AUSTRALIAN DENTAL ASSOCIATION

Australian Dental Association Inc.
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22 December 2017

Business Improvement and Support Section
Medical Devices and Product Quality Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

By email:

Dear Sir/Madam

Re: Proposed regulatory changes related to personalised and 3D printed medical devices

The Australian Dental Association (ADA) welcomes the opportunity to comment on the Proposed regulatory changes related to personalised and 3D printed medical devices, outlined in the discussion paper issued by Department of Health, Therapeutic Goods Administration.

The ADA is the peak professional body representing more than 15,000 dentists and students in Australia. Our members work in both the public and private sector and across all areas of practice.

The ADA supports in principle, the proposed regulatory changes related to personalised and 3D printed medical devices. The ADA understands that the quick progression of 3D technology and in particular, its application in the medical environment has undermined the intent of the existing regulatory framework.

The ADA agrees with the intent of the original framework to allow exemption from inclusion in the Australian Register of Therapeutic Goods (ARTG) for low risk medical devices and understands that this would remain under the changed regulations, although the pathway to the exemption would differ from the existing framework to encompass different approaches to 3D printing systems.

The ADA also agrees with adding greater definition to what constitutes a *custom made device*, including *medical device production systems*.

The ADA would be keen to review the categorisation of what items may be considered to be high risk if this were to change.

Should you require any further information, please contact Mr Damian Mitsch, Chief Executive Office on 02 9906 4412 or ceo@ada.org.au.

Yours sincerely,

Dr P H Sachs
Federal President