

— Submission

Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin

This submission is tendered by the Australian Dental Industry Association (ADIA),
the peak business organisation representing manufacturers
and suppliers of dental products.

Comments —

The Australian Dental Industry Association (ADIA), as the peak business organisation representing dental product manufacturers and suppliers, welcomes the opportunity to submit this response to the Therapeutic Goods Administration (TGA) consultation on the proposed reclassification for substances introduced into the body via a body orifice or applied to the skin.

Overall, ADIA supports harmonisation of classification rules for medical devices with key international regulatory partners such as the EU and USA.

It is noted that the proposed new classification rule will impact ADIA members, with the new requirements and costs associated with Conformity Assessment by a Notified Body, and increased TGA application and annual fees, without any demonstrated change in risk associated with medical devices that have limited, local effect when applied via the oral cavity. These increased costs of business are weighed against the desire for alignment with international best regulatory practice.

With respect to the transition arrangements, given that many Australian suppliers will be reliant on the changes to EU Conformity Assessments to support their reclassification applications, it would seem reasonable to align the Australian transition timetable with the EU, and provide clarity on continuing supply for medical devices between 2024-2025.

Overall, ADIA supports harmonisation of classification rules for medical devices with key international regulatory partners such as the EU and USA, so cannot object to the principle of this proposal.

Whilst TGA is undertaking this comprehensive series of consultations on the regulatory framework for medical devices, ADIA would encourage TGA to review the existing Classification Rule 5.5 as the scope of this Rule appears to be broader than the EU, and there would not appear to be a strong rationale for maintaining unique Australian regulatory requirements over and above international regulatory best practice.



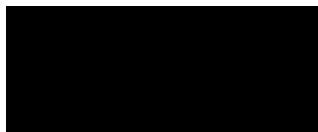
Australian Dental Industry Association Ltd
ABN 32 003 314 396

National Office: GPO Box 960, Sydney, NSW, 2001
Government Affairs: GPO Box 1, Canberra, ACT, 2601
t: 1300 943 094 f: 1300 943 794
e: government.affairs@adia.org.au
www.adia.org.au

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ADIA appreciates the opportunity to engage in this consultation.



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ADIA An Introduction —

Founded in 1925, the Australian Dental Industry Association (ADIA) is the peak business organisation representing suppliers of products and services to dental professionals.

The ADIA membership ranges in size from the local operations of multi-national corporations through to small family-owned entities. They share common aspirations for the growth of their business, the creation of jobs and an industry that's sustained through the provision of quality products and services to dental professionals.

ADIA Mission —

ADIA is the peak business organisation representing manufacturers and suppliers of products to oral health professionals.

ADIA Vision —

An industry that empowers oral health professionals to advance the health and well-being of all Australians.

The high level of support and engagement that ADIA enjoys from the industry – more than two hundred member businesses that supply more than 95% of the dental products supplies in Australia – provides it with the resources to deliver a comprehensive range of services that allow member businesses to grow, create jobs and operate sustainably. The support from industry also places ADIA in a leadership position where parliamentary and departmental stakeholders look to ADIA as a source of authoritative advice and guidance on matters of policy.

ADIA's greatest asset is its members, the businesses who allow their employees to volunteer and serve on the ADIA Board, national committees, state branches and special interest groups. This contribution, when coupled with the expertise and leadership provided by ADIA staff, is what has contributed to ADIA's long-term growth and acknowledge capacity to support not only its members, but the broader dental industry.

A major project for ADIA is the biennial ADX Sydney exhibition, the nation's premier dental event that attracts more than 10,000 stakeholders from across the dental community to see the nation's largest healthcare trade show.

Key affiliations include the Australian Chamber of Commerce and Industry (AusChamber), the association of International Dental Manufacturers (IDM) plus the Australian Made Campaign in addition to the American Chamber of Commerce in Australia (AmCham) and the Australia China Business Council (ACBC).

ADIA provides leadership, strategy, advocacy and support. Our members set our agenda, fund our activities and directly benefit from the results.

To keep up to date with changes in this area you can subscribe to the Twitter feed @AusDental or follow us on Facebook at www.facebook.com/dental.industry. Alternatively, you can contact the Association via email at national.office@adia.org.au or by telephone on 1300 943 094.

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