NSS Health Facilities Scotland

NHS National Services Scotland

Equipment Co-ordinator Group

Workshop Development Notes

- EU Regulation on Medical Devices 2017/745 (MDR)
- EU Regulation on In Vitro Diagnostic Medical Devices 2017/746 (IVDR)

In-house Manufacture by Health Institutions

IRIC Incident Reporting & Investigation Centre

Contents

A. What are the Medical Devices Regulations?

Previously, the three Directives[1] harmonised the laws relating to medical devices and in vitro diagnostic medical devices (IVDs) in the European Union (EU). Products conforming to any of the directives have a CE mark applied before being placed on the market. However, the three directives were replaced in 2017 with two new sets of regulations:

- General medical devices: The EU Regulation on Medical Devices 2017/745 (MDR)
- In vitro diagnostic medical devices (IVDs): The EU Regulation on In Vitro Diagnostic Medical Devices 2017/746 (IVDR)

The MDR and IVDR will fully apply from 26 May 2020 and 2022 respectively. Formal guidance on the changes will be made available from the Medicines and Healthcare products Regulatory Agency (MHRA) which regulates manufacturers.

Some services within the health institutions (NHS Boards and local authorities) have a long-established history of manufacturing medical devices or IVDs. They were exempt from the three directives but the MDR and IVDR place new requirements on health institutions that manufacture devices in-house.

This guidance highlights some of the areas that health institutions must address now if they are to continue to manufacture medical devices in-house beyond 26 May 2020. Health Institutions are defined as, “an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health”.

[1] **The three directives:**
- Medical Devices Directive 93/42/EEC (MDD)
- Active Implantable Medical Devices Directive 90/385/EEC (AIMD)
- In Vitro Diagnostic Medical Device (IVDD) Directive (98/79/EC)

B. What are the main changes that will affect services delivered by the NHS?

Under the three directives, manufacturers had to comply with regulatory requirements when their products were, “placed on the market”. Health institutions were automatically exempt on this basis. However, the new regulations make requirements when devices are, “put into service”. Consequently, the automatic exemption no longer applies.

Health institutions manufacture devices in-house therefore have to choose whether to comply with regulatory requirements or whether to declare Health Institution Exemption (HIE). However, to declare HIE they will need to fulfil the following:

- ensure devices meet the General Safety and Performance Requirements (GSPR)
- have an appropriate Quality Management System (QMS)
- have a justification for applying the exemption to each device or group of devices
- have technical documentation for all devices manufactured

Some of this information will have to be made publically available by NHS Boards.

Custom Made Devices

If, on the other hand, the health institution declares that a device is “custom made” then they are not obliged to provide a justification for manufacturing in-house, although the other requirements will remain and they will additionally need to

- ensure that the device has an authorised prescriber
- name a Person Responsible for Regulatory Compliance
- ensure there are Periodic Safety Update Reports

C. How do we know what services are affected?

Cleaning, decontamination, repair and maintenance are not considered manufacture as long as these activities are carried out in accordance with manufacturer’s instructions.

Any health institution that is manufacturing or modifying a medical device, or sub-contracting these activities, would be considered the manufacturer and must meet the new requirements. Activities which might be considered as manufacturing or modifying a device include:

- Building a device from raw materials or component parts
- Rebuilding or refurbishing an existing device
- Making a new device from used devices
- Device software development
- Using a product for a medical purpose that is not CE marked as a medical device
- 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
- Using an existing device for a different purpose to that intended by the manufacturer
- 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.

Health institutions that subcontract manufacturing will need to be able to demonstrate sufficient responsibility and control of the contractor to ensure the requirements of their exemption applies.

Health institutions need to be aware of the scope of their manufacturing activity to ensure their services are compliant with the new regulations. The following services are notable for their long-established manufacturing activities:

- Medical Physics and Bioengineering
- Wheelchair & Seating
- Pathology
- Software
- Orthotic & Prosthetic
- Podiatry
- Maxillofacial Laboratory
- Oncology
- Dental
- Speech and Language

D. What are the main requirements for Health Institution Exemption?

NHS Boards and local authorities declaring a Health Institution Exemption will have to meet the following requirements.

a) Ensure that devices are not transferred to another legal entity.

If the Health Institution allows the device to be transferred to another legal entity then it will need to apply the regulations in full and CE mark the device. There are exemptions for transferring devices between two health institutions but both are required to declare the exemptions separately. Devices essential to the continuity of patient care such as implanted devices or assistive technology may transfer with the patient without declaring exemption.

b) Ensure their services follow the General Safety and Performance Requirements (GSPR).

The GSPR are detailed in Annex 1 of the regulations. NHS Boards manufacturing devices need to evidence compliance with the GSPR. This is likely to form part of the device’s technical file.

c) Establish an appropriate Quality Management System.

The regulations state that the manufacture and use of devices occur under an appropriate Quality Management System (QMS). The most widely recognised QMS for medical devices is BS EN ISO 13485:2016 Medical Devices. Quality management systems. Requirements for regulatory purposes (referred to as ISO 13485).

Whilst health institutions do not require to be externally certified to manufacture Class I Medical Devices they will need to declare that they operate an appropriate QMS. For “custom made” devices, health institutions need to demonstrate that the QMS includes all components described in Section 10.9 of the regulations. It is widely accepted that the best way to show compliance with this requirement is to be certified to ISO 13485.

d) Justify that the target group’s specific needs cannot be met by an equivalent device on the market.

Health institutions will need to list all medical devices that they manufacture and provide a justification for manufacturing each device. The justification may be, for example, that there is no CE marked device that meets the identified patient need or because of device performance, reliability, turn-around times or systems compatibility.

The justification needs to be evidenced and may need to be reviewed regularly. For some services the main reason for manufacturing in-house has been to reduce costs. Reduction of costs is no longer an acceptable reason for not using an equivalent CE marked medical device so compliance may have financial implications for these services.

e) Make information available to competent authorities on request.

In addition to the information made public, the MHRA may request information about medical devices manufactured by the Health Institution and may inspect these services using its enforcement powers.

f) Declare certain details publicly.

Health institutions will have to declare the name and address of the legal entity and a contact person for providing additional information about medical devices they manufacture. They will have to list the devices they are claiming exemption for and these may be grouped using a recognised coding system.

g) Document evidence of compliance with GSPR.

The NHS Board needs to have documentation for each device or group of devices it manufactures that includes the specification of the device, it’s intended use, a justification for manufacturing, reference to relevant sections of the QMS and a checklist referring to documented evidence of compliance with GSPR.

h) Review experience gained from clinical use of the devices and take all necessary corrective actions.

The NHS Board must have a surveillance system in place to gather experience of clinical use of the devices it manufactures. This surveillance system must include not just the identification and reporting of incidents but also include details of corrective and preventative actions and a record of their effectiveness.

E. What do health institutions need to do?

NHS Boards and local authorities declaring a Health Institution Exemption will have to do the following:

a) Be aware of the scope of their current manufacturing activities.

b) Ensure that all manufactured devices:
   - are covered by an appropriate Quality Management System (QMS)
   - meet the General Safety and Performance Requirements (GSPR)
   - and have appropriate levels of technical documentation.

c) Declare a Health Institution Exemption (HIE) to cover the manufacture of medical devices that includes evidence of the justification for manufacture.

d) Health institutions which manufacture custom-made devices should designate a Named Person Responsible for Regulatory Compliance and arrange for Periodic Safety Update Reports.

e) Health institutions which cannot ensure these requirements are met before 26 May 2020 should consider alternative arrangements for the continuation of services.

F. Questions and Answers

Disclaimer

This document is based on an understanding of the relevant EU and UK laws at the date of publication. It is not, and should not be read as, a statement of the definitive legal position on any matter. NHS Boards, local authorities and other organisations should consult their own legal advisors for advice on any legal issues that arise regarding the matters covered in this document.

(i) Q: Is there a need for a contract between the purchaser and provider Boards to address possible in-house manufacture and formally delegate clinical decision making on this as part of the service provision?

A: The purchasing Board should be able to demonstrate that the service it is purchasing meets all appropriate regulatory requirements. Consideration could be given to including this within the contract terms, although most of the information required for assurance should be publically available within the provider’s HIE and ISO certification.

(ii) Q: When a patient moves to another Board area and takes their in-house manufactured device with them, the receiving Board takes on the patient’s care. However, it also takes on the liabilities and responsibilities of using a second hand, non CE-marked product for a medical purpose. This would be addressed in the care plan and the receiving Board would either provide a CE-marked device or adopt the existing one into their HIE. Would the receiving Board’s QMS need specific provisions to address this scenario?

A: The receiving Board would need assurance that the product was manufactured to the appropriate requirements. As the new owner of the device, the receiving Board will need to declare an HIE, include this product in its documentation and make sure that its QMS has reference to the technical documentation and risk management of the device. The receiving Board will have to demonstrate sufficient knowledge and control of the original manufacturer to assure that the regulatory requirements are met.

(iii) Q: If a patient moves to another Board area, the receiving Board may not have the instrumentation and expertise to take on the previous Board’s in-house manufactured product. What happens if an alternative product is offered in its place but patient prefers the one they have been using and refuses to accept the alternative?

A: Regulatory requirements cannot be ignored based on patient preference. If the receiving Board does not have the expertise or QMS, then it should not take on ownership. The Board would then have to offer a CE marked alternative to the patient. There may be some issues with patient compliance but if the regulatory and safety concerns are explained then most patients will comply.

(iv) Q: If a patient moves to a new Board area with an in-house manufactured passive implant, would the receiving Board be required to make an HIE declaration? If so, would it be on the basis that the implant requires no ongoing maintenance? Also, if the receiving Board needed to repair or modify the fixings for example, would it need to declare HIE at that point?

A: In this example the Board taking on ownership does not need to make an HIE declaration. However, this is not due to the lack of an ongoing maintenance requirement. It is because there is an exemption to the transfer of legal entity requirement if the device is implanted or is classified as Assistive Technology. If the implant subsequently needs repair then the new owner would follow whatever servicing and maintenance instructions are stated by the Board that manufactured it.

(v) Q: Is there a requirement for more education and training to help health institutions prepare for MDR and IVDR?

A: Many services are not prepared and managers and clinicians are not familiar with the new requirements of MDR and IVDR. Consequently, there is a requirement for more education and training.