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To Whom It May Concern:

I am writing in response to the regulatory changes on the provision of medical devices (Proposal 3).

We are an Australian wheelchair manufacturer supplying electric and manual wheelchairs to Australia and exporting to a global market. Our product is sold to a niche market of clients who have special requirements in the seating arrangement and control systems. Our business model is to customise each wheelchair to the user's special need. This is a Class 1 medical device.

We currently have 3 basic platforms

- A manual wheelchair (Jewel) for nursing homes
- A mid wheel drive electric wheelchair (Frontier)
- An all wheel drive electric wheelchair (Extreme)

All chairs are standards tested in Australian, American and European laboratories.

Our clients are individually measured for wheelchair fit and component position. For example

- footplate height for clients of a different height
- centre of gravity
- armrest height
- leg-rest position
- headrest position
- seat size
- back rest size

None of these measurements change the components or basic platform, which are put together for the build process.

Clients are also measured for customised parts, which we make in our facility. This can range from

- foam inserts to the seating configuration
- extra straps
- extra cushions

None of these extras change the basic build process or manufacture of the prime functionality of the wheelchair

Clients also asked for options to be added to their chair for the drive function

- chin controls

- head controls
- elbow controls
- mouth controls
- mouse controls
- various joysticks

These items are purchased from authorised suppliers of wheelchair components and retro-fitted onto the wheelchair. None of these items change the basic platform of the wheelchair and do not affect the risk to the client or require any further standards testing.

In response to your change in regulation, it is our proposal that we itemise our wheelchairs at the “platform” level (Jewel, Frontier and X8). Any other option would simply put us out of business due to the amount of bureaucracy of identifying each custom chair that is built. There are an infinite number of combinations that can be created, all from the same mechanical framework. In order for you to understand the impact this would have on us, 2 - 5 new applications would be submitted each day. I don’t believe that either party would find this palatable. Your proposal provides us with little guidance on the detail of the level of control you want to impose, and so it is difficult to interpret. We have read it and applied common sense to it, so that we can continue building custom wheelchairs without individual assessment.

Each wheelchair that we manufacture is uniquely identified with a serial number and an associated build sheet with documentation of the fittings and measurements taken. Our records of reportable incidents simply do not justify this level of control.

It is very important to our clients that we supply customised wheelchairs as it gives them independence from carers and government financial support.

We are disappointed that this proposal was “found” by us. I see that there was one token consultation in Melbourne with no invitation sent to us. Please consider our comments to your proposed changes and how it would impact our business (i.e. drive it to closure) and should you need further clarification from us, please contact us so that we can discuss our business model further.

Yours truly,

Jill Barnett
General Manager