HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Frequently Asked Questions on
# Notification for In-house Manufacturers of Medical Devices and *in vitro* Diagnostic Medical Devices

## SCOPE

This guide is intended to inform in-house manufacturers of the requirement to notify the Health Products Regulatory Authority (HPRA) of their activities and to provide clarity on the process and information to be provided.
Further information on the requirements for health institutions who manufacture and use in house IVDs is available on the HPRA website.

## FREQUENTLY ASKED QUESTIONS

### 1 Who is this notification process for?

This notification process is intended for health institutions that manufacture and use in-house medical devices (MDs) and *in vitro* diagnostic medical devices (IVDs) in Ireland. The term health institution is defined in Regulation (EU 2017/746) on *in vitro* Diagnostic Medical Devices (IVDR) Article 2(29) as an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.

### 2 Why do I need to submit a notification?

Health institutions that manufacture and use in-house MDs and IVDs within that institution are required under the national law S.I. No 691/2021 Medical Devices (Registration) Regulations and S.I. No. 365/2022 *In Vitro* Diagnostic Medical Devices (Registration) Regulations 2022, to identify themselves to the HPRA and supply any information about the in-house MD/IVD on request.

### 3 How do I submit a notification?

Open the online in-house manufacture notification form, which can be found on the HPRA in-house IVD webpage. Complete all mandatory fields and submit the form.

### 4 What information will I need to complete this notification?

(i) Details of the health institution:
- Name
- Address
- Telephone Number
- A general email address for the health institution, where applicable, e.g. info@companyname.ie

(ii) Where available, the URL where the health institutions public declaration is made (see section 5)
(iii) A contact point and contact details within the health institution (see section 8 to 11)
(iv) Confirmation that you are notifying the HPRA for in-house MDs or in-house IVDs
(v) Acceptance of the terms and conditions (see section 11 to 12)

## 5 What if I do not have a public declaration available on my website?

To be compliant with the provisions for in-house MDs and IVDs, a public declaration is required. Further details are described in Article 5(5e) of Regulation (EU) 2017/745 on Medical Devices (MDR) and in Article 5(5f) of IVDR. The HPRA may request this information at a later date, if you are unable to provide it at the time of submission of your notification.

## 6 Do I need separate notifications for MDs and IVDs?

As part of the notification process, both Regulations are listed as options for selection. Where you can make the notification for both in-house MDs and IVDs at the same time, you can make a single notification. You can also make separate notifications for in-house MDs and IVDs.

## 7 Do I need separate notifications for each laboratory?

Laboratories within a health institution do not need to notify the HPRA separately. You are advised to coordinate between the laboratory/laboratories when identifying who within the health institution should submit the notification (see section 8).

## 8 Who within the health institution should submit the notification?

An individual, who has the authority to make the declaration on behalf of the health institution should submit the notification. This individual:

- Accepts the terms and conditions and serves as a contact point for the health institution. The HPRA may contact this individual for further information, as required.
- Should be able to liaise and coordinate with the various departments who manufacture and use the in-house MDs or IVDs. For example, in the case of in-house IVDs, they would need to coordinate with the laboratories involved.
- Should ensure that all appropriate governance structures within the health institution have been informed about the notification.

## 9 What if the contact details change?

If the contact details change for the individual who submitted the notification, please notify the HPRA by email at deviceregister@hpra.ie. Please quote the original notification case reference number in your correspondence and outline the change.

## 10 What if I wish to add more than one contact point?

If you wish to add more than one contact point, you can email the HPRA at deviceregister@hpra.ie. Please quote the original case reference number in your

correspondence. For any additional contact points, please clearly outline their role and the scope of the in-house MDs or IVDs for which they are contact points. We ask that you keep the number of additional contact points to a minimum.

## 11 What are the terms and conditions for an in-house medical device or *in vitro* diagnostic medical device?

Notifications of in-house manufacturing of MDs are made in accordance with S.I. No. 691/2021 Medical Devices (Registration) Regulations, while those of in-house manufacturing of IVDs are made in accordance with S.I. No. 365/2022 *In vitro* Diagnostic Medical Devices (Registration) Regulations. The onus is on your health institution to ensure compliance with the Regulations and to ensure the information and data that is provided to the HPRA is accurate and current.

As outlined in the second paragraph of Article 5(5) of the MDR and the IVDR, the HPRA, as the competent authority for medical devices and *in vitro* diagnostic medical devices, reserves the right to restrict the manufacture and use of any specific type of in-house medical device, to carry out documentary, physical and/or laboratory checks to verify compliance with the requirements of the Regulations and to inspect the activities of in-house manufacturers.

By agreeing to the declaration, you, as the authorised regulatory contact for your health institution, confirm that your health institution is aware of its legal obligations to comply with the requirements of the MDR, S.I. No. 261/2021 and S.I. No. 691/2021, as appropriate, for in-house manufacturing of MDs and with the requirements of the IVDR, S.I. No. 256/2022 and S.I. No. 365/2022, as appropriate, for in-house manufacturing of IVDs.

You also agree to notify the HPRA of any substantial changes to the information submitted to the HPRA or if you are no longer the authorised regulatory contact.

## 12 When should I submit a notification?

You should notify the HPRA once you identify your health institution is manufacturing and using in-house MDs or IVDs.

## 13 What happens after I submit a notification?

The HPRA will contact you by email to provide you with a case reference number for the notification.

## 14 Is there a cost for this notification?

There is no cost associated with this notification.

HPRA
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