, clinical control and value-based healthcare. The detail of this justification will need to be proportionate to the risk class of the device. See https://www.ipem.ac.uk/ScientificJournalsPublications/FreePublications.aspx for a useful risk classification app.
Article 5.5d)	Provide information upon request on the use of such devices to MHRA, which shall include justification of their manufacturing, modification and use	The HI should have a readily available summary document as part of their QMS which lists all types of devices manufactured and justification on the requirement for in-house manufacturing. MHRA provide suggested templates for this.
Article 5.5e)	Provide a declaration which is publicly available, including (i) name, address of manufacturing health institution; (ii) details necessary to identify the devices and (iii) declaration that the devices meet the GSPR (Annex I) or information if not fully met with reasoned justification	One method to achieve this requirement is to publish the information on the HI's website.

MDR Requirement		Application to RE services
Article 5.5f)	Documents the manufacturing facility, manufacturing process, the design and performance data of the devices, including the intended purpose (sufficiently detailed to enable MHRA to ascertain that the GSPR are met)	Each medical device/or family of medical devices to have standardised technical documentation which may contain: • GSPR checklist which may include reference to many of the below areas, • Device description and specification, including variants and accessories, intended purpose and target patient population • Technical drawings with material details (with reference to system for recording batch numbers) • Manufacturing facility and processes • Competence of staff necessary for the design and manufacturing of the particular device • Risk Assessment • Clinical Evaluation Report (CER) (refer to MDR's Article 61 for further details). MHRA's guidance states that a CER will be required for all medical devices, including custom- made devices and medical devices manufactured under the HIE to make it possible to have an understanding of the performance data of the devices manufactured. MHRA does not provide any further details or guidance. Good practice is that a clinical evaluation contains a critical assessment of the literature, comparison with similar devices as well as clinical investigation/trial performance data. This could potentially be completed for a 'family' of devices having similar characteristics. Further advice should be sought from MHRA on this topic. • Specific needs of the patient/patient group and the assessment method used • Outline of review of potentially equivalent devices • Compliance to appropriate standards
Article 5.5g)	Take all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to above in point f	Audit processes would satisfy this as outlined in the QMS.
Article 5.5h)	Reviews experience gained from clinical use of the devices and takes all necessary corrective action	The QMS should define methods for reviewing experience from clinical use of the device and how this informs corrective action. The regulations require that the health institution should have a surveillance system in place. Good practice for Rehabilitation Engineering services is to carry out patient reviews to manage risks as locally appropriate. MHRA expect that health institutions continue to report all adverse incidents associated with devices whether CE marked or exempted.
Article 5.5	Devices are not manufactured on an industrial scale	Audits may be used to demonstrate this requirement as outlined in the QMS. For example, audit of the number of devices that are manufactured/modified by the HI at a pre-determined frequency.

Examples

1 - Seating modification

A Rehabilitation Engineering department routinely modifies a manufacturer's wheelchair seating component; a pommel.

The pommel is constructed using the original manufacturer's plywood base and mounting bracket. The polyurethane foam is removed and replaced with a more dense foam (chipfoam and evazote) to enhance the performance of the device and nylon rods with screw inserts are embedded in the centre to provide further durability and strength. The item is covered in Dartex material.

Question		Yes/No	Comments
1	Are you working in a health institution?	YES	NHS service/department
2	Does the activity involve a medical device or an accessory for a medical device (both referred to as a medical device)?	YES	The modified pommel is an accessory for a Class 1 medical device. It intended to be used together with a particular medical device, a wheelchair in this case.
3	Are you putting the medical device into use within the same health institution (legal entity) within which you work?	YES	The device is issued to a patient who is under the care of the same Health Institution in which the device was modified.
4	Are the target patient group's specific needs met or met at the appropriate level of performance by an equivalent medical device available on the market?	NO	There is no equivalent device available on the market with these particular features and performance requirements.
5	Is this manufacturing activity under the request of a professional for the use of a particular named patient (i.e. custom-made device)?	NO	It is a modification that the department routinely performs for the majority of patients requiring a pommel.
6	Are you manufacturing / modifying /repairing/using a CE marked device explicitly in line with the manufacturer's intended purpose and instructions for use (IFU)?	NO	The manufacturer does not intend for the device to be modified. Assess and document the deviations.
7	Do the deviations significantly alter the function, safety or performance or intended purpose of the device?	YES	The modification is to enhance the performance of the device.

HIE Article 5.5 does apply.

2 - Wheelchair modification (non-structural)

A clinician has requested that a foot support (e.g. ankle hugger or foot skate) is attached to a wheelchair footplate. There are no pre-existing holes in the footplate, so it is necessary to drill fixing holes.

Question		Yes/No	Comments
1	Are you working in a health institution?	YES	NHS service/department
2	Does the activity involve a medical device or an accessory for a medical device (both referred to as a medical device)?	YES	Both the device and the accessory are medical devices and CE marked.
3	Are you putting the medical device into use within the same health institution (legal entity) within which you work?	YES	The device is issued to a patient who is under the care of the same Health Institution in which the device was modified.
4	Are the target patient group's specific needs met or met at the appropriate level of performance by an equivalent medical device available on the market?	NO	The foot support is not provided as an option by the wheelchair manufacturer, nor does the manufacturer supply a footplate to which the additional support could be fitted without modification.
5	Is this manufacturing activity under the request of a professional for the use of a particular named patient (i.e. custom-made device)?	NO	The modification is required for a specific patient, but may be an option for others.
6	Are you manufacturing / modifying /repairing/using a CE marked device explicitly in line with the manufacturer's intended purpose and instructions for use (IFU)?	NO	The manufacturer does not intend for the device to be modified. Assess and document the deviations.
7	Do the deviations significantly alter the function, safety or performance or intended purpose of the device?	NO	It does not impact on the function, performance or intended purpose as the location of the holes drilled does not adversely affect the structural integrity of the footplate.

The MDR does NOT apply to this activity (because question 7's answer is NO) – best practice is to document in technical documentation.

3 - Wheelchair modification (structural)

A clinician has requested that an additional support is attached to a wheelchair side frame near the tie down point. The pre-existing holes in the side frame are not in the correct position, so it is necessary to drill additional fixing holes.

Question		Yes/No	Comments
1	Are you working in a health institution?	YES	Commissioned service provider to the NHS
2	Does the activity involve a medical device or an accessory for a medical device (both referred to as a medical device)?	YES	Both the device and the accessory are medical devices and are CE marked.
3	Are you putting the medical device into use within the same health institution (legal entity) within which you work?	YES	The device is issued to a patient who is under the care of the same Health Institution in which the device was modified.
4	Are the target patient group's specific needs met or met at the appropriate level of performance by an equivalent medical device available on the market?	NO	There are no alternatives for this particular wheelchair that could be fitted without modification.
5	Is this manufacturing activity under the request of a professional for the use of a particular named patient (i.e. custom-made device)?	YES	The modification is required for a specific patient.
6	Are you manufacturing / modifying /repairing/using a CE marked device explicitly in line with the manufacturer's intended purpose and instructions for use (IFU)?	NO	The manufacturer of the wheelchair did not intend the support to be fitted. Assess and document the deviations.
7	Do the deviations significantly alter the function, safety or performance or intended purpose of the device?	YES	It could impact on the function, safety, performance or intended purpose as modification is required to a structural element which could be significantly stressed under load.

HIE Article 5.5 does apply.

4 - Fitting a charger to wheelchair batteries

It is sometimes useful for powered wheelchair users to charge electronic devices from their powered wheelchair (a mobile phone or augmentative and alternative communication device, for example). While there are charging devices on the market that connect to the charger port on the wheelchair, these have been specifically excluded by the controller's manufacturers because the effects may be unknown or unpredictable. Commercially available chargers are available that connect directly to the wheelchair's batteries.

Question		Yes/No	Comments
1	Are you working in a health institution?	YES	NHS service/department
2	Does the activity involve a medical device or an accessory for a medical device (both referred to as a medical device)?	YES	The wheelchair is a medical device. The charger is **not** an accessory to the wheelchair (from a regulatory point of view), as the wheelchair can function without it.
3	Are you putting the medical device into use within the same health institution (legal entity) within which you work?	YES	The device is issued to a patient who is under the care of the same Health Institution in which the device was modified.
4	Are the target patient group's specific needs met or met at the appropriate level of performance by an equivalent medical device available on the market?	NO	There are no wheelchairs on the market fitted with a personal device charging point.
5	Is this manufacturing activity under the request of a professional for the use of a particular named patient (i.e. custom-made device)?	NO	Although performed infrequently, this modification may be repeated for another patient.
6	Are you manufacturing / modifying /repairing/using a CE marked device explicitly in line with the manufacturer's intended purpose and instructions for use (IFU)?	NO	The manufacturer may not intend for the device to be fitted. Assess and document the deviations.
7	Do the deviations significantly alter the function, safety or performance or intended purpose of the device?	YES	It may impact on the function of the wheelchair (e.g. the range of the wheelchair due to the potential drain on the battery)

HIE Article 5.5 does apply.

5 - Manufacture of a ventilator carrier for a wheelchair

It is sometimes necessary for a wheelchair user to carry a ventilator on their wheelchair. An off-the-shelf accessory is not available commercially, or if they are available, they may be poor quality, or do not adequately support the ventilator. A Rehabilitation Engineering service manufactures a repeatable design used for a number of patients.

Question		Yes/No	Comments
1	Are you working in a health institution?	YES	NHS service/department
2	Does the activity involve a medical device or an accessory for a medical device (both referred to as a medical device)?	YES	The wheelchair and ventilator is a medical device. The ventilator carrier itself is not a medical device nor an accessory for a medical device because it is not necessary for the ventilator to function.
3	Are you putting the medical device into use within the same health institution (legal entity) within which you work?	YES	The device is issued to a patient who is under the care of the same Health Institution in which the device was modified.
4	Are the target patient group's specific needs met or met at the appropriate level of performance by an equivalent medical device available on the market?	NO	Commercially available products are not appropriate from a safety, quality or functional point of view.
5	Is this manufacturing activity under the request of a professional for the use of a particular named patient (i.e. custom-made device)?	NO	The design is repeated and manufactured on various occasions.
6	Are you manufacturing / modifying /repairing/using a CE marked device explicitly in line with the manufacturer's intended purpose and instructions for use (IFU)?	NO	The wheelchair manufacturer did not intend for a ventilator to be fitted to the wheelchair. The activity is putting together a combination of devices. Assess and document the deviations.
7	Do the deviations significantly alter the function, safety or performance or intended purpose of the device?	YES	There are potential performance implications of the wheelchair e.g. stability. There may also be potential performance implications to the ventilator if transported not as the ventilator manufacturer intended.

HIE Article 5.5 does apply.

6 - Environmental Control System – combining devices

An NHS service provides an environmental control system to a patient. An environmental control system may control a household lamp, TV as well as to access emails and Facebook, for example. The solution provided is a Gridpad which is a tablet computer with a box which transmits infrared and easywave signals. It is sometimes necessary to plug a switch into the switch port on the Gridpad to allow the user to control the software with a switch. The commercially available switch being used is not a medical device.

Question		Yes/No	Comments
1	Are you working in a health institution?	YES	NHS service/department
2	Does the activity involve a medical device or an accessory for a medical device (both referred to as a medical device)?	YES	The Gridpad is a CE marked Class 1 medical device which is being used in combination with other devices to provide a solution. The switch being used is not a medical device.
3	Are you putting the medical device into use within the same health institution (legal entity) within which you work?	YES	The device is issued to a patient who is under the care of the same Health Institution in which the system was setup.
4	Are the target patient group's specific needs met or met at the appropriate level of performance by an equivalent medical device available on the market?	YES	These devices are available separately on the market, but not available as a complete system.
5	Is this manufacturing activity under the request of a professional for the use of a particular named patient (i.e. custom-made device)?	NO	It is being set up for a specific patient assessed by a healthcare professional but may be used as a routine solution for other patients.
6	Are you manufacturing / modifying /repairing/using a CE marked device explicitly in line with the manufacturer's intended purpose and instructions for use (IFU)?	YES	The Gridpad instructions state that it can be connected to a third party switch. This activity is in line with the manufacturer's intended use and they are designed to work together. Assess and document the deviations.
7	Do the deviations significantly alter the function, safety or performance or intended purpose of the device?	NO	This addition of a third party switch does not alter the intended purpose of the Gridpad.

The MDR does NOT apply to this activity (because question 7's answer is NO) – best practice is to document in technical documentation.

Key Definitions

Custom-made device

'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.'

Medical Device

'any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.'

Note that 'software' is a medical device if it is intended to have one of the specific medical purposes. Mobile apps and spreadsheets may be considered a medical device, as well as complex software such as treatment planning systems.

Accessory for a medical device

'an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)'.

An 'accessory for a medical device' is regulated as if it is a medical device.

Health Institution

'an organisation whose primary purpose is the care or treatment of patients or the promotion of public health'.

These definitions have been taken from MDR 2017: 745.

Acronyms

CER	Clinical Evaluation Report
GSPR	General Safety and Performance Requirements
HI	Health institution
HIE	Health institution exemption
IFU	Instructions for use
MDR	Medical Device Regulation
MHRA	Medicines and Healthcare products Regulatory Agency
QMS	Quality management system
RESMaG	Rehabilitation Engineering Services Managers Group