



# White Paper

## Purchasing Medical Appliances from Overseas

With the ease of purchasing products from overseas via the Internet, direct importing medical appliances appears a very favourable prospect. But is it really? The answer is maybe, but there are some pitfalls that could lead to disappointment.

There are usually only two reasons why you might choose to direct import a medical device. Sometimes it will be because the product you want is not available through a New Zealand supplier, but most commonly the motive will be price.

Medical devices sold through some New Zealand suppliers often come with notoriously high price tags and it can be argued that mark-ups must be quite considerable. A little research will however show that New Zealand prices are usually in keeping with those in Australia, the USA and most of Europe. Given the cost of freight, there is usually no advantage in direct importing an item from those countries, and probably little advantage even in importing multiple items.

According to research by Pacific Bridge Medical, Asia (excluding Japan) is the fastest growing medical device market, having increased by 28% between 2006 and 2013, and in 2013 held a 10% share of worldwide sales. Add in Japan and the share rises to just on 23%. Furthermore, inexpensive electronics manufacturing in Asia, and especially China, means many medical devices are assembled in Asian plants for sale in Western and European markets. The East is churning out medical devices like never before.

The Asian market is less regulated overall and lower compliance costs mean that products for sale to the local market are cheap compared to other countries. Numerous small companies have set up to sell to the local market, which is highly competitive. They are equally happy to sell to offshore customers where profit margins can be somewhat better.

Given the well-established freight logistics from countries such as China, Korea and India, and ease of payment by credit card or electronic transfer, importing direct seems a very attractive option. Let's look at the pitfalls. We'll focus on the sorts of things that you would purchase to use in a general medical, physiotherapy or dental practice.

### **Warranty**

If you purchase a medical device from overseas the supplier is not legally obliged to provide any guarantee or warranty, and even if they do the practicalities of exercising your rights to a timely repair might be difficult. Unless you are dealing with a large and reputable company, you should work on the assumption that there will be no warranty on your purchase. That said, the device you purchase may well be reliable and give many years of faultless service. The risk is difficult to quantify but very real nonetheless.

### **Counterfeit items**

As with any other well branded product, opportunistic manufacturers will make lookalike copies. Medical equipment is no exception and there's a reasonable chance that a 'too good to be true' deal on a brand name item may in fact be a cheap rip-off. It's not as common as with fashionware and consumer electronics, but it does happen and you probably won't find out until you open the box.

### **Damaged goods**

There are also stories about marked, reject or refurbished items being sold and these may be quite common. Just check the number of E-bay sales that say 'may not be supplied in original packaging' and you will appreciate this is a real risk.

### **Foreign language**

The advertising might be in English, or an approximation of English, but when your product arrives you discover the user manual is in Chinese or Korean. Even worse, so are the panel markings and the LCD display. Surprised? You shouldn't be!

### **Compliance**

There are CE marks and UL marks that give credibility to medical devices, but the gold standard is proof of manufacture to ISO 13485. While this won't guarantee compliance with all relevant New Zealand standards, it does provide assurance that the device has been tested and proven adequate for its intended use. There are many products sold that clearly have not been manufactured or tested to any standard and some of these could well be described as ineffective at best and downright dangerous at worst.

For the New Zealand market one of the main considerations must be suitability for use with our electricity supply system. Appliances intended for the US market or any country with a 110 volt supply won't be suitable, unless they have been made with dual voltage capability. The use of step down transformers is no longer permitted on new equipment. Remember too that our power supply frequency is 50Hz, whereas the US uses 60Hz. This will be important for power supplies, transformers and filters. It is important that these aspects are checked out before purchase or your new device might not work and your money may well be wasted.

Importing of medical devices (or any electrical equipment for that matter) for sale in New Zealand is reasonably well controlled and regulated, but if you are importing for your own use rather than resale that is not necessarily the case. In fact you can import pretty much anything and start using it to treat patients. However as soon as you cause somebody harm, you are in big trouble. The beauty therapy industry is a very good example right now. Laser equipment can be imported with no controls and operators can begin treatments with little or no training. There are several recent examples of people having suffered burns and other side effects that are currently being investigated and we can expect to see some prosecutions. The same could well apply in the medical area, not only from harm being done to a patient, but also through misdiagnosis or sham treatment. You need to be confident that any device you use is safe, accurate and effective.

At Meditest in the course of our safety testing work we do occasionally find non-compliant products. Where these have been supplied locally the purchaser can approach the dealer to have the matter put right. Sometimes it's easily remedied by fitting the correct power cord or changing a power supply, but every so often we encounter a product that clearly should not have been sold here. Where the problem can be remedied, the local dealer covers the cost, but if there is no local dealer then the purchaser must wear the expense (or in some cases the loss). With the protection of the law, there is seldom an issue with resolving such problems when they have been supplied locally, certainly with

the major and respected suppliers anyway. However our worry is that a (fortunately very small) number of operators continue to use imported products that are clearly not compliant with our regulations.

### **Consumables, spare parts and accessories**

Many medical devices rely on an ongoing supply of consumables, parts and accessories. Such items might include chart paper, electrodes, batteries, cables and disposables for ensuring sterility. Many of these will be specific to the device and, if they are not readily available from a New Zealand supplier, the costs of importing must be factored into a purchase decision. Over the lifetime of a device such costs can be substantial, not only in terms of the purchase price, but also the time involved in arranging purchase and shipping. The reliability of an ongoing supply is also important and checking to see if items are available from more than one supplier may give some surety of continuity if your normal supplier goes out of business or can no longer deliver for whatever reason. Selecting a device that utilises generic rather than proprietary supplies is a good idea.

### **Freight and Customs**

It used to be complicated to import goods into New Zealand, but in the past decade that has changed dramatically. No longer do you need an army of Customs agents and bankers to help you. It's as simple as a credit card payment or bank transfer to the supplier, and your goods are on their way. When they arrive in New Zealand (and assuming you haven't ordered a prohibited import) you will receive a call from the freighting company to tell you how much GST and other fees you need to pay. Another credit card transaction and a couple of days later the goods are delivered to your door. And if the value of your item comes below the GST threshold, you may even be lucky enough to avoid that step.

### **Repairs**

Repairs to medical equipment in New Zealand are costly. Probably no more costly than in other similar countries and maybe less, but certainly more costly than fixing a TV or washing machine. What this means is that many less expensive medical devices need to be viewed as throw away items if they go wrong. Maybe not very eco-friendly, but more a question of economics (one wonders why 'economics' starts with 'eco').

For a larger investment purchased off-shore you are not going to have the benefits of local customer support. There will be no spare parts, no service manuals and your product may be unfamiliar to the service engineer. Don't count on a timely and cost effective repair, because it's probably not likely or even possible. Even a recognised brand name may not be easily serviced by the local agents, particularly if it's a different model to that sold here. And if you haven't purchased it from the local dealer, you can hardly expect them to bend over backwards for you. The reality is that the throwaway threshold is probably much higher than you might think, and with the absence of a warranty it more than likely kicks in from the outset.

### **NZ Suppliers**

There are some merits in cheap products being available from overseas; they provide a level of competition on the local market and this has helped to bring prices down.

The benefits of using a local supplier are that they will provide you with a warranty and they are also required by law to ensure that their products are compliant with New Zealand standards and are safe to use.

The slightly higher price you pay when you purchase from a New Zealand supplier buys you a number of things: warranty, surety of compliance with New Zealand standards and a recall system in the case of problems, continuity of supply of consumables, and customer service if you need repairs or advice.

Because importing is so easy, there is something else to beware of and it's not to do with doing the importing yourself. Within New Zealand there are a number of companies that see an opportunity in importing cheap medical equipment for resale. They range from small part-time garage start-ups to more established suppliers. While this is another subject in its own right, the message is that shoddy or non-compliant products could well be available from New Zealand suppliers. Take some time to check out your supplier before you buy.

### **The Verdict**

Purchasing direct from overseas can almost certainly save you money if you do it right and are aware of the risks and pitfalls. Our advice is to do your homework first, and to go into any such purchase knowing that there is some risk it may not work out as intended. Above all check out that devices are safe to use and that any medical electrical appliance you purchase meets New Zealand standards.