PEHNZ
Product Evaluation Health NZ

Product Evaluation Health New Zealand
National Group
New Zealand

To whom it may concern

REMINDER TO SUPPLIERS OF HEALTHCARE PROVIDERS in New Zealand

We are endeavouring to work closely with the industry suppliers in order to foster reliable and creditable working relationships for the betterment of healthcare delivery. In order to achieve this we would appreciate you taking the time to review the detail here, share it with your colleagues, and endeavour to follow it in every case 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 collectively anticipate that the following information is provided to the Clinical Product Co-ordinator, or similarly titles/roles, at the outset of any introduction of any new or replacement medical device that you wish to introduce to customers in the NZ market.

The introduction of these medical devices includes the requirement for all appropriate, relevant information on that product, to be made available for review by the intended customer/user prior to any decision to accept the item for use.

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.

Our primary objective is to protect and maintain patient safety.

This information below is to be provided to the CPC (Clinical Product Coordinator) or designated Procurement personnel.

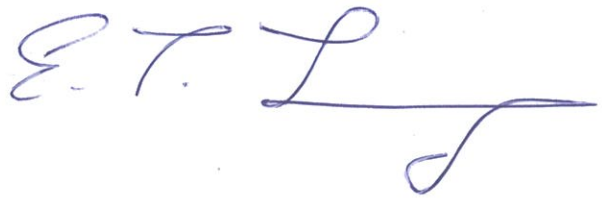
- Completed PEHNZ form (2020 form current)
- Evidence of Medsafe WAND listing confirmation
- Copy of all current relevant standards/compliance certification applicable to the medical device – such as relevant CE, ISO, IEC, TGA, FDA, electrical safety, sterilisation, AS/NZS Medical Device Safety Construction Standards – this list is not exhaustive
- Service agreement (where applicable)
- Copy of relevant standards/compliance certification for electrical safety
- Technical specifications/Service manuals including Functional testing criteria for Clinical Engineering Team
- Brochure for medical device and any related consumables
- User guide/Operating instructions

- Quote
- 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 that a newer version may be pending release e.g. 6 months from release, or when a system will require a software upgrade shortly after purchase e.g. in 2 months' time that may be unbudgeted for.
- Cleaning instructions for the device/ product and can be cleaned with hospital grade disinfectants that meet Infection Control requirements. In particular it must be cleanable with 1% Sodium Hypochlorite solution, 70% Isopropyl Alcohol, Tuffie5 , ViraClean, Reynard Detergent Wipes, Whiteley V-Wipes. (DHB/Hospital Specific requirements)
- Statement confirming both Latex/DEHP/Chlorhexidine **free** status
- Results of efficacy studies (if applicable)
- Sustainability Statement. Is the Product Single Use Only, Single Patient Use, Biodegradable or Recyclable?

Attached is a current member list for PEHNZ, from which this communication comes, including the committee members. If you have any queries please feel free to approach a committee member for feedback.

We appreciate your anticipated assistance with meeting this requirement moving forward.

Yours sincerely,



Liz Young
As President for PEHNZ group
27th January 2021