



A C Denture Pty Ltd
t/as Albany Creek Denture Clinic
& Universal Dental Laboratory
09/08/2021

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 **A C Denture Pty Ltd t/as Albany Creek Denture Clinic & Universal Dental Laboratory** 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.

A C Denture Pty Ltd t/as Albany Creek Denture Clinic & Universal Dental Laboratory 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
38588	Denture Complete Maxillary	Class I	CMMD-13273	ANON-62JU-PHC6-R
38589	Denture Complete Mandibular	Class I	CMMD-13294	ANON-62JU-PHCU-Q
38590	Implant Retained Overdenture	Class I	CMMD-13307	ANON-62JU-PHCU-R
17845	Partial Denture	Class I	CMMD-13315	ANON-62JU-PHC5-Q
42879	Denture Clasp, Metal, Custom Made	Class I	CMMD-13381	ANON-62JU-PH2N-Y
43025	Dental Occlusal Splint	Class I	CMMD-13336	ANON-62JU-PH2Q-2
38620	Mouthguard Custom Made	Class I	CMMD-13326	ANON-62JU-PH2P-1
63350	Teeth Whitening Tray	Class I	CMMD-13358	ANON-62JU-PH2F-Q
38645	Dental Veneer, Custom Made	Class I	CMMD-13410	ANON-62JU-PH29-A
35310	Orthodontic Retainer	Class I	CMMD-13389	ANON-62JU-PH2K-V
47527	Maxillar-repositioning sleep orthosis	Class I	CMMD-13396	ANON-62JU-PH2M-X
47526	Mandible-repositioning sleep orthosis	Class I	CMMD-13403	ANON-62JU-PH2B-K
64556	Custom-Made Dental Anatomy Model	Class IIa	CMMD-66865	ANON-62JU-PH21-2

Company Name:

A C Denture Pty Ltd t/as
Albany Creek Denture Clinic
& Universal Dental Laboratory

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