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HPRA MEDICAL DEVICES
NEWSLETTER

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In this Issue

Contacting the HPRA

- Medical device adverse incident reporting, information regarding serious risk, falsified devices and any issue regarding device safety: devicesafety@hpra.ie
- Medical device registration and other queries: devices@hpra.ie

HPRA UPDATES

Adoption of amendment to extend MDR and IVDR transitional provisions

On 20 March 2023, Regulation (EU) 2023/607 entered into force. This Regulation introduces a staggered extension to the transitional provisions of the MDR as follows:

- 2026 for class III custom made devices,
- 2027 for class III and class IIb implantable devices,
- 2028 for other class IIb, class IIa and class Is, Im devices, and
- 2028 for class I up classified devices.

The Regulation also removes the 'sell off provision' for both the MDR and IVDR. This means that devices already placed on the market can continue to be made available or put into service until the revised expiry of the certificate or until the shelf life of the device.

We recommend you read the Regulation to understand how it may affect your organisation.

The Commission has developed a Q&A document. This gives practical information on the application of the extension. The Q&A is available on our MDR transitional provisions webpage.

The extension only applies to devices which meet the criteria outlined in Regulation (EU) 2023/607 as follows:

- the device continues to comply with the previous Directives,
- the device does not undergo a significant change to its design and intended purpose,
- the device does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health,
- the manufacturer has a QMS in accordance with Art 10(9) in place by 26 May 2024,
- the manufacturer or authorised representative has lodged an application for MDR certification with a notified body by 26 May 2024,
- the manufacturer has signed a written agreement with a notified body by 26 September 2024.

Where the certificate of a Directive-compliant device expires after 20 March 2023 and that device meets the relevant criteria it will benefit from the extension.

Where the certificate of a Directive-compliant device expires before 20 March 2023 and that device has been subject to a national derogation in accordance with Article 59 or Article 97, you should email us directly at devices@hpra.ie for more information.

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HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Distinguishing between importers and distributors

This article is intended to help economic operators identify their role within the medical device supply chain. It sets out several scenarios to help distinguish between the role of an importer and the role of a distributor under the MDR and IVDR.

Scenario	HPRA position
Irish-based company buys device from EU-based manufacturer. Invoiced & shipped from EU-based manufacturer.	The legal and financial ownership of the device is transferred from a legal manufacture located in the EU. As such, the Irish company is considered a distributor.
Irish company buys device from EU-based supplier. Legal manufacturer is based in a third country. The device is shipped from the EU. The Irish company is invoiced by the third country manufacturer.	If there is a legal transfer of ownership from the third country legal manufacturer to the EU supplier, the EU supplier would likely meet the definition of an importer. If the ownership of the device is then subsequently transferred from the EU supplier to the Irish company, the Irish company would likely meet the definition of a distributor. However, if the EU supplier does not have legal ownership of the device, and the transfer of ownership is between the third country manufacturer and the Irish company, the Irish company would likely meet the definition of an importer. This remains the case even if the devices are shipped from the EU.
Irish company buys device from EU-based supplier. Legal manufacturer is based in a third country. The device is shipped from the third country of the legal manufacturer. Irish company is invoiced by the EU-based supplier.	If there is a legal transfer of ownership from the third country manufacturer to the EU supplier, the EU supplier would likely meet the definition of an importer. If the ownership of the device is then subsequently transferred from the EU supplier to the Irish company, the Irish company would likely meet the definition of a distributor, even if those devices are shipped from the third country of the legal manufacturer. In this scenario, the EU importer would have to fulfil MDR/IVDR importer obligations in full, including verification checks.
Irish company buys devices from a manufacturer based in a third country. Devices are shipped from the third country of the legal manufacturer.	The legal and financial ownership of the device is transferred from a legal manufacture located in a third country to the Irish company. As such, the Irish company is considered an importer.
Irish company buys devices direct from a third country manufacturer. The third country manufacturer 'identifies their importer' in the EU and advises the Irish company that they are a distributor. The devices are shipped from the third country of the legal manufacturer and the Irish company is invoiced by the third country manufacturer.	The legal and financial ownership of the device is transferred from a legal manufacture located in a third country to the Irish company. As such, the Irish company is considered an importer.
Irish company buys devices direct from a third country manufacturer. The third country manufacturer 'identifies their importer' in the EU and advises the Irish company that they are a distributor. The devices are shipped from the EU and the Irish company is invoiced from the third country manufacturer.	As above, the legal and financial ownership of the device is transferred from a legal manufacture located in a third country to the Irish company. As such, the Irish company is considered an importer, irrespective of the fact that the devices are shipped from within the EU. If the ownership of the device was transferred from the EU entity in this scenario to the Irish company, the Irish company would likely meet the definition of a distributor.

Annex XVI Commission Implementing Regulation 2022/2346

On 2 December 2022, the Official Journal of the European Union published the Commission Implementing Regulation (EU) 2022/2346, laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI of the MDR.

Implementing regulation 2022/2346 will apply from 22 June 2023, however, Article 2(3) will apply from 22 December 2022. Affected products are classed into six broad groups:

1. Contact lenses or other items intended to be introduced into or onto the eye.
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts, except for tattooing products and piercings.
3. Substances, combinations of substances, or items intended for facial or other subcutaneous, submucous, or intradermal injection or other introduction, excluding those for tattooing. Examples include dermal fillers.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. High-intensity electromagnetic radiation (such as infra-red, visible light and UV) emitting equipment intended for use on the human body. Examples include lasers and intense pulsed light (IPL) equipment for tattoo or body hair removal.
6. Equipment intended for brain stimulation that applies electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

While most of the same obligations for medical devices with a medical purpose will apply, Implementing Regulation 2022/2346 will introduce some product specific requirements. For example, the label of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection must contain:

a) the text: *"Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law"*.

b) a clear indication that devices are not to be used in persons who are less than 18 years old.

Manufacturers of products listed in Annex XVI should read and review this Regulation to ensure they identify and fulfil their applicable obligations from its date of application.

Decommissioning of the Extranet online registration system

We have decommissioned our Extranet online registration system. For more detailed information on who this will affect and why we decommissioned our Extranet registration system please see our dedicated webpage.

Registrations previously completed through our Extranet system will remain valid in the context of the MDD, IVDD and AIMDD. We have decommissioned our Extranet registration system due to the application of the MDR and IVDR. We built our Extranet registration system to facilitate registrations under the Directives and it has since reached its end of service life. All economic operators and devices should be registered under the MDR and IVDR accordingly.

Stakeholders no longer have access to the Extranet system and cannot update or withdraw economic operator details or device information under the Directives. It is no longer possible to amend or withdraw device information or pull device reports from the Extranet system for Directive compliant devices.

We will only accept changes to information relating to the registered address of an organisation or the description of the device used to identify it. You do not need to notify us of changes to other information for Directive compliant devices previously registered via the Extranet such as changes to GMDN codes.

Should you need any device reports please contact us directly at deviceregister@hpra.ie.

MDR and IVDR regulatory information published by the HPRA

We have published a new website section, which provides information in one central location on the Medical Devices Regulation and the *In Vitro* Diagnostics Regulation. The information is relevant to industry stakeholders, including manufacturers, authorised representatives, importers and distributors working to implement the Regulations.

The new website section includes newly published guidance on a number of key topics and collates previously published topics together for ease of reference. The new structure aims to make it easier for stakeholders to navigate and locate our regulatory information.

The topics on the page cover the following areas:

1. The Medical Devices Regulation (MDR) including topics such as:

- Clinical investigations,
- Medical device classification, and
- MDR transitional provisions.

2. The *In Vitro* Diagnostic Medical Devices Regulation (IVDR) including topics such as:

- Performance studies for IVDs,
- IVD classification, and
- European Union reference laboratories.

3. Common aspects of the Regulations including topics such as:

- Notified body designation and oversight,
- HPRA inspections, and
- Documents and guidance

This is not an exhaustive list of topics covered. Please visit the Medical Devices Regulatory Information page for more information.

Published documents

Title And Link	Publication	Description
Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices	February 2023	This document aims to clarify important terms and concepts that are outlined in Section 2 of Chapter VII of the Regulation (EU) 2017/745 on medical devices (MDR). Establishing a common understanding of these terms and concepts is necessary for an effective and harmonised implementation of the vigilance requirements under the MDR. The document is written for competent authorities, economic operators and other relevant parties.
Update - MDCG 2020-16 Rev.2 - Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746	February 2023	This guidance, relating to the application of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) addresses the classification of in vitro diagnostic medical devices (IVDs) and provides clarifications on the classification rules as set out under Annex VIII. This classification guidance also applies to diagnostic or information society services performed on EU patients or devices put in to service through distance sales.
MDCG 2023-2 - List of Standard Fees	January 2023	The templates for "List of Standard Fees" provided in this guidance document are intended to assist notified bodies defining their list of fees for publication in accordance with MDR Article 50 and IVDR Article 46.
MDCG 2023-1 Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	January 2023	The provisions in Article 5(5) are the basis for the regulatory control and oversight of inhouse devices. This document provides guidance on the application of some of these rules. It is written for healthcare professionals and researchers of health institutions aiming to design, manufacture, modify and use in-house devices. In addition, this guidance document intends to foster harmonised application of Article 5(5) by the national competent authorities.
MDCG 2022-21 - Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022	December 2022	The main objective of this guidance document is to assist manufacturers to implement the legal requirements laid down in Article 86 MDR. However, manufacturers should have reasonable time to adapt their quality management systems and sufficient flexibility2 when they draw up and update a PSUR as long as they can demonstrate that it is in line with Article 86 MDR

Title And Link	Publication	Description
MDCG 2022-4 rev.1 - Guidance on appropriate surveillance regarding MDR Art.120 transitional provisions - devices covered by MDD or AIMDD certificates	December 2022	This guidance document outlines the activities to be performed by notified bodies as part of the appropriate surveillance defined in Article 120(3) second subparagraph MDR. In order to clarify elements to be verified by notified bodies, this guidance document also covers requirements concerning certain manufacturers' obligations, especially in respect to their quality management system. The document applies to notified bodies that have lawfully issued certificates under the MDD or the AIMDD, regardless of whether or not those notified bodies have applied for designation or are designated under the MDR (see MDCG 2019-10 rev.19) as long as the respective authority responsible for notified bodies has the right to and does monitor notified body's activities under Article 120(3) MDR.
Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices	December 2022	This manual provides practical guidance regarding the qualification and classification of borderline products.
MDCG 2022-20 - Substantial modification of performance study under Regulation (EU) 2017/746	December 2022	The sponsor of a performance study is required to notify the Member State in which a performance study is being or is to be conducted if it intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the performance study. In the absence of EUDAMED, a series of performance study application/ notification documents have been created to support performance study procedures with respect to the IVDR. This document is intended to be facilitative and its use by the competent authorities and sponsors is encouraged.
Updated information pack for candidate EU reference laboratories	November 2022	This information pack aims to summarise key information in an accessible way. It is subject to change. Please refer to the relevant legislation and text of the call for applications for full details and/or contact your Member State for further information (contact details below)
MDCG 2022-16 - Guidance on Authorised Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 2022	This guidance document is written for authorised representatives, manufacturers and other economic operators, and intends to provide guidance on relevant requirements under the Regulations. Where clarification is already covered by other MDCG guidances, this guidance on authorised representatives includes a reference.
MDCG 2019-6 Rev.4 - Questions and answers: Requirements relating to notified bodies	October 2022	This document presents questions and answers on requirements relating to notified bodies under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). The issues covered by this document have been identified in the context of joint assessments, and the document may be updated from time to time as new issues are identified.

Stakeholder engagement

We encourage engagement from all stakeholders. If you have any queries in relation to medical devices, please email us at devices@hpra.ie.

By signing up to MyHPRA, stakeholders can receive notifications of HPRA publications and notices.