



Medical Devices

User Guide for NZ WAND

(Web Assisted Notification of
Devices)

1 February 2010

Version 2

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Definitions

Medical Device

Any device, instrument, apparatus, or contrivance, including component parts and accessories thereof, that is manufactured, imported, sold or supplied for use wholly or principally on or by one or more human beings for a therapeutic purpose; and includes bandages and other surgical dressings, except medicated dressings where the medication has a curative function that is not limited to sterilizing the dressing; but does not include-

- a. Any ultrasonic therapy apparatus within the meaning of section 2 of the Physiotherapy Amendment Act 1953:
- b. Except in section 38 of this Act, any irradiating apparatus within the meaning of section 2 (1) of the Radiation Protection Act 1965:
- c. Any article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of article that is not a medical device for the purpose of this Act

Therapeutic Purpose

In this Act, unless the context otherwise requires, the term "therapeutic purpose" means-

- a. Treating or preventing disease; or
- b. Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or
- c. Effecting contraception; or
- d. Inducing anaesthesia; or
- e. Altering the shape, structure, size, or weight of the human body; or
- f. Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way; or
- g. Cleaning, soaking, or lubricating contact lenses.

Sponsor

In relation to a medical device-

- a. means-
 - i. person in New Zealand who exports, or arranges the exportation of, the device from New Zealand:
 - ii. person in New Zealand who imports, or arranges the importation of, the device into New Zealand:
 - iii. a person in New Zealand who manufactures the device in New Zealand, or arranges for another person to manufacture the device in New Zealand, for supply (whether in New Zealand or elsewhere); but
- b. does not include a person who-
 - i. exports, imports, or manufactures a device; or
 - ii. arranges for the exportation, importation, or manufacture of a device, -

on behalf of another person, who, at the time of the exportation, importation, manufacture, or making of the arrangements, is a resident of, or is carrying on business in, New Zealand.

Introduction

WAND (Web Assisted Notification of Devices) is the medical device notification database for New Zealand. WAND has been upgraded and the new “New Zealand WAND” database will be used from 3 August 2009.

This document is a guide to local Sponsors of medical devices when notifying a medical device to the NZ WAND database.

Background

The Medicines (Database of Medical Devices) Regulations 2003 came into force on 1 January 2004. Under these regulations a Sponsor manufacturing, supplying or exporting medical devices in New Zealand is, with few exceptions, required to complete a notification to the WAND database within 30 days of the device being placed on the market or exported.

The previous WAND database was hosted by the Australian Therapeutic Goods Administration (TGA), and was modeled on and shared some information with their equivalent DEAL database. This co-existence of WAND/DEAL ceased to exist on 28 October 2008 and, as a result, two separate databases have emerged.

The NZ WAND database has been established and is now hosted by Medsafe. We are no longer using the Interim WAND process that was established as a temporary notification system. All Interim WAND notifications have been uploaded to the NZ WAND database.

Although the new process for submission of a medical device notification by a Sponsor will be similar to the process that was previously used, there will be some small changes.

Reminder: NZ WAND is a notification database only, and is reliant only on information provided by Sponsors about their products. Inclusion of a notification on NZ WAND does NOT indicate approval or any other endorsement of the device by Medsafe.

Changes to the WAND Notification Process

Although we have endeavoured to minimise change from the end user perspective, you should be aware of the following changes and new features.

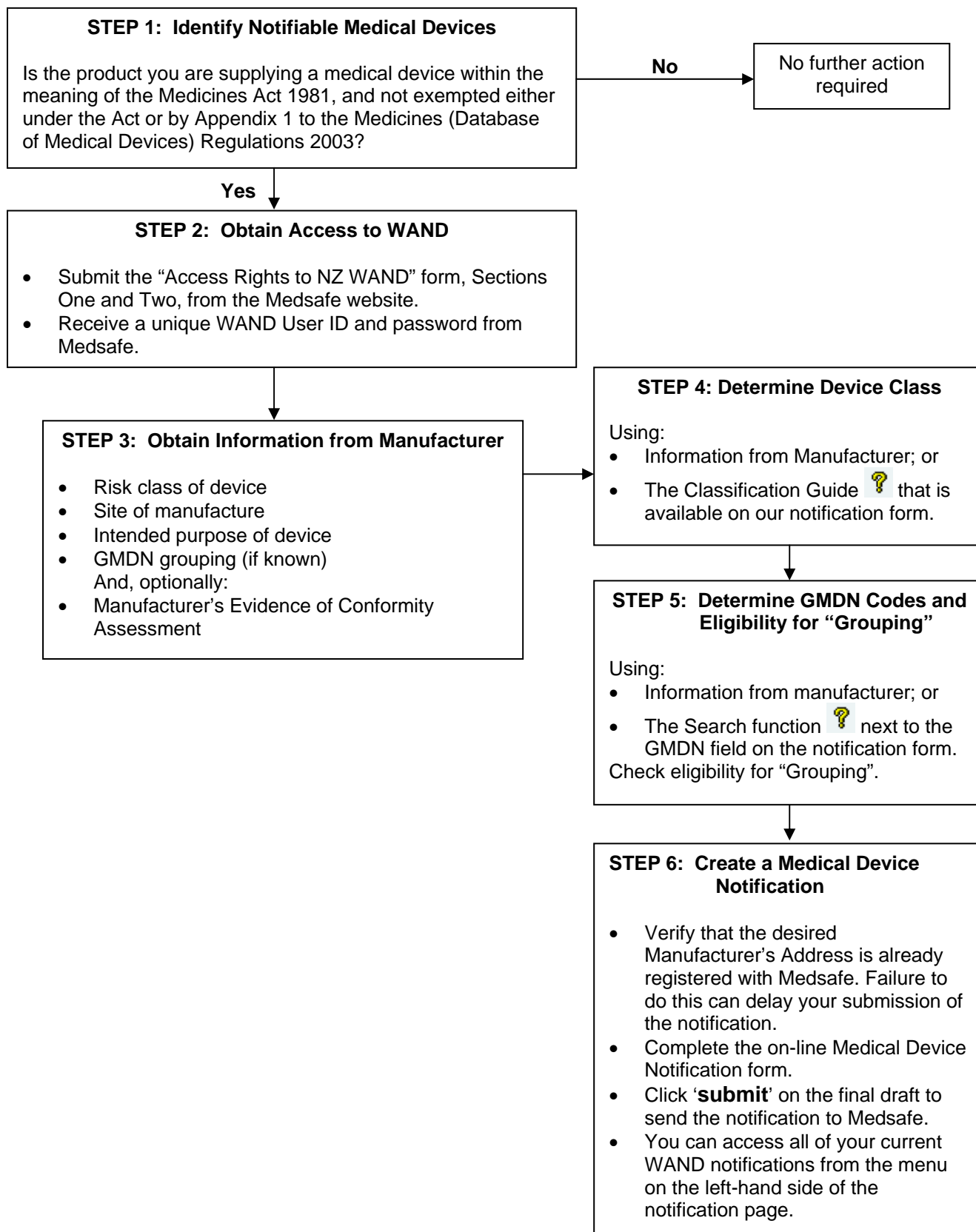
- Upon the launch of NZ WAND in August 2009, **all existing NZ Sponsors** will receive new passwords to access their WAND notifications. These passwords will be sent electronically to the registered WAND Administrator.
- The Interim WAND system needed ONLY the User ID to login. The NZ WAND database requires both the User ID and a password.
- Sponsors can now login to NZ WAND to view all current medical device notifications. It is their responsibility to edit/update their notifications as necessary in accordance with Regulation 8-9 of the Medicines (Database of Medical Devices) Regulations 2003.
- Read-Only WAND, housed by the Therapeutic Goods Administration, is now rendered obsolete. All current WAND notifications have been uploaded to the NZ WAND database, which is operated by Medsafe.
- It is not possible to “clone” data from the TGA DEAL system to NZ WAND.
- There is only one WAND Administrator for each NZ Sponsor. This person is responsible for maintaining current contact details with Medsafe. If the WAND Administrator changes for a company, it is their responsibility to notify Medsafe (via the NZ WAND Administrator Details Update Form) and to provide the details for the new WAND Administrator. Failure to do this will result in correspondence from Medsafe continuing to be sent to the old WAND Administrator’s e-mail address.
- A Sponsor is now asked to verify the contact details of their NZ WAND Administrator **each** time they login to the NZ WAND database.
- A Sponsor is now able to reset their own password if their existing login details are lost/incorrect, provided they maintain their five digit Sponsor ID. The new password will be sent electronically to the WAND Administrator’s e-mail address that is registered with Medsafe.
- A Sponsor is now able to “delete” WAND Notifications by returning the notification to “Draft” mode and selecting ‘**Obsolete**’ from the drop-down menu at the bottom of that notification. This is to ensure compliance with Regulations 5-8 of the Medicines (Database of Medical Devices) Regulations 2003.
- A Sponsor is now able to notify IVDs if they choose, by selecting ‘**IVD**’ from the ‘**Classification**’ drop-down menu. New Zealand legislation does not currently require IVDs to be notified to NZ WAND, but this may change with future legislation. Medsafe encourages the notification of IVDs as it coincides with Global Harmonising principles.
- Medsafe no longer accepts ‘Change of Sponsorship’ requests from Sponsors. If a Sponsor wishes to transfer WAND notifications to another existing Sponsor, it is the new Sponsor’s responsibility to submit each WAND notification to Medsafe. Once this has been done, the former Sponsor can delete those notifications from their folder.
- The NZ WAND database does not house Manufacturer’s Evidence. Instructions for submitting Manufacturer’s Evidence to Medsafe are included in this manual.
- A sorting option is now available for viewing all “Current” notifications. Notifications can be sorted by the WAND reference, Sponsor’s reference, GMDN code and Manufacturer.

- A Sponsor can now view a “shortened” version of each device notification that only contains the Sponsor (name), WAND reference, Sponsor’s own reference and the GMDN code.

All current WAND notifications should be available on NZ WAND. This includes notifications made during the Interim WAND process. Please verify that each notification is valid and intact.

Key Steps in Completing a Medical Device Notification to NZ WAND

Further description of these steps is provided in subsequent text.



Step 1: Identify Notifiable Medical Devices

Is the Product a Medical Device?

All medical devices (as defined in the Medicines Act 1981) are required to be notified, unless specifically exempted in the Act or under Schedule 1 of the Medicines (Database of Medical Devices) Regulations 2003.

Medical devices that are currently exempted from notification are:

- certain specific types of device as set out in Section 2 of the Act
- products made specifically in accordance with a request by a registered health professional and intended to be used only in relation to a particular individual
- imported devices held in bond for export
- *in vitro* diagnostic devices (IVDs)
- medical devices supplied as part of a clinical trial
- items imported for personal use but not for resale or use on others.

The Director-General of Health may also exempt other specified medical devices. These are notified in the *New Zealand Gazette* and publicised on the Medsafe website.

Some products that are considered medical devices overseas are regulated as **medicines** in New Zealand. **Such products are not notifiable medical devices.** Prior to supply, a Sponsor must obtain the Minister of Health's consent for distribution of these products as medicines in New Zealand. They include:

- contact lens cleaning and soaking solutions
- pregnancy test kits
- bone cement containing an antibiotic
- condoms containing a spermicide
- intrauterine contraceptive devices (IUCDs) containing copper
- some dental products containing fluoride
- injections for a therapeutic purpose that is achieved by physical rather than pharmacological means, e.g. collagen injections
- medical gases.

If in doubt, please contact Medsafe for advice.

Step 2: Obtain Access to NZ WAND

New Sponsors: How do I Obtain Access to the NZ WAND Database?

To obtain access to the NZ WAND database, go to the Medsafe website at:
<http://www.medsafe.govt.nz/regulatory/wand.asp>

Complete both of the New Zealand WAND Application Access forms (Section 1 and Section 2) from the Medsafe website and submit these to Medsafe by following the instructions on the forms.

Once the applications are accepted, Medsafe will send a unique Sponsor ID number and a password to the email address supplied in Section 2 of the access forms.

The Sponsor ID is a five digit number and will be your "WAND User Name".

The password can be re-set at any time, with the new password being electronically sent to the e-mail address of the company's WAND Administrator. This password should be kept secure and must be used when notifying/updating medical device information to Medsafe.

WAND is a secure database. The User ID is required to ensure security when notifying new products. If you have lost your User ID, please do not re-apply for WAND Access, but contact the DART team at dart@moh.govt.nz.

Existing Sponsors: How do I Access Current WAND Notifications?

Upon the launch of NZ WAND in August 2009, all existing Sponsors will receive new passwords. These passwords will be sent electronically to the registered WAND Administrator. Sponsors can use the new password along with their current User ID to access their notifications on NZ WAND.

All current WAND notifications should be available. This includes notifications made during the Interim WAND process. Please verify that each notification is valid and intact.

Step 3: Obtain Information from Manufacturer

Before you start entering a notification you will need to obtain certain information about the medical device you distribute.

The manufacturer of the device should provide you with the following information:

- risk class of the device
- site of manufacture (manufacturer's address)
- statement of the intended purpose of the device
- the Global Medical Device Nomenclature (GMDN) code (if known)
- optionally, valid and current evidence that the device from that Manufacturer has been assessed by a recognised regulatory agency ("Manufacturer's Evidence of Conformity Assessment").

Conformity assessment documents available from the manufacturer will generally include all the above information. It is suggested you keep these documents in your files in support of your device notification.

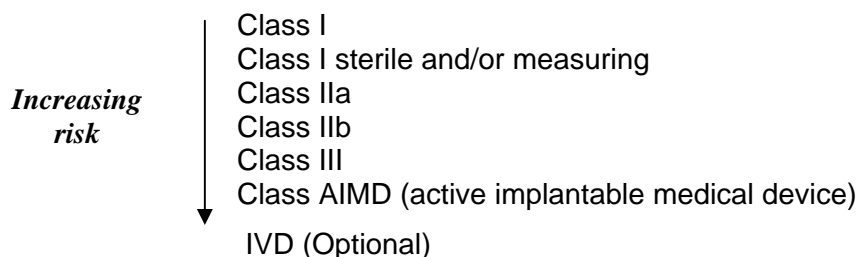
Please note that conformity assessment for Class I non-sterile/non-measuring devices may be limited to self-certification by the manufacturer.

Step 4: Determine Device Class

What are the Device Classes?


The device risk classes used in WAND will continue to be based on the European, Australian and Global Harmonisation Task Force (GHTF) risk classification system for medical devices. Risk class is based on both the nature of the device and its intended use.

There are six current risk classes for medical devices and one optional class, for the notification of IVDs:



What Class does my device belong in?

If risk class is not available from the manufacturer, you can determine the risk class by:

- using the guide  on the notification form, which assesses the risk class based on your responses to a sequence of questions about the intended purpose of the device; or
- using the classification system in Appendix 2 of the Medicines (Database of Medical Devices) Regulations 2003, which is available online at www.legislation.govt.nz.

An IVD Class has been included on the NZ WAND Classification drop-down menu. Medsafe encourages Industry to notify IVDs to the NZ WAND database as it coincides with Global Harmonising principles. However, it is not a mandatory requirement at this time.

Default Risk Class

Class I is the “default” risk class when the class is not otherwise defined for low risk devices. It is **not appropriate** for any device that:

- the manufacturer intends to supply in a sterile state; or
- has a measuring function.

Step 5: Determine Global Medical Device Nomenclature (GMDN) Codes and Eligibility for “Grouping”

How do I find the GMDN code?

This is a code to provide clear identification of the device.

An appropriate code is selected from a set of standard codes provided by the GMDN Agency in Europe.

The code used is determined by how the device is described by the manufacturer. In many cases, the manufacturer will already have a code for the device. Alternately, you can use the **Search** tool provided on our web-based notification form as follows:


- Log on to the notification form by going to:
www.medsafe.govt.nz/regulatory/MedicalDevices/Login.asp
- Enter one or more words describing the device in the GMDN box and click ‘**Search**’.

The search will look for the word at the beginning of each term name. If you would like to search the entire GMDN descriptor for the words you have provided, use the ‘%’ wildcard at the end of the word.

For example:

*-by typing **bandage%** in the Search box, the database will provide a list of all GMDN terms that contain the word “bandage” **anywhere in the descriptor***

*-by typing **bandage** in the Search box, the database will only provide a list of all GMDN terms that **start** with the word “bandage”*

- A second box will appear with a list of possible GMDN descriptors.
- Scroll down the list and select an appropriate term.
- Check if this is appropriate by clicking the yellow  which gives a full description of the GMDN term in a drop-down window.

***Note:** If you **cannot locate your GMDN code** on NZ WAND, please contact Medsafe for assistance at dart@moh.govt.nz

Some novel devices may not have a code assigned. If this is the case you must approach the GMDN Agency to have a new code created. **As a short-term expedient only** the “unclassified” code 38442 may be used. If an “unclassified” code is used, it will be followed-up by Medsafe within 90 working days. It is the Sponsor’s responsibility to secure the appropriate GMDN code during this time.

Medsafe cannot assign a code for you, since by so doing we would pre-empt the manufacturer in determining the nature and use of your device.

“Specified” GMDN terms

For a basic Class I device **only**, a “Specified” GMDN descriptor may be used if an exact term is not available. In this case the term defines a group of similar devices, with the “specify” field providing a general descriptor.

How Can Devices Be “Grouped”?

If desired, devices in Classes I, IIa and IIb can be grouped and only one notification submitted for each group.

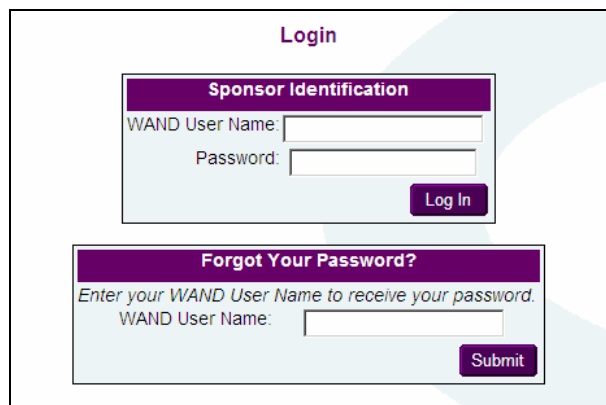
To be eligible for grouping the devices must be substantially similar and have the same GMDN code, manufacturer address, sponsor, risk class, and intended purpose. For example, if a sponsor is marketing different brands of similar latex examination gloves, these can be grouped provided they are made by the same manufacturer. More information on “grouping” medical devices can be found in Regulation 5 of the Medicines (Database of Medical Devices) Regulations.

Step 6: Create a Medical Device Notification

Accessing the NZ WAND Notification Form

Go to www.medsafe.govt.nz/regulatory/MedicalDevices/Login.asp

Enter your WAND User Name (your 5 digit Sponsor ID number) and your password. Click 'Log In'.



The screenshot shows a web form titled "Login". It contains two main sections. The first section, "Sponsor Identification", has a purple header and contains two input fields: "WAND User Name:" and "Password:". A purple "Log In" button is positioned to the right of the password field. The second section, "Forgot Your Password?", also has a purple header and contains the instruction "Enter your WAND User Name to receive your password." followed by a "WAND User Name:" input field and a purple "Submit" button.

***Note:** If you have forgotten your password, you must enter your WAND Username in the '**Forgot Your Password**' box. By submitting this to Medsafe, you are re-setting the current password. The new password will automatically be sent to the e-mail address of your company's WAND Administrator.

If you have forgotten your Sponsor ID, contact Medsafe for assistance at dart@moh.govt.nz

Verify Your Sponsor Details

Once logged into WAND, you must verify your Sponsor Details. This is to ensure compliance with Regulations 5-7 of the Medicines (Database of Medical Devices) Regulations 2003. Once these details have been verified, you will then be granted access to your WAND notifications.

Sponsor's Name	:	Medsafe
Address	:	PO Box 5013 Wellington NEW ZEALAND
Email	:	John_Smith@fake.com
Are these details correct?	:	<input type="radio"/> Yes <input type="radio"/> No

By clicking 'Yes', you are making a declaration that your contact details are correct. If your details need updating, please complete a 'Sponsor Details Update' form. You can access this form by either clicking 'No' in response to the question, "Are these details correct?" or by selecting 'Change Sponsor Details' from the Menu on the left-hand side of the page.

Web Assisted Notification of Devices

Sponsor Details Update Form

Sponsor Name :

Address :

City :

Country : NEW ZEALAND

New Zealand WAND Administrator Details

Contact Person :

Position :

Phone :

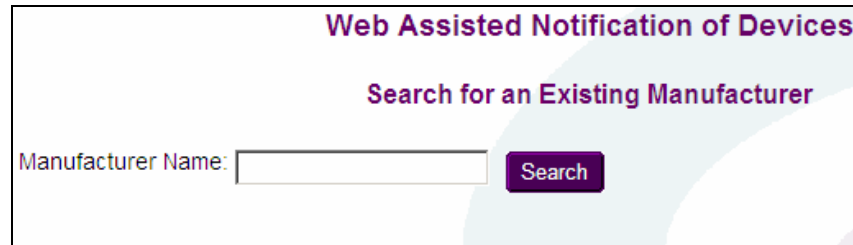
Email :

***Note:** The **NZ WAND Administrator** is the person responsible for correspondence with Medsafe concerning WAND notifications. If a password is electronically re-set by a User, the new password will automatically be sent to the WAND Administrator's e-mail address that is registered above. Please update your NZ WAND Administrator details as soon as there is any change within your company by completing a NZ WAND Administrator Details Update Form and submitting it to Medsafe. Failure to do so may result in loss of User Access for your company to NZ WAND.

Verify the Manufacturer's Address

Before beginning your New WAND Notification, you must first verify that your Manufacturer's address has been registered with Medsafe. Your notification will **not** be saved if you have to stop half-way through a notification to complete a '**Manufacturer Notification**' form.

To Search for the Manufacturer of your device, select '**Manufacturer Search**' from the Menu at the left-hand side of your screen. Once you have selected this link, type the name of your Manufacturer in the '**Search**' box. Click '**Search**'.

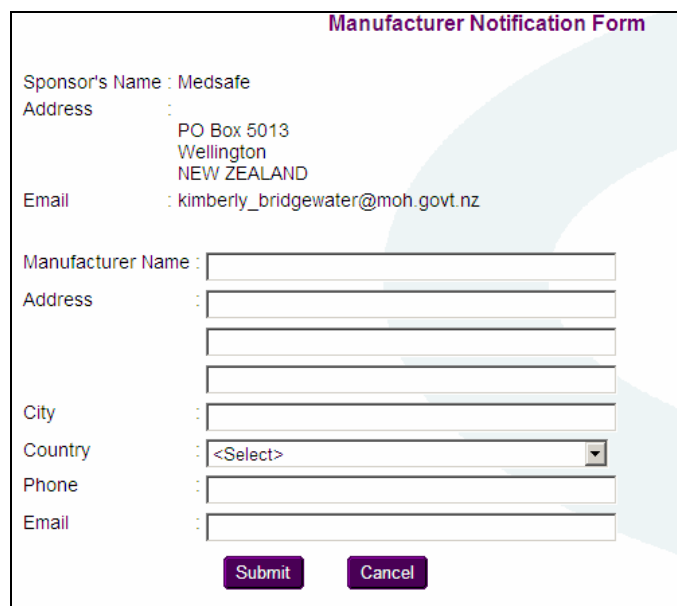


The screenshot shows a web interface titled "Web Assisted Notification of Devices" with a sub-heading "Search for an Existing Manufacturer". Below the heading is a form with the label "Manufacturer Name:" followed by a text input field and a purple "Search" button.

A list will appear with all manufacturers (and addresses) that are on the Medsafe database. If your Manufacturer is on this list, you can proceed with your WAND Notification by selecting '**Add a New Device**' from the Menu on the left-hand side of the page.

Notifying a New Manufacturer to Medsafe

If the desired Manufacturer's address is **not** listed in NZ WAND, you must select the '**Notify a New Manufacturer**' link, located in the Menu on the left-hand side of the field, and complete the '**Manufacturer Notification Form**' that appears.



The screenshot shows a form titled "Manufacturer Notification Form". It contains the following fields and information:

- Sponsor's Name : Medsafe
- Address : PO Box 5013, Wellington, NEW ZEALAND
- Email : kimberly_bridgewater@moh.govt.nz
- Manufacturer Name : [Text input field]
- Address : [Text input field]
- City : [Text input field]
- Country : [<Select> dropdown menu]
- Phone : [Text input field]
- Email : [Text input field]

At the bottom of the form are two buttons: "Submit" and "Cancel".

***Note:** The address of the manufacturer **MUST** be the street address. A postal address will **NOT** be accepted on this form.

Once this has been submitted to Medsafe, it will take **2-3 business days** for us to verify this address. You should be able to notify your device once **verification is complete** and the new Manufacturer's address appears in our database.

Add a New Device to Your Current WAND Notifications

Completion of a new WAND notification is straightforward, and a series of “drop-down” menus will assist. However, please pay particular attention to the following:

- if your product is intended to be supplied in a **sterile** state please indicate this
- if your product is a **kit, procedure pack** or **multi component system** please ensure you indicate this and **do not identify the product as a single device**
- if your product is **active** (powered by an energy source other than human effort or gravity), please ensure it is identified as such
- if your device contains **components**, please list each of the components in the appropriate field
- if your product is **medicated** or **formulated** (made by mixing a series of known ingredients in specific proportions) please identify this, and include details of medication or formulation. Please advise Medsafe if this information is confidential.

Filling Out the Form:

Sponsor's own Reference * :

Class * : ?

GMDN * : Search ?

Intended Purpose *
(Manufacturers intended use/therapeutic purpose of the device) :

Manufacturer * : Search

ARTG ID(if known) :

Sponsors Own Reference

This field is for your reference.

Class

Please choose a device classification from the drop-down menu. If required, use the ? for classification guidance. Refer to **Step 4** of this guide for more information.

GMDN code

Please choose the GMDN code specified by the device manufacturer. Click the ? to read the full definition of your GMDN code.

***Note:** See **Step 5** of this guide for more information.

Intended Purpose

Please state the purpose(s) that the device manufacturer intends the device to be used for. This field is where the Sponsor must clarify the manufacturer's *therapeutic purpose* of the device, as defined by Section 4 of the Medicines Act 1981.

***Note: The intended purpose is defined by the device manufacturer, not the local Sponsor.**

Manufacturer

You should have previously verified that your Manufacturer is registered on the database (see page 2 for more information). Enter the name of the desired Manufacturer and click '**Search**'.

A list of registered manufacturers matching the search term will appear. Select the Manufacturer of the device from this list.

ARTG (if known)

This is an optional field. If you have registered the device with the ARTG, please insert your ARTG number in this field. Otherwise, leave it blank.

In the second half of the WAND Notification, you will be asked to enter specific details about the device, such as whether the device is supplied sterile, whether the device is active (powered), whether the device is for single or multiple use, if it has materials of biological origin and whether it is a single device or system or procedure pack.

Additionally, if the medical device includes a medicine (see examples on page 7), is formulated, or is made up of several components as a system or procedure pack, this should be indicated. If you indicate the product is medicated or formulated you will be required to enter additional information identifying the medication or detailing the formulation. If this information is confidential to the Manufacturer please contact Medsafe for advice.

If you indicate the device is a system or procedure pack you will be required to identify the independent components.

***Note:** Notifications for Class III or AIMD devices cannot be grouped. They **must** include a unique product name, functional description and specific details about the device to ensure identification of each specific device.

Filling Out the Form:

Is the device or any form of the device supplied sterile? If **'Yes'**, please select the appropriate sterilization method from the drop-down menu.

The screenshot shows a form field titled "Is the device or any form of the device supplied sterile? *". To the right of the question are two radio buttons: "Yes" (which is selected) and "No". Below the question is a label "Sterilisation method:" followed by a dropdown menu. The dropdown menu is open, showing a list of sterilization methods: "<Select>", "<Select>", "Aseptic handling", "Beta irradiation", "Chemical", "Dry heat", "Electron beam sterilisation", "Ethylene oxide", "Filtration", "Gamma irradiation", "Gas plasma sterilisation", and "Glutaraldehyde".

Is the device intended to be invasive? Please select **'Yes'** or **'No'**.
Invasive medical device means a medical device that is intended by the manufacturer to be used, in whole or in part, to penetrate the human body through a body orifice or through the surface of the body.

Is the device or any form of the device intended for single use? Please select **'Yes'** or **'No'**.

Is the device an active device? Please select **'Yes'** or **'No'**.
Active medical device (a) means a medical device that is intended by the manufacturer-
(i) to depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human

being or gravity); and
(ii) to act by converting that energy; but
(b) does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between a medical device to which paragraph (a) applies and a human being without any significant change in the energy, substance, or other element being transmitted

Does the device contain material or ingredients of microbial origin?

Please select '**Yes**' or '**No**'.

Does the device contain material or ingredients manufactured or formulated using a genetically modified organism?

Please select '**Yes**' or '**No**'.

Does the device contain material or ingredients of human origin?

Please select '**Yes**' or '**No**'.

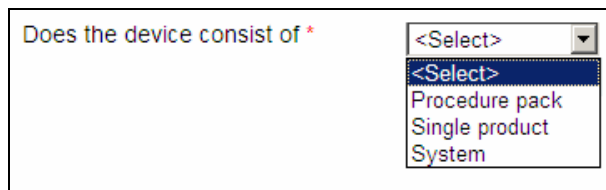
Does the device contain human blood or its components?

Please select '**Yes**' or '**No**'.

Does the device consist of

Please select one of the following descriptors from the drop-down menu:

- **Procedure Pack**
- **Single product**
- **System**



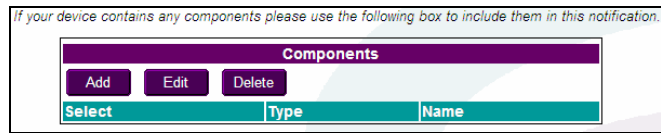
The image shows a screenshot of a web form. On the left, there is a text label "Does the device consist of *" in a light blue font. To the right of this label is a dropdown menu. The dropdown menu is currently open, showing a list of options: "<Select>" (highlighted in blue), "<Select>" (in black), "Procedure pack" (in purple), "Single product" (in purple), and "System" (in purple). The dropdown menu has a small downward-pointing arrow on its right side.

A **Procedure Pack** is a group of components which include medical device(s) and is intended to be used for a specific purpose. The pack itself must be notified and the components listed in the notification. If these are also supplied separately, the medical device components must also be notified individually to NZ WAND.

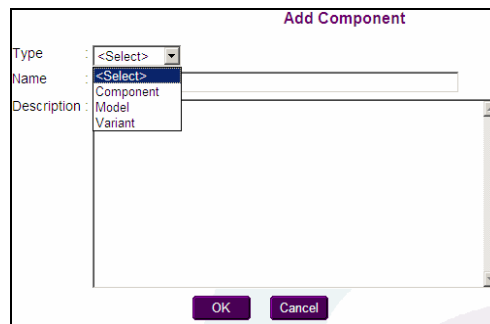
A **System** is a group of devices intended to be used together. A single notification can encompass the entire system unless

the individual components are also supplied separately, in which case individual notification is also required.

If your device includes components, different models, or variants, please click the **'Add'** button in the **Components** box.

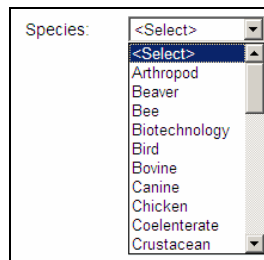


When adding Components to your notification, you must first select the Type: Component, Model or Variant. Once this is done, please type the name and a brief description of *each* component and click **'OK'**.

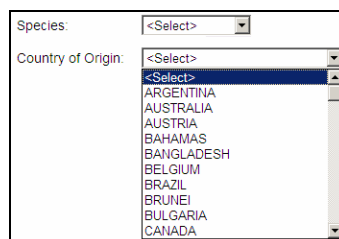


Does the device contain any material or ingredients of animal origin?

If **'Yes'**, please use the drop-down list to select the Species from which the material or ingredient is derived.



Next, select the Country of Origin from the drop-down menu.



**Is the device medicated?
Is the device formulated?**

Please select **'Yes'** or **'No'** for each of these questions.

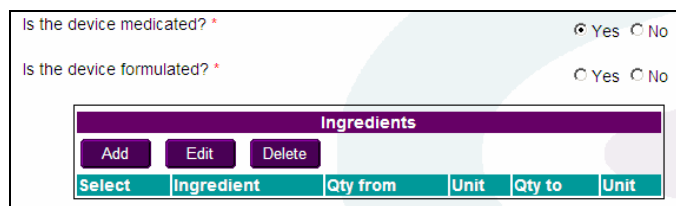
*A **Medicated** device is one in which a medicine is included in, or with, the device. If the product contains a medicine, it will*

need to be submitted to Medsafe for categorization. Please contact dart@moh.govt.nz for further information.

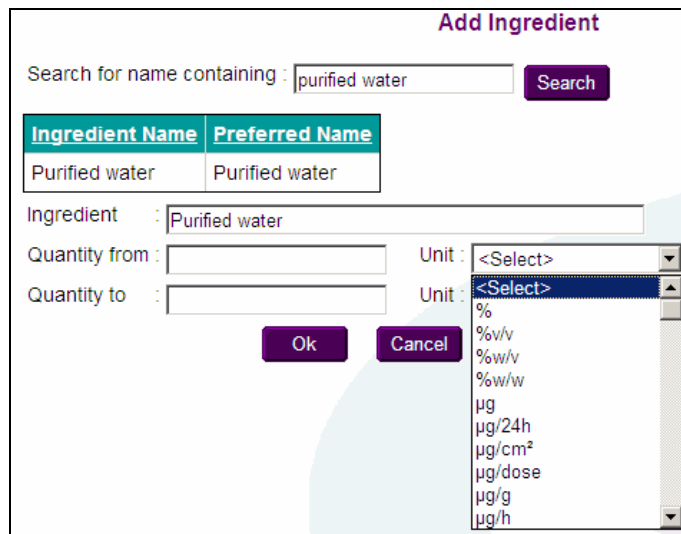
***Note:** If the medicine is not approved, or if the intended purpose of the combination is primarily medicinal, then the product is likely to be considered a medicine, and requires approval as such. Contact Medsafe for advice if uncertain.

A **Formulated** device is one in which the device is formed by mixing specific components (none of which are medicines) in defined proportions. Examples include fillers, lubricants and adhesives.

If **'Yes'** is selected for either, the following Ingredients box will appear on the notification:



Click the **'Add'** button in the **Ingredients** box and the following **Search** box will appear:



Type the name of the ingredient in the Search box and click **'Search'**. A list of both Ingredient Names and Preferred/Synonym Names will appear. From either list, choose the correct ingredient for your device.

You will now need to enter the quantity and the unit of the ingredient that you have selected.

For example, 0-5% Purified Water. If your device contains exactly 5% Water, please enter the values as 5%-5% Water.

***Note:** If you cannot locate your desired ingredient, please contact Medsafe at dart@moh.govt.nz for assistance.

Does the product contain a medicine that has consent for marketing in New Zealand?

Please select **'Yes'** or **'No'**.

Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device?

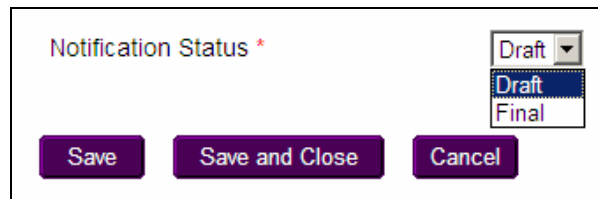
Please select **'Yes'** or **'No'**.

Notification Status

At the bottom of your notification, the Status box will default to **'Draft'**. If you wish to keep this notification in your **'Draft'** folder, click **'Save and Close'**. You can now access your notification in your **'View Draft Devices'** folder from the left-hand Menu on the homepage.

***Note:** Notifications in your Draft folder are **not** considered valid until they have been submitted to Medsafe.

If you wish to submit the notification to Medsafe, select **'Final'** from the drop-down box.



The screenshot shows a form titled "Notification Status *". On the right side, there is a dropdown menu currently set to "Draft", with a list of options including "Draft" and "Final". Below the dropdown are three buttons: "Save", "Save and Close", and "Cancel".

Once **'Final'** has been selected, the declaration will become visible and the **'Submit'** button will appear.

Making a Declaration

Before submitting the notification to Medsafe the Sponsor **must** make an electronic declaration that attests that the Sponsor accepts the responsibilities associated with supplying a medical device in New Zealand or exporting a medical device.

In completing the declaration, the Sponsor is declaring that:

- the product is a medical device;
- the device will only be recommended by the sponsor for the purpose specified by the manufacturer; and
- the information included in, or with, the notification is complete and correct.

The declaration is made by checking the box next to '**I Agree**' on the final draft of the notification form before submitting to Medsafe.

***Note: A Notification will not be accepted without a valid declaration.**

Part 1 of the Declaration is **mandatory** for all New Zealand Sponsors:

Part 1 (compulsory)

I, being a person authorised to make this application hereby certify that:

- a. devices of the kind in question are medical devices; and
- b. the kind of device is correctly classified according to the medical device classifications; and
- c. the notified device will only be recommended by the sponsor for use for its intended purpose; and
- d. the information included in or with the application is complete and correct.

In electronically submitting this application to Medsafe, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

Agree Disagree

Part 2 of the Declaration is **optional**:

Part 2 (optional)

I, being a person authorised to make this application certify that:

- e. devices of that kind comply with the essential principles listed in the WAND on-line user guide; or
- f. I
 - i. have available sufficient information to substantiate that compliance with the essential principles; or
 - ii. have procedures in place to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
- g. an appropriate conformity assessment procedure has been applied to devices of that kind; and
- h. I
 - i. have available sufficient information to substantiate that compliance with the essential principles; or
 - ii. have procedures in place to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and

I declare this application meets the criteria specified above in Part 2 (optional) of the declaration.

Yes No

Submitting the Notification Form

When the medical device notification is completed, and the declaration signed, submit the notification electronically by clicking '**Submit**'. Medsafe cannot accept faxed or mailed copies of notifications.

Once submitted, you will be able to view your NZ WAND Notification immediately in your '**Current WAND Notification**' folder, located on the Menu on the left-hand side of your screen. At this point, the notification process is complete.

Medsafe will subsequently review the information you have provided, and will contact you if this is incomplete or inaccurate.

Step 7: Manufacturer Evidence of Conformity Assessment

What information is required for this?

Evidence of conformity assessment assists in demonstrating the safety and efficacy of your device. However, Sponsors are not currently required to notify their Manufacturer's Evidence information to the NZ WAND database. Medsafe, instead, requests that you keep this information in your company files in case it is required in the future.

European (CE) certifications, TGA certification, and (for US manufacturers) FDA approval are all acceptable. Note, however, that CE certificates must refer to Council Directive 90/385/EEC for Active Implantable Medical Devices or Council Directive 93/42/EEC For Medical Devices.

***NOTE: ISO 9000 certificates are not adequate for this purpose.**

Editing Information on NZ WAND

Regulation 8 of the Medicines (Database of Medical Devices) Regulations 2003 states that:

- (1) *Subclause (2) applies if any information recorded on the database in respect of a medical device or kind of medical device ceases to be accurate or complete (whether because of a change of circumstances, for example, a change in the name of a manufacturer or sponsor, or a lapse in any certification relating to the device or kind of device, or otherwise).*
- (2) *If this subclause applies, the sponsor must, within 10 working days of the information ceasing to be accurate or complete, ensure that the Director-General or any person who maintains the database on behalf of the Director-General is notified of the correct details, or the complete information, as the case requires.*

The following instructions are intended to assist Sponsors in keeping their notifications to NZ WAND up-to-date.

Updating Sponsor Details with Medsafe

There are three ways in which a company can currently update their contact information with Medsafe:

1. *Sponsor Details Update Form*, located within the NZ WAND database, is *only* for the changes to the postal address of the NZ Sponsor.
2. *The Sponsor Details Update Form*, located on the Medsafe website at <http://www.medsafe.govt.nz/regulatory/Wand/SponsorDetailsUpdateForm.doc>, is a more comprehensive form for all other company detail changes. This is the form where a business can update the details of the business, phone number, etc.
3. *NZ WAND Administrator Details Update Form*, located on the Medsafe website at: <http://www.medsafe.govt.nz/regulatory/Wand/NZWANDAdministratorDetailsUpdateForm.doc> is to be completed each time the nominated NZ WAND Administrator changes for a WAND account. This person is the primary contact for Medsafe regarding all notifications on WAND.

Editing/Updating a Current WAND Notification

A User of NZ WAND can now edit their current WAND notifications when changes occur. To do this, you must first return the **'Active'** WAND notification to **'Draft'**.

Select the WAND notification to be edited from your **'Home (Current WAND notifications)'** folder, located in the Menu on the left-hand side of the homepage. Open up the notification and scroll down to the bottom. Underneath the **'Status'**, you are given several options.

To edit the notification, click **'Return to Draft'**.



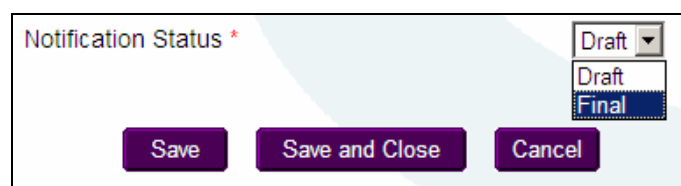
Once this has been done, you must click on the **'View Draft Devices'** folder, located in the Menu on the left-hand side of the homepage. Your WAND notification should now be in this folder.

***Note:** A WAND notification is not considered valid or current while it is in **'Draft'** mode.

Open the WAND notification and edit the desired fields. Notice that the **Notification Status** at the bottom of the page is **'Draft'**.

You can save your changes in the **'Draft'** folder for as long as you need to by keeping the status as **'Draft'** and clicking **'Save and Close'** at the bottom of the notification.

When you have completed changing details of the notification, and are ready to submit it to Medsafe, change the **Notification Status** from **'Draft'** to **'Final'** at the bottom of the screen.

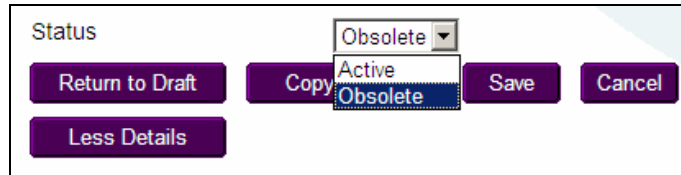


Once a notification has been put back to **'Final'**, the declaration will appear. You must first sign the declaration before submitting it to Medsafe (see Step 6 for more information).

The notification should immediately appear in your **'Current Notifications'** folder.

Making a Current WAND Notification "Obsolete"

If a device is no longer being sponsored by your company in New Zealand, it is the Sponsor's responsibility to delete it from the NZ WAND database. This is done by selecting the desired notification from your **'Current WAND notifications'** folder and scrolling to the bottom to view the (notification) Status.



To delete your WAND notification, select '**Obsolete**' from the drop-down menu next to the '**Status**' field. Once this is done, click '**Save**' at the bottom of the screen. The device is now deleted from your '**Current WAND notification**' folder.

Other Features:

Viewing/Sorting your Current WAND Notifications

When viewing your Current WAND notifications, you have several options to sort them. By clicking on the desired title on the table containing the list of notifications, you can sort them accordingly.

WAND Reference	Sponsors Reference	GMDN	Manufacturer
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Your sorting options include:

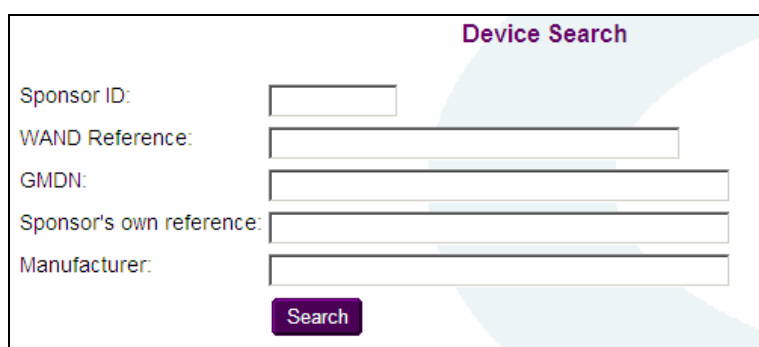
- **WAND Reference:** This will sort your WAND notifications by the **date**. The first six digits of any WAND Reference number represents the date that the notification was initially submitted to Medsafe.
*For example, a notification containing the WAND reference number, **070331-WAND-72Y5CX**, was submitted to Medsafe on **31/03/07***
- **Sponsors Reference:** This will sort your WAND notifications in alphabetical order according to your Sponsors reference to the device.
- **GMDN:** This will sort your WAND notifications by GMDN code.
- **Manufacturer:** This will sort your WAND notifications by Manufacturer of the device.

***Note:** After a WAND notification has been accessed and closed, the screen will automatically return to the original sorting order. To maintain your chosen sorting order, use the 'back' icon on your browser instead of clicking 'cancel' on the notification.

Searching For a Specific Device in Current Notifications

If you are looking for a specific WAND notification for your company, you can click on 'Device Search' from the Menu on the left-hand side of the screen.

The following 'Device Search' box will appear:



The image shows a 'Device Search' form with the following fields and a search button:

- Sponsor ID:
- WAND Reference:
- GMDN:
- Sponsor's own reference:
- Manufacturer:
- Search button:

You can locate the desired WAND notification by entering the WAND Reference number, the GMDN code, the Sponsor's own reference, or the Manufacturer. Click 'Search' and the notification will appear.

Viewing a Shortened Version of a Notification

To view a shortened version of a current WAND notification, open the notification from your Current WAND notifications folder and scroll down to the bottom. There is an option called '**Less Details**', which will allow you to display only the following details of the notification:

- Sponsor
- WAND Reference
- Sponsors Own Reference
- GMDN Code

This option enables Sponsors to print shortened versions of their WAND notifications.

Hospital Recall Contacts

The 'Hospital Recall Contacts' feature is located on the Menu on the left-hand side of the homepage. This Directory is a downloadable listing of the points of contact that may be used when advising hospitals (public and private surgical hospitals) of medical device corrective actions. Information contained within this Directory is updated as contacts change so should only be downloaded at the time it is required.

****Note: This Directory should only be used following consultation with Medsafe regarding the conduct of a medical device corrective action.***

For further information about the Medical Device Recall Contacts Directory or about conducting a corrective action please contact Robert Jelas (robert_jelas@moh.govt.nz).

Getting Help

The Medsafe website contains a series of topic-specific help files structured as Frequently Asked Questions (FAQs).

For queries about interpretation of current Legislation in relation to your products contact your DART advisor directly or send an e-mail to the DART mailbox dart@moh.govt.nz. Inclusion of full product description, instructions for use, labelling and promotional material will facilitate resolution of queries.

For queries about how to use WAND, or to report problems first review the FAQ section at the end of this document, then if problems persist contact the DART team at dart@moh.govt.nz.