TGA PERSONALISED MEDICAL DEVICES FRAMEWORK

GUIDANCE FOR ASO MEMBERS

This information has been produced for ASO members as GUIDANCE only.

Please note that the TGA continues to consult with the ASO and the dental sector on regulatory refinements to the personalised medical devices framework and as such the recommendations contained in this document are likely to continue to change. Future changes to the regulatory framework will need to be agreed to by the Australian Government before they are made.

We will continue to inform members of updates as further information becomes available and please refer to the TGA Hub on our Member Website.

Date: 9 November 2021

Australian Society of Orthodontists

Background

On 25 February 2021 a new framework for regulating personalised medical devices commenced, and this regulatory framework includes new definitions for custom-made medical devices. The main impact of the new regulations is that the majority of devices previously supplied under the exemption for custom-made medical devices no longer meet the definition of a custom-made medical device and will now need to be included in the Australian Register of Therapeutic Goods (ARTG). Most laboratory fabricated orthodontic appliances are now classified as "patient-matched medical devices" and therefore must now be included in the ARTG. The manufacturer or the sponsor of these devices must apply to *transition* to the new regulatory framework before 25 August 2022 with the deadline for inclusion in the ARTG being 1 November 2024.

The requirement for orthodontists to register patient-matched medical devices has been removed in August 2021, unless they are importing materials, components or devices or manufacturing devices with materials not already on the ARTG, in which case they need to apply for transition.

*If this applies to you, please ensure you have submitted your device notification form and the transition notification form to the TGA **by 25 August 2022** to ensure you can continue to supply your devices while the consultation responses are analysed and regulatory refinements are processed.*

Before you complete the application for transitional arrangements form, you will need to have completed the online *device notification form* informing the TGA that you are supplying this kind of device. This is a simple form that only requires your contact information and the description, GMDN code and Classification of the kind of device you are supplying.

Below you will find suggestions from the ASO regarding most common orthodontic devices, their current classification level (I or IIa) and the current applicable GMDN codes.

Please also see the separate step-by-step guide to assist you in completing the online TGA transition form. We recommend all members follow this guidance to help ensure industry wide consistency.

Devices that will continue to be exempt from inclusion in the ARTG

The TGA has confirmed that devices that will continue to be exempt from the requirement to be included in the Australian Register of Therapeutic Goods (ARTG) include:

- Protective Mouthguards for sport

Examples of adaptable devices that should be included in the ARTG before they are supplied to you

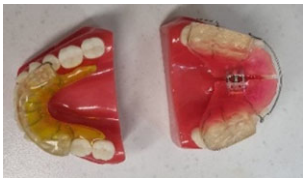
- Orthodontic springs (e.g. Forsus springs, Coil springs)
- Orthodontic anchoring screw (TAD's /Miniscrews)
- Orthodontic brackets
- Orthodontic bands
- Orthodontic archwires
- Orthodontic extra-oral headgear (e.g. Facemask)

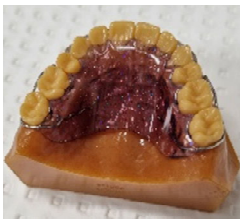
Devices that will need to be included in the ARTG

Below is a list of commonly used orthodontic devices which need to be included in the ARTG under the new personalised devices framework. We have grouped these devices based on their current classification i.e. Class I or Class IIa. You will find the complete GMDN code table on the ASO website.

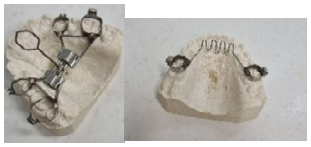
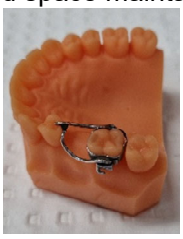
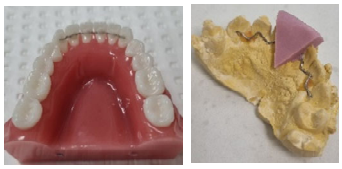
Note that TGA is working to clarify which materials, components and appliances meet the definition of a medical device, therefore the lists included in this document are indicative only and subject to change. If in doubt, you should register for transition and stay up to date on information as it is made available.

Class I devices

Device category and example image	Examples of devices	GMDN code	Notes
Self-removable orthodontic appliances 	Twin Blocks Bionator Frankel Activator Schwartz URA LRA	65301	

Device category and example image	Examples of devices	GMDN code	Notes
Removable retainers 	Hawley Begg Tru-Tain/Essix	35310	
Clear aligners 	In-house custom aligners only	44738	Proprietary aligner systems (e.g. Invisalign) require ARTG inclusion by the company
Occlusal splint	Custom-made dental occlusal splint	43025	
Orthodontic appliance positioning tray (Tray will be Class I because it's in the mouth for less than 30 days. Brackets in the tray will be Class IIa because they will be cemented to the teeth for more than 30 days.	Indirect bonding tray, basic	63997	May be exempted after TGA review
	Indirect bonding tray, preloaded	64010	May be exempted after TGA review

Class IIa devices

Device category and example image	Examples of devices	GMDN code	Notes
Palatal expanders (Fixed) 	Quadhelix RME Fixed Anti-Habit	64769	
Fixed space maintainer 	Band & Loop Distal shoe Lower Lingual Arch Nance Arch Transpalatal arch	31754	
Fixed (bonded) retainer 	Lingual/Palatal Bonded retainers	35310	
Fixed tooth moving appliance or Class II corrector	Hilgers Beneslider Herbst Pendulum/Pendex Mara	41678	
Custom-made dental anatomy model	Study models/working models (plaster or 3D printed)	64556	May be exempted after TGA review