

Frequently Asked Questions (FAQs):

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I. Basic requirements to supply medical devices in New Zealand

- **Will I still need a NZ resident Sponsor?**
Yes, this is obligatory.
- **Do I have to establish a NZ branch company?**
No, an individual can act as Sponsor provided they can undertake all of the post-market requirements for products that they supply.
- **Can I now supply directly to NZ customers from overseas?**
No, supply must be arranged through your local Sponsor.
- **Do I need to notify product to WAND if I source from a NZ supplier?**
Unless you intend to export the products from NZ, this is not necessary.
- **The medical devices I supply are approved in Australia; can I supply these in NZ?**
Regulatory requirements differ; you must still notify to WAND.
- **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 the products meet all other requirements for medical devices under the “Medicines Act 1981”, the “Medicines (Database of Medical Devices) Regulations 2003” and the “Medicines Regulations 1984”.
- **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. In addition a cosmetic may also have a therapeutic purpose. Refer to Medsafe for clarification.

- **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.
- **I would like Medsafe to advise how my products will be categorised for regulation in New Zealand. 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.

II. Identifying notifiable devices

- **Do all medical devices have to be notified?**
If not exempted, all medical devices supplied in New Zealand must be notified to WAND.

If you think your product is exempt please refer to Schedule 1 of 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.
- **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, however, if you use it on others (whether for a fee or otherwise) you are required to notify the device.
- **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.
- **If I buy a medical device from a NZ supplier to add to a procedure pack I make up do I have to notify the device?**
You have to notify the procedure pack itself, but not the device you have included.

III. Gaining access to WAND

- **Where do I find the forms?**

These are down-loadable from the Medsafe website (www.medsafe.govt.nz) under the Web Assisted Notification for Devices tab.

If you want to access the Device Notification form you will first need a user ID. To get this you must fill out the user access forms, and submit these to Medsafe. You can do this electronically by clicking “submit”, or you can print these out and mail to Medsafe.

If these are OK you will receive your user ID in a few days. Keep this safe as you will use it to access the Notification form.

- **Where do I send them?**

Electronic submission directs documents automatically to the devices team at Medsafe.

If you wish to mail documents you may send them to:

**DART Team
Medsafe
PO Box 5013
Wellington
New Zealand**

- **Is there a fee payable for notification?**

Presently there is no fee for notifying to WAND or maintaining a notification.

IV. The notification process

- **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 and how it is used. Very broad descriptions such as “for surgery” are not sufficient to define the device.

- **Risk classification:**

Risk classification should be specified by the Manufacturer. Alternately, risk classification can be determined by either using the electronic guidance on the Device Notification form or by referring to the classification scheme in Appendix 2 to the “Medicines (Database of Medical Devices) Regulations 2003”.

Note: The risk classification to be included is the **highest risk** intended use of the device.

- **Finding a GMDN code**

The Global Medical Device Nomenclature (GMDN) 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 drop-down table in the Device Notification form.

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. While Medsafe may be able to offer some assistance we cannot determine the "correct" GMDN code for your product.

Novel products may not have a GMDN code assigned. In this case use of the "undefined" GMDN code is acceptable as a short term expedient only; you must apply to the GMDN Agency (www.gmdnagency.com) to have a new code assigned to your device.

- **How do I notify 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.

- **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. If the product contains a medicine, it will need to be submitted to Medsafe for categorisation.

***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.*

V. Evidence

Evidence consists of documents from a recognised regulatory authority that the product and/or manufacturer has been assessed against international guidelines to determine the product is both safe and effective when used for its intended purpose.

- **How do I include evidence?**

If this is available in electronic form, attach to an e-mail to dart@moh.govt.nz. It is essential that you include a cover note specifying your used identification and the WAND notification number(s) to which the evidence is to be applied.

If you do not have this in electronic form copies may be mailed to:

**DART Team
Medsafe
PO Box 5013
Wellington
New Zealand**

- **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 with ISO 9000 are not acceptable as evidence*

- **How do I update expired evidence?**

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

VI. Cancelling or changing notifications:

- **How do I cancel a notification?**

Send an e-mail with your request to dart@moh.govt.nz or by letter to: DART team, Medsafe, PO Box 5013, Wellington, identifying which WAND notifications are to be deleted. Please ensure WAND identification number(s) are correct and specify who will be responsible for product already supplied by you to the NZ market.

- **How do I change Sponsor details?**

If any changes have occurred within your company (i.e. - contact details, WAND Administrator, etc.), please complete the "Sponsor Details Update Form" (found on the Medsafe website on the "Web Assisted Notification of Devices" page), and submit it to Medsafe as soon possible via one of the stated methods.

Note: According to the "Medicines (Database of Medical Devices) Regulations 2003":

Regulation 8

Requires that if there is a change in the information that relates to a notification that the information is updated within 10 days of that change being known.

Regulation 8 - Updated information to be supplied by sponsor

(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.

- **Transferring notifications to a new Sponsor**

This can be done by either:

- having the new Sponsor complete new notifications then applying for cancellation of the originals; or
- having both present and new Sponsor complete the Change of Agency forms on our website and submitting these to dart@moh.govt.nz or by letter to: DART team, Medsafe, PO Box 5013, Wellington.

Note: In either case, you should identify which Sponsor will be responsible for product currently supplied in NZ.