



Medical Devices

Frequently Asked Questions (FAQs) for NZ WAND

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Version 1

Frequently Asked Questions (FAQs):

- I. Definitions
- II. Basic Requirements to Supply Medical Devices in New Zealand
- III. Identifying Notifiable Devices
- IV. Gaining Access to WAND
- V. The Notification Process
- VI. Accessing WAND Notifications
- VII. Adding Evidence
- VIII. Deleting or Editing Notifications

I. Definitions

1. What is a **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:*

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

2. Am I a **Sponsor**?

A Sponsor means:

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.*

3. What is a **therapeutic purpose**?
- 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*
Cleaning, soaking, or lubricating contact lenses.
4. What is an **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.*
5. What is the **intended purpose** of a device?
- Intended purpose, in relation to a medical device, means the purpose for which the manufacturer of the device intends it to be used, as stated in-*
- a) *the information provided with the device; or*
 - b) *the instructions for use of the device; or*
 - c) *any advertising material relating to the device.*
6. What does **invasive** mean?
- 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.*
7. What are **spare parts, accessories, systems** and **procedure packs**?
- *A **spare part** is a product that substitutes for a component already included in the medical device. As a consequence, it does not require separate notification from the device.*
 - *An **accessory** is a product that may be used in conjunction with the medical device to enable or facilitate the intended purpose. In NZ an accessory to a medical device is regulated as a medical device and must be notified separately.*
 - *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 required.

- 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.

8. What are **formulated** and **medicated** devices?

- 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 the device is notified as a formulated product the formulation must be specified.
- A **medicated** device is one in which a medicine is included in or with the device.

Provided the action of the medicine is secondary to the device, and the medicine is approved for supply in New Zealand, notification of the combination as a device is allowed.

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

Note: If your device is formulated or contains medicine, you will need to enter **each** ingredient in the “Ingredients” portion of the WAND notification.

II. Basic Requirements to Supply Medical Devices in New Zealand

9. How can I view the Medicines Act 1981 and the Medicines (Database of Medical Devices) Regulations 2003?

Copies of the legislation can be viewed at www.legislation.govt.nz.

10. Will I still need a resident New Zealand Sponsor?

Yes, it is a compulsory requirement set by the legislation. See **page 4** of the WAND User Guide for the definition of a “Sponsor”.

11. Do I have to establish a NZ branch company?

No, an individual can act as Sponsor provided they can undertake all post-market requirements for products they supply. A Sponsor must have valid New Zealand contact details, including a New Zealand street and/or postal address.

12. Can I now supply directly to NZ customers from overseas?

No, supply must be arranged through your local Sponsor.

13. Do I need to notify a product to WAND if I obtain it from a NZ supplier?

This is not necessary unless you intend to export the products from NZ.

14. The medical devices I supply are approved in Australia; can I supply these in NZ?

Regulatory requirements differ between the two countries; you must still notify to WAND.

15. The products I supply are exempt from notification; do I have other obligations?
Yes, exempt products are regulated as medical devices. Thus, you must still ensure that the products are safe and effective when used for their intended purpose and that they meet all other legislative requirements. More information can be found in the Medicines (Database of Medical Device) Regulations 2003.
16. The products I supply are described by the manufacturer as cosmetics. Can I supply them as such in New Zealand?
Possibly. categorisation of some products in New Zealand differs from other countries. Refer to Medsafe for clarification.
17. What additional regulatory requirements are there for medical devices in New Zealand?
This depends on the nature and use of the products. Electrically powered devices may be regulated by the Energy Safety Service, and irradiating apparatus by the National Radiation Laboratory. If unsure, refer to Medsafe for clarification. For more information, visit www.energysafety.govt.nz and www.nrl.moh.govt.nz.
18. I would like Medsafe to provide advice on the categorisation of my products under New Zealand legislation. What information do I need to provide?
Medsafe will require a full description of the products, copies of labelling and instructions for use, promotional material and links to associated websites to offer an opinion. This information should be sent to dart@moh.govt.nz.

III. Identifying Notifiable Devices

19. Do all medical devices have to be notified?
*If not exempted, all medical devices supplied in New Zealand **must** be notified. If you think your product is exempt please refer to Schedule 1 to the Medicines (Database of Medical Devices) Regulations 2003 and Section 2 of the Medicines Act 1981, which you can access on line at www.legislation.govt.nz.*

Common exemptions are when devices are:

- *custom-made for a particular patient*
- *supplied for a clinical trial*
- *used for in-vitro diagnosis*

If you are still not clear, please contact Medsafe for advice.

20. If I import only for my own use am I required to notify the device?
If you only use it on yourself or your immediate family, you do not have to notify the device. If you use it on others (whether for a fee or otherwise), you are required to notify the device.

21. If I buy a non-medical device then supply it for medical use do I have to notify it?
Yes, by re-defining the intended use you have effectively created a new medical device, hence, you are the “manufacturer”.
22. If I buy a medical device from a NZ supplier to add to a procedure pack that I create, do I have to notify the device?
*If you create a procedure pack, you have become the manufacturer of that pack (device). You have to notify the procedure pack itself but not the device you have included. In the WAND notification, you must list **each** component of the procedure pack in the ‘Components’ section.*

IV. Gaining Access to WAND

23. Where do I find the forms?
If you want to access NZ WAND, you will first need a user ID and password. To receive these, you must complete the User Access Forms (available at <http://www.medsafe.govt.nz/regulatory/Wand/AccessForms.asp>) and submit these to Medsafe.
24. Is there a fee payable for notification?
Presently there is no fee for notifying to WAND or maintaining a notification.

V. The Notification Process

25. How can I submit a new notification to NZ WAND?
The new process for submission of a medical device notification by a Sponsor will be similar to the process that was previously used; however, there will be some small changes. Please see the WAND User Guide for more information.
26. Can I use the DEAL cloning option when submitting a notification to NZ WAND, as I used to do before?
No, this option is no longer available. You must submit new notifications to NZ WAND following the instructions in the WAND User Guide.
27. Can I use “Read-only WAND” as a source of reference?
This option is no longer available. It was temporarily acceptable in this format to support the transition to the new WAND platform. Sponsors can now access all of their notifications on NZ WAND.
28. How do I find the “Intended Purpose”?
*This is up to the manufacturer of the device. Note that the intended purpose should describe the intended use(s) of the device, and not just the device itself. The intended purpose should be sufficiently detailed to clearly define what the device is intended to be used for (the therapeutic purpose) and how it is used. Very broad descriptions such as “for surgery” **are not** sufficient to define the device. Please see **page 19** of the WAND User Guide for more information.*

29. How do I determine the ‘Risk Classification’?
*Risk classification can be determined either using the electronic guidance on the NZ WAND Notification form or by referring to the classification scheme in Appendix 2 to the Medicines (Database of Medical Devices) Regulations 2003. Please refer to **Step 4** of the WAND User Guide for more information.*
***Note:** The risk classification to be included is the **highest risk associated with** the intended use of the device.

30. How do I find the “GMDN code”?
The Global Medical Device Nomenclature system is an internationally recognized means to identify medical devices. Each code number is associated with a specific device description.

When notifying products to WAND you should either obtain the GMDN code from the manufacturer (this may be included on certificates of compliance) or use the ‘Search’ function in NZ WAND to locate and select the appropriate code.

*Please choose a GMDN code that is consistent with the intended use of the device. If you can’t identify an appropriate GMDN code for your product please contact the manufacturer for advice. Please see **Step 5** of the WAND User Guide for more information.*

VI. Accessing WAND Notifications

31. How do I access my current WAND notifications?
*To access your current NZ WAND Notifications, go to the Medsafe website. Select “To login to your existing NZ WAND account” from the devices menu to login. All current notifications can be viewed by clicking “Home (Current WAND Notifications)” from the Menu at the left-hand side of the homepage. See **Step 2** of the WAND User Guide for more information.*
32. I do have notifications on WAND that are DEAL clones. Are they still valid?
*Notifications (including DEAL clones) submitted on WAND before the **29 October 2008** are still valid. DEAL clones were no longer accepted by Medsafe as of 29 October 2008. New notifications must be submitted using the process outlined in **Step 6** of the WAND User Guide.*

VII. Adding Evidence

Evidence consists of documents from a recognised regulatory authority that the product and/or manufacturer have been assessed against international guidelines to determine the product is both safe and effective when used for its intended purpose. Please see **Step 7** of the WAND User Guide for more information.

33. Do I have to submit Manufacturers evidence for my device to Medsafe?
No. 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.

34. I would like to submit evidence for Medsafe to keep in their file. How do I do this?

*If the evidence is available in electronic form, attach to an e-mail and send to dart@moh.govt.nz following the instructions outlined in **Step 7** of the WAND User Guide.*

If you have this as hard copy only, scan this and send with the e-mail as above.

****Note:** It is essential that you include a cover note specifying the details outlined in the User Guide. Please see **Step 7** of the WAND User Guide for more information.*

35. What is acceptable as evidence?

Current certificates from a European Notified Body, Health Canada, TGA or FDA attesting compliance with medical device directives and/or standards.

****Note:** Certificates of compliance against other standards such as ISO 9000 are not acceptable as evidence.*

36. How do I update expired evidence?

Submit new certificates as described above, and include a cover note identifying which certificates are being replaced.

37. I have already submitted evidence for my device into the old WAND system. Is it still valid and can I still access it?

If you have existing evidence on the previous WAND database, Medsafe will retain this information in our files. You will no longer be able to access it, however, using NZ WAND. If you require copies of your evidence, please contact dart@moh.govt.nz for assistance.

VIII. Deleting or Editing Notifications

38. Can I delete my own WAND notifications if they are obsolete?

*Yes, please refer to **page 30** of the WAND User Guide for instructions on how to do this. You can also do this if you are transferring your notifications to a new Sponsor (See question 41 below).*

39. I have a new manufacturer address to add to my current WAND notification. Do I need to notify Medsafe of this?

*Yes. You must follow the instructions in the User Guide for editing a notification. In order to make the changes, you must first put the notification back into 'draft' mode. Once this has been done, you must verify that the new Manufacturer's address is in our database by selecting 'Manufacturer Search'. If the correct address is not in our database, you must complete a 'Notify a New Manufacturer' request. Once this has been processed by Medsafe, you can complete editing your notification. It will take Medsafe 2-3 business days to add the new Manufacturer Address to the new database. Once the edited version of the notification is ready for submission, change the status from "Edited" to "Active" at the bottom of the screen and submit to Medsafe. See **page 29** of the WAND User Guide for more information.*

40. How do I change my Sponsor details?

The **Sponsor Details Update Form**, located within the NZ WAND database, is only for the contact details of the **NZ WAND Administrator**. This form includes the Sponsor name, mailing address, name, phone number and e-mail address of the Administrator.

The **Sponsor Details Update Form**, located on the Medsafe website at <http://www.medsafe.govt.nz/regulatory/Wand/SponsorUpdateForm.asp>, is a more comprehensive form that is for all other company detail changes. This is the form where a business can update the details of the business, including phone number, name, address, etc. (if different from the WAND Administrator).

Please see **page 29 of the WAND User Guide for more information.*

41. How do I transfer my notifications to a new Sponsor?

*It is the responsibility of the new Sponsor to notify each device that is supplied in New Zealand to NZ WAND. Once this has been done, the previous Sponsor can delete these medical devices from their current notification folder by following the instructions on **page 28** of the WAND User Guide. Medsafe no longer actions a transfer of notifications request for the Sponsor.*