Under Regulation 10.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* manufacturers of a custom-made medical device/s are required to notify TGA within two months of initial supply.

I can confirm **Absolute Orthodontic Services -ABN:74084944355** has notified TGA of the custom-made medical devices we manufacture as per the current regulations.

I can also confirm we have applied for transition (due 25 August 2021) and will therefore not require ARTG registration until 1 November 2024.

Our notification reference numbers for your records are detailed below.

Absolute Orthodontic Services is therefore fully compliant with the current regulatory framework.

CONFIRMATION OF NOTIFICATION TO TGA

GMDN	DESCRIPTION	CLASSIFICATION	CUSTOM MADE MEDICAL DEVICE NOTIFICATION REFERENCE	TRANSITIONAL FORM REFERENCE
38587	Denture <specify>	Class I	CMMD-62841	ANON-62JU-PRTU-J
38616	Bonded Dental bridge	Class IIa	CMMD-	ANON-
38615	Dental bridge, ceramic	Class IIa	CMMD-	ANON-
38614	Dental bridge, metal-ceramic	Class IIa	CMMD-	ANON-
37543	Dental bridge, metal-polymer	Class IIa	CMMD-	ANON-
37542	Dental bridge, polymer	Class IIa	CMMD-	ANON-
38594	Artificial crown, all ceramic	Class IIa	CMMD-	ANON-
38593	Dental crown, metal/ceramic	Class IIa	CMMD-	ANON-
38591	Dental crown metal	Class IIa	CMMD-	ANON-
38596	Dental crown, metal/polymer	Class IIa	CMMD-	ANON-
38595	Dental crown, polymer	Class IIa	CMMD-	ANON-
38645	Dental Veneer, custom-made	Class IIa	CMMD-	ANON-
34690	Orthodontic appliance <specify> [removable]	Class I	CMMD-62834	ANON-62JU-PRTF-3
34690	Orthodontic appliance <specify> bonded/fixed	Class IIa	CMMD-62840	ANON-62JU-PRT2-F

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