To whom it may concern

Thank you for the opportunity to be part of the consultation process for the Proposed refinements to the regulation of personalised medical devices.

Unfortunately the document is fundamentally flawed from the beginning. If you could please consider the following points:

"The manufacturer **assigns** the intended purpose of the medical device" *(Background - 3rd paragraph)*

Assigns means: designates or sets; allocates
A device manufactured by a dental technician is created according to the requirements of the orthodontist or dentist as specified on the prescription. It does NOT have an assigned use by the dental technician. If the orthodontist sees fit to use it for any other purpose or any other manner than that which it is usually used for, it is TOTALLY out of the hands and responsibility of the dental technician. A dental technician has not consulted with the patient, seen the patient, have x-rays or photos of the patient and is therefore unable to assign any intended use on any device. A dental technician is not trained to read or interpret any medical records. It is therefore completely unfair to hold the technician responsible to any conformity assessment on this basis.

"Conformity assessment procedures are requirements placed on the manufacturer of a medical device. They include controls around manufacture (**design** and construction)" *(Background - 4th paragraph)*

Design means: plan or drawing produced to show the look and function or workings of a building, garment, or other object before it is made.
A bricklayer builds a house according to the DESIGN that an architect draws. The bricklayer is responsible for ensuring the building is built exactly to the requirements of the architect, but is NOT RESPONSIBLE if the architect fails to place support beams where required and the building collapses. The position of a dental technician is no different. A dental technician CAN NOT make a device different to a design requested by a specialist orthodontist or they will no longer have a job or business!! **Why is the dental technician being held liable and legally responsible for the DESIGN created by an independent specialist and furthermore, then providing instructions on how to use the same device to the specialist who designed the device in the first place??**

Page 7 states the following professionals are manufacturers and sponsors of patient-matched medical devices. Please see the following table to compare the inequality of the new framework.

	Education	**Qualified to consult with patients**	**Qualified to DESIGN prescribed patient matched devices**
Dentists, prosthodontists & orthodontists	University	Yes	Yes
Dental technicians	**TAFE**	**No**	**No**
Dental prosthetists	TAFE + further education	Yes (minimal)	Yes (minimal)
Orthotists	University	Yes	Yes
Rehabilitation engineers	University	Yes	Yes
Radiation therapists	University	Yes	Yes
Audiologists	University	Yes	Yes
Prosthetists	University	Yes	Yes
Osteopaths	University	Yes	Yes

Page 9 states “the regulatory requirements associated with the manufacture and supply of a medical device.” These are difficult to comply with as they need to be met by different parties as shown in the table below.

Orthodontist	**Dental Technician**
Designing the device	Producing (construction) of the device - according to prescription supplied by specialist
Evidence demonstrating the long term safety of the device	Only educated in the construction of the device
Packaging & labelling to the end user	Packaging & labelling is only for the Orthodontist
Instructions for use (as the Orthodontist has been educated on HOW to design the device to get the end result)	Not educated in HOW the device works
Keeping records of devices supplied	Keep records of appliances constructed
Reporting adverse events	Adverse events would be reported to the Orthodontist

Page 11 states: “It is considered that where a medical device has been “prescribed” by a registered health professional and is manufactured by a qualified or accredited professional according to the specifications provided by the healthcare practitioner, risks can be adequately mitigated.” We agree totally with this statement for **ALL** devices made by a dental technician but it makes the rest of the proposed changes futile. (This paragraph looks as though it only refers to exempt devices.)

I have a concern that doubt is being cast upon the ongoing education and qualifications of both Dentists and Orthodontists and their ability to be capable of mitigating risks relating to the quality, safety, efficacy and performance of the therapeutic goods being supplied in Australia.

As one of the major suppliers of Orthodontic Medical Devices in Western Australia, I am very concerned regarding the proposed changes. I refuse to be held legally responsible for the design created by a specialist. This will leave me being forced to close my business. Other laboratory’s around Australia have the same concerns. If laboratories close around Australia as of November 2024, I can only see that work will be sent overseas, which I’m not sure that that is the TGA’s intention.

Regards

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ORTHO-DESIGN
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