HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide for
On-line Registration System for Medical Devices

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1 SCOPE

This document provides instructions for use of the online medical device registration system, Medical Devices Extranet.

2 INTRODUCTION

The Human Products Authorisation and Registration Department of the Health Products Regulatory Authority (HPRA) upgraded the online registration system for medical devices in July 2012 to increase functionality and to allow for communication with the EUDAMED system.

3 ACCESSING THE ONLINE REGISTRATION SYSTEM

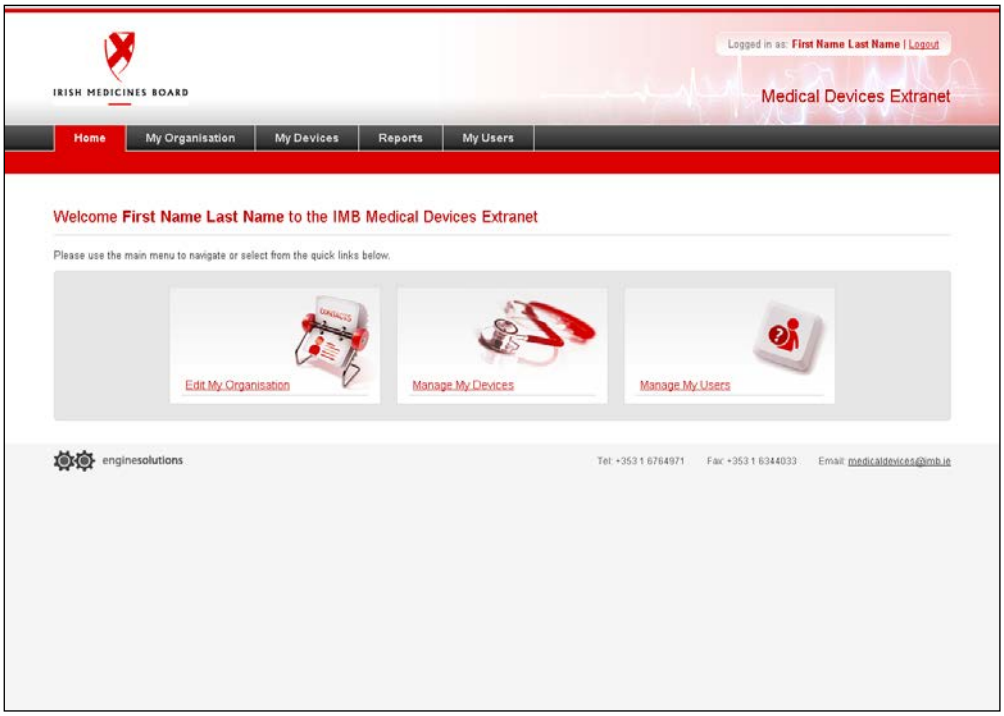
New users of the medical device on-line registration system receive a username and password when they first register their organisation online, submit payment and submit the signed terms and conditions document to the HPRA. The username and password allow the user to access the Medical Devices Extranet.

If difficulties are experienced in accessing this system, please contact the Human Products Authorisation and Registration Department immediately using the contact details in Section 4.

Users can log onto the registration system through the web address https://access.medicaldevices.ie. Once the username and password is correctly entered, the organisation's homepage will appear on the screen. The user has the ability to edit organisation details, manage devices, manage users and generate device reports, see Figure 1.

FIGURE 1: ORGANISATION HOMEPAGE

Please note that the IMB rebranded to become the HPRA in July 2014. The extranet may be rebranded to the HPRA brand colours but the content will remain the same.



3.1 Edit My Organisation

To edit the organisation details, click on the 'Edit My Organisation' quick link on the homepage or click on the 'My Organisation' tab in the navigation bar. The organisation details currently registered with the HPRA are shown on the screen.

The company name, address and contact numbers are editable from this screen. Certain fields, for example, organisation type, organisation role and primary contact name cannot be changed through the online system. To amend these, or any other details which are not available for editing through the online system, please contact the Human Products Authorisation and Registration Department.

Organisations also have the option to add a trading name which is associated with the registered organisation. To do so, enter the trading name into the free text box and click the adjacent add button. A list of all trading names associated with the organisation appears. Remove a trading name by clicking the adjacent 'Delete' button.
Once changes have been made, they are submitted by clicking on the 'Submit' button located at the bottom left of the screen. To cancel any changes which were made click on the 'Cancel' button. The changes submitted do not come into effect until the HPRA has reviewed and approved them.

3.2 Manage My Devices

To manage devices registered to the organisation details, click on the 'Manage My Organisation' quick link on the homepage or click on the 'My Devices' tab in the navigation bar. The details of devices currently registered with the HPRA are shown on the screen. Searches for devices can be made using status, description or registration number filters.

3.2.1 Registering a new device

To register a device, click on the 'Add Device' button. Depending on the type of device (i.e. general medical device or *in vitro* diagnostic medical device) and its classification, the screen may refresh with different data fields, see Figure 2. Once all the relevant data fields have been completed, click the 'Submit' button at the bottom of the screen. If the appropriate data fields are not completed, the submission will not proceed. Fields with missing data are highlighted in red, move the cursor over these fields to view further details on the error.

All users are encouraged to use a preferred GMDN term. If a suitable GMDN term is not available, another internationally recognised nomenclature may be used. Users may search either by device description or GMDN code by selecting the 'Search' link. The search results will appear in the Device Code (GMDN) drop down box.

Descriptions of several data fields are provided in Appendix 1.

If the details entered are not to be submitted, click on the 'Cancel' button located at the bottom of the screen to revert to the previous screen.

FIGURE 2: GENERAL MEDICAL DEVICE DETAILS

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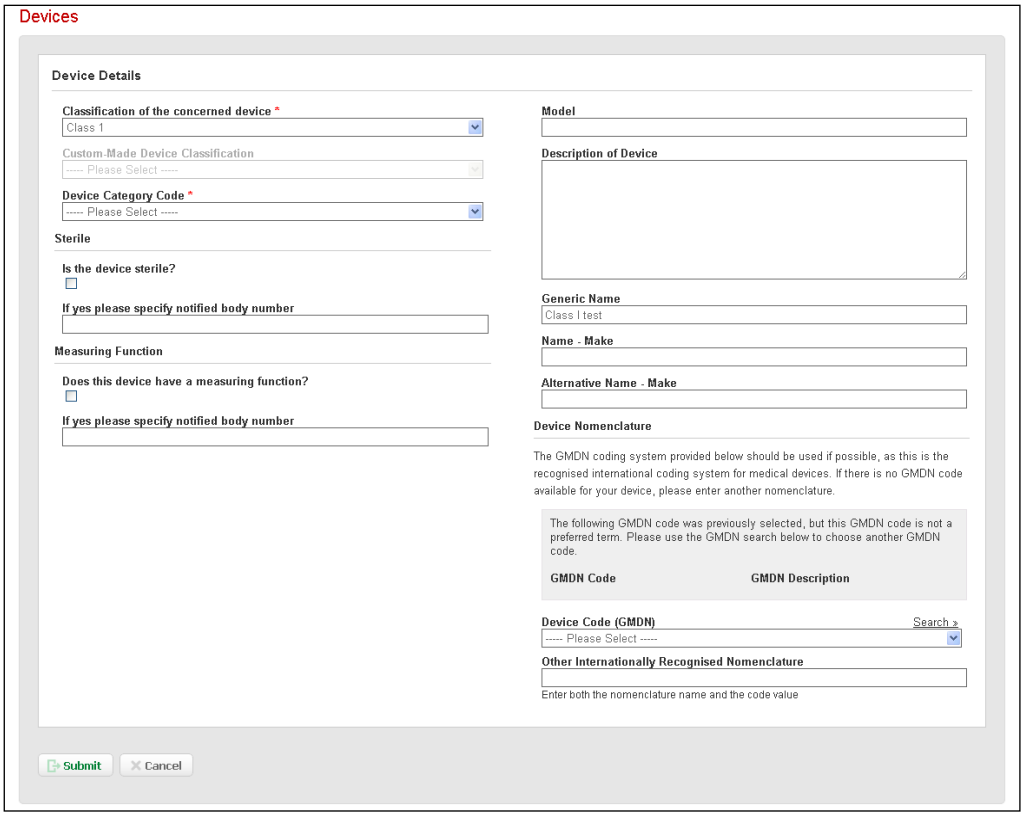

When a device has been submitted to the HPRA for registration, it appears on the 'My Devices' screen as 'Not Registered Yet' and the status of the registration i.e. '(N) Awaiting Review' can be seen. While the device is 'Not Registered Yet', the device details submitted can be edited by selecting the 'Edit' button and making the relevant changes.

When the device has been registered by the HPRA, the device registration number appears on screen and the status changes from '(N) Awaiting Review' to 'Registered'.

Where queries arise relating to the device details submitted, the status appears as '(N) Further Information Required' and the primary user will be contacted by the Human Products Authorisation and Registration Department directly, see Figure 3.

FIGURE 3: DEVICE STATUS PAGE

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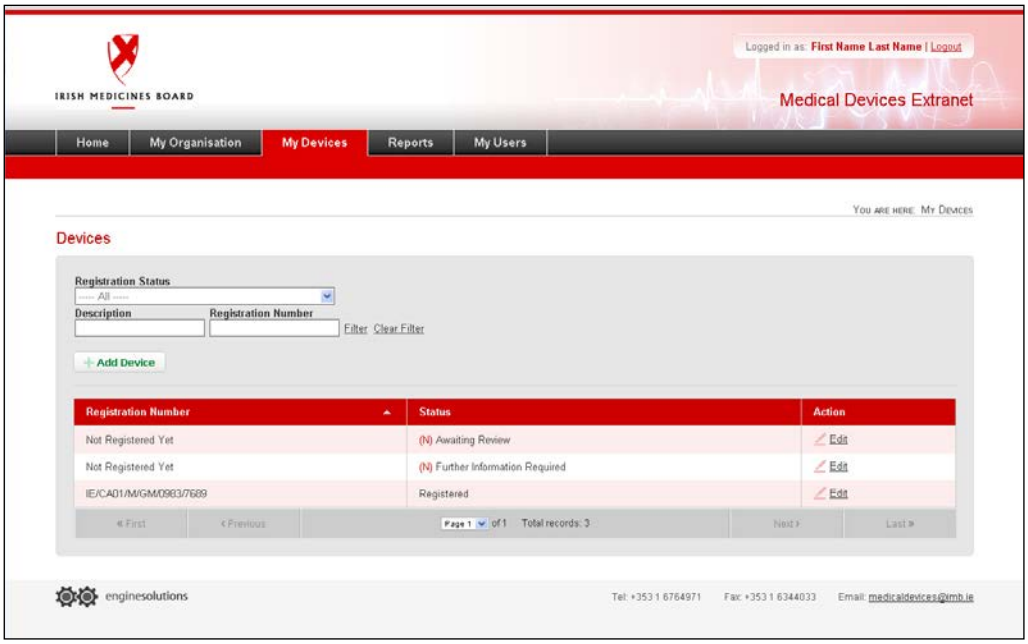

3.2.2 Editing an existing registered device

Click on the 'Manage My Organisation' quick link, or the 'My Devices' tab in the navigation bar to display a list of the devices currently registered or awaiting registration.

To edit the details of a particular device, click on 'Edit', which is located to the right of each registered device. The device details which were previously registered with the HPRA will appear on the screen. Then make the relevant changes to the device and submit the changes to the HPRA by clicking on the 'Submit' button at the bottom of the page. If the details entered are not to be submitted, click on the 'Cancel' button located at the bottom of the screen to revert to the previous screen.

When changes are submitted to the HPRA, the status of the device appears on the 'My Devices' screen as 'Awaiting Review'. During this time the device details submitted can be edited by selecting the 'Edit' button and making the relevant changes.

When these device amendments have been registered by the HPRA, the device registration status changes from 'Awaiting Review' to 'Registered'. Where queries arise relating to these changes, the status appears as 'Further Information Required' and the primary user will be contacted by the Human Products Authorisation and Registration Department directly.

3.2.3 Withdrawing an existing registered device

To withdraw a particular device, select the 'Edit' button, which is located to the right of each registered device.

The device details previously registered with the HPRA appear on the screen. Select the 'Withdraw Device' button, located at the bottom left hand corner of the screen. Once this action has been completed, the device is withdrawn with immediate effect i.e. there is no HPRA approval of withdrawal applications.

When the device has been withdrawn, the status of the device changes to 'Withdrawn'.

3.3 Reports

Details registered with the HPRA can be viewed, downloaded and printed through the 'Reports' tab in the navigation bar. Once the 'Device Report' link is selected, the report appears on screen and can be downloaded in pdf, Word or Excel formats by clicking the export icon located at the top of the report, see Figure 4 below (icon highlighted in red).

FIGURE 4: DEVICE REPORTS

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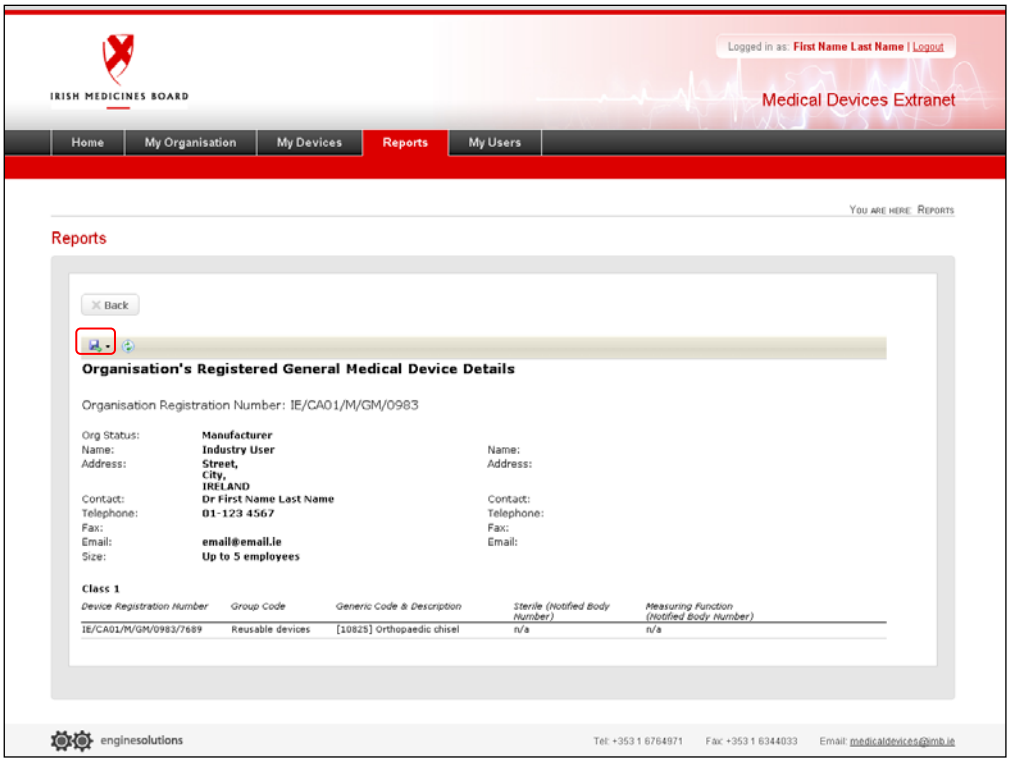

3.4 Manage My Users

After initial registration and receipt of a username and password, user details can be added, edited, disabled or deleted. To manage registered users click on the 'Manage My Users' quick link on the homepage or click on the 'My Users' tab in the navigation bar. A list of all users associated with the registered organisation is shown.

To add a user click the 'Add User' tab at the top of the page. Provide the first name, surname, password and e-mail address of the new user. The e-mail address provided will become the username and a password consisting of at least seven digits must be generated; it is recommended that an alphanumeric password is used. To submit the details of the new user to the HPRA, select the 'Submit' button. If the user does not wish to submit the details, select the 'Cancel' button to revert to the previous screen. Once the details of a new user have been submitted, the new user can immediately start to use the registration system. The user does not need to receive confirmation from the HPRA.

To edit or disable a user, select the 'Edit' link under 'actions for the concerned user'. All user details may be amended, however a valid e-mail address must be used for the username. To disable a user, check the disable box at the bottom of the page. All amendments to user details must be submitted by selecting the 'Submit' button at the bottom of the page. If the details entered are not to be submitted, click on the 'Cancel' button located at the bottom of the screen to revert to the previous screen, see Figure 5.

To delete a user select the 'Delete' button located to the right of the user's name under actions. The text box 'Are you sure you want to delete this user?' appears. To proceed, select 'OK' or select 'Cancel' to return to the list of users. If 'OK' is chosen, the selected user will be deleted and a list of the existing users appears on the screen. Deleted users will not be shown on the screen.

FIGURE 5: USER DETAILS PAGE

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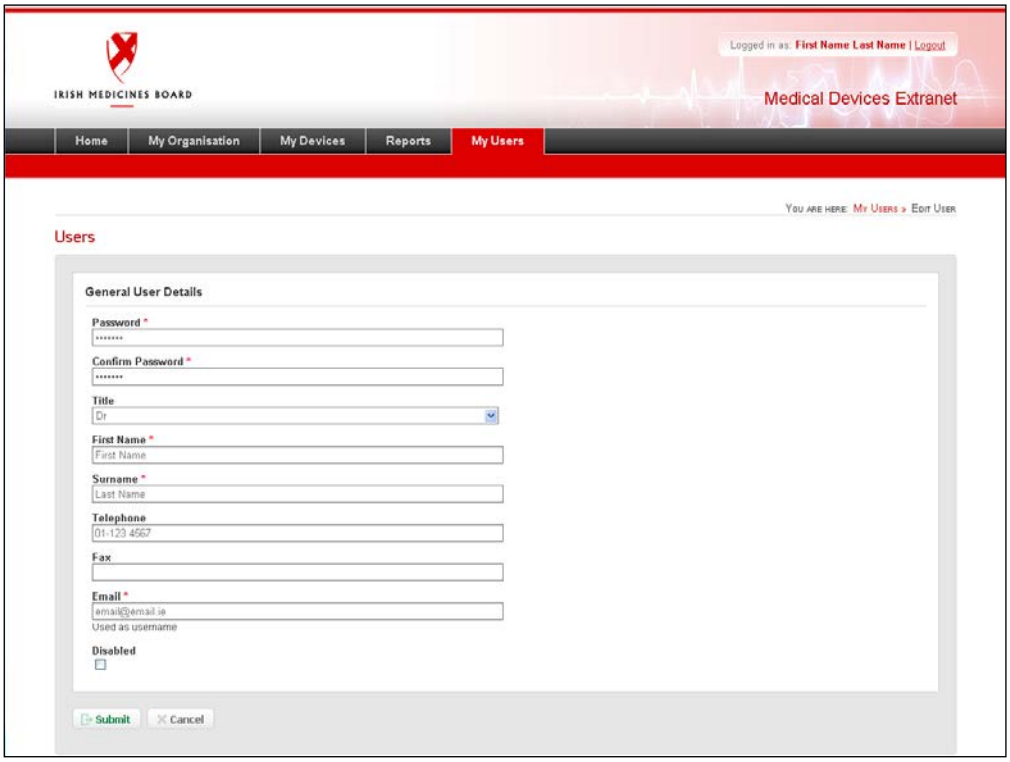

4 HPRA CONTACT DETAILS

If you experience any problem with the registration system please contact the medical device clinical assessment team of the Human Products Authorisation & Registration Department at:

Clinical Assessment (Medical Devices)
Human Products Authorisation & Registration Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Telephone: 01-6764971
Fax: 01-6764061
E-mail: devices@hpra.ie. or deviceregister@hpra.ie

The HPRA encourages communication with stakeholders. Please send any comments relating to the system or any suggestions for future improvements to devices@hpra.ie.

APPENDIX 1 DATA FIELD DESCRIPTIONS

Description of Device
A generic description of the type of device being registered.

Model
The reference of the device model as assigned by the manufacturer.

Generic Name
The generic name of the device as assigned by the manufacturer.

Name – Make
The brand name (trademark) under which the medical device is marketed.

Alternative Name – Make
An alternative brand name under which the medical device is also marketed.