Let's Get It Clear No.27
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When is an optional extra an accessory?

The use of the correct terminology becomes important when considering what is an accessory, as compared with an option, or an optional extra. This is especially so when the device under discussion is a medical device, within the terms of the old Medical Devices Directive, and the EU replacement, the Medical Device Regulations. It also can be important when looking at how the HMRC views an imported item and what duty tariff it might fall under.

When you buy a new car, you will have **options** such as colour, engine size, etc., but these are components of the car, without which it will not be able to be on the road. You will have **optional extras** such as a built-in satnav, heated seats, etc which once in the car will be there for the rest of its life. And you will have **accessories,** such as removable floor carpets which will protect the floor from wear, but you may choose to dispose of or replace as they become worn out. For people these days we refer to their luxury items as being accessories, which might be a handbag or a small dog.

However, when you buy a medical device, each of these terms has an opposite connotation and impact. When you import or export a product, these variances may also have an impact on the product's tariff and therefore the duty involved.

Definitions

Let's start with medical devices, and extracts from the definitions chapter in the Medical Device Regulations (MDR). First, a medical device:

"A 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

Fashion accessory?

The following products shall also be deemed to be medical devices:

- Products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point."

and then an accessory:

"An '**accessory for a medical device**' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)."

From the MDR's point of view, this means that any accessory within this definition needs to be registered as a medical device in its own right, and its Class level will be that of the device for which it is an accessory.

Examples

First of all, a medical device is only a medical device if the manufacturer is making a claim for it to be one, within the bullet points listed in the definition of a medical device. Thus, it could be argued that a commode, for example, does not fit this requirement.
A cushion would not initially be considered to be a medical

device – unless the manufacturer claimed that it could prevent a pressure injury. If such a claim were made, then it would have to be registered as a medical device.

The next complication comes as to the Class level to attach to the product, because that cushion would have to be registered as a Class IIa product if the manufacturer claimed that it modified the anatomy or physiological state of the user (which could be a valid claim for some pressure care cushions). Manufacturers would prefer a cushion to be Class I, since they can then self-classify and avoid the extra costs involved in Class II and higher classification. So the wording in any of a manufacturer's claims is critical.

As another example: if a product is marketed as a disinfectant to be used on a medical device, then that chemical has to be registered as a Class IIa device, or higher. But what about a bottle dispensing the disinfectant? If the bottle is any spray bottle that could be used for spraying any liquid, then that bottle is not an accessory, but an optional extra. However, if the bottle has been specifically designed for use with that Class IIa disinfectant, and with that disinfectant alone, for example to dispense a fixed dose, then within the definition of accessory for a medical device, that bottle becomes a medical device under the MDR, and has to be classified and registered as the same Class as the disinfectant.

Within the Medical Devices Directive, and the MDR, a machine designed to wash medical devices is considered a Class I device, but a machine designed to wash and disinfect through thermal disinfection of medical devices needs to be registered as Class IIa and above (since the machine is doing the disinfection). A washer that applies a chemical disinfectant is still a Class I device (because the machine is not doing the disinfection), but any disinfectant that the machine applies at the end of the wash still has to be Class IIa!

Options

The medical device may come with different **options**, such as size or colour, but provided the options do not affect the claims and the evidence for the medical claims, then the different versions fall under the same registration.

Any extra devices, such as handles for easier use, are **optional extras** provided that they are not essential for the functionality of the medical device, within the claims made for the device. The moment they become essential for the device to operate as claimed, they become accessories and have to be registered as such.

The Breezi activity chair

Parts

In some countries, such as the United States, who have signed up to the 'Nairobi Protocol' in full, assistive technology medical devices are exempt from duty. However, when the UK signed the agreement, we exempted ourselves from the assistive technology products clause, and so all these medical devices still have import tariffs and associated duties applied when imported into Great Britain.

Parts can be another game park. Wheelchairs have tariffs with 0 % duty, but so do parts and accessories designed specifically for use with wheelchairs. Wooden chairs (such as the Breezi with medical claims for their benefits with their accessories) come under a 0 % tariff of 94036090 (as wooden furniture), but if you were to buy an extra part, such as an extra footplate, a wooden part comes under tariff code 94039100, which attracts a 2 % duty. For some clients, that footplate might be essential to use the rest of the 'medical device' and so becomes an accessory from an MDR point of view, while remaining a part from the HMRC point of view.

Who'd be a manufacturer with these crooked paths to wind our way through?