Product Evaluation Health New Zealand
National group
New Zealand

To whom it may concern

SUPPLIERS TO HEALTHCARE PROVIDERS in New Zealand

We are continuing to work closely with the industry suppliers in order to foster reliable and creditable working relationships for the betterment of healthcare delivery. Our primary objective is to protect and maintain patient safety. In order to achieve this we would appreciate your taking the time to review the detail here, share it with your colleagues, and endeavour to follow it where appropriate.

'Medical Device' is now the NZ legislated term for any equipment, product or consumable for use across the spectrum in healthcare delivery.

As part of the National group, Product Evaluation Health NZ (PEHNZ), we require the following information to be provided to the Clinical Product Co-ordinator (or similar titled roles) at the outset of any agreed introduction process for any new or replacement Medical Device that you wish to introduce to customers in the NZ market. This activity would commence on the basis that a clinician has requested internally, or a Clinical Product Coordinator (CPC) has requested on behalf of their organisation. No medical device review or consideration will proceed in the absence of these factors.

Acceptance for continued use of a medical device, will be formally advised if and when appropriate.

The need to ensure that a medical device meets NZ regulatory and legislated requirements, and is identified appropriately as meeting relevant international manufacturing standards, **is not negotiable** for all facilities that employ these PEHNZ member roles in NZ.

This information below is to be provided to the CPC or the formal requestor of the information within the criteria laid out above.

- Completed PEHNZ form (Dec 2014 form is current), in addition completing an additional product submission form if requested by a PEHNZ member organisation – please delete previous blank file versions of this PEHNZ form
- Medsafe WAND listing confirmation – screen dump from Medsafe website
- Copy of all current relevant standards/compliance certification applicable to the medical device – i.e. CE, ISO, IEC, TGA, FDA, sterilisation, AS/NZS Medical Device Safety Construction Standards – this list is not exhaustive
- Cleaning requirements if reusable items/equipment
- Copy of relevant standards/compliance certification for electrical safety (where applicable)
- Manufacturer statement confirming both Latex/DEHP **free** status

Additional information that may be requested:

- Service agreement (where applicable)

- Technical specifications/Service manuals including Functional testing criteria for Bio-Medical Engineering
- Brochure for medical device and any related consumables
- User guide/Operating instructions
- Quote /Indicative pricing
- Price of consumables where relevant for compatibility with equipment – as above
- Lead time/availability
- Warranty /service guidelines/local service agents (where applicable)
- Software/System upgrades – Customers are to be advised in advance that a newer version may be pending release e.g. 6 months from release, or advise when a system will require a software upgrade shortly after purchase e.g. in 2 months' time that may be unbudgeted for.
- Results of efficacy studies (where applicable)
- Material Safety Data Sheet – MSDS (where applicable)
- Hazard classification (where applicable)

Attached is a current member contact list for PEHNZ, including the committee members. If you have any queries please approach the writer for feedback

We appreciate your assistance with meeting this need.
Yours sincerely,

Helen CAMERON
As President for PEHNZ group
21st January 2015

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Accompanying this letter are PEHNZ associated documents

- a copy of the current PEHNZ form Dec 2014
- a current member list for contacting