



ADTA Dental Laboratory Certification

This quality management system (QMS) provides certification to standards set by the Australian Dental Technicians Association Incorporated (ADTA). This certification may be used as evidence of conformity when listing personalised medical devices (PMD) within the Australian Register of Therapeutic Goods (ARTG).

The principal is the designated responsible person of the applicant laboratory, and must ensure that all conditions in this document are met. It is the responsibility of the principal to ensure the applicant meets all relevant regulatory obligations including those relating to the manufacture, supply and use of medical devices. If this certification is denied, lapses or is cancelled, the dental laboratory will be required to attain evidence of conformity elsewhere and risks operating illegitimately.

Applicants must agree to all of the following conditions;

1. The principal of the laboratory holds suitably recognised qualifications in dental technology or dental prosthetics.
2. The principal of the laboratory maintains financial membership with the ADTA.
3. The laboratory has a current Australian Business Number (ABN).
4. Devices manufactured by the laboratory comply with current government legislation and TGA regulation by;
 - a. Being listed and/or when exempt constructed from materials and components listed within the ARTG;
 - b. Constructing and/or using the materials and components for the purpose which they were intended;
 - c. Meeting the Essential Principles;
 - d. Implementing quality control and assessment procedures;
 - e. Providing the required information with each device;
 - f. Reporting adverse events;
 - g. Complying with advertising regulations;
 - h. Retaining records for a period of no less than 7 years.
5. The laboratory meets all state and federal government employee and workplace regulations including those covered in the Fair Work Act, Workers Compensation Act and Work Health and Safety Act (WHS) and will ensure;
 - a. Requirements for remuneration, superannuation, and workers compensation are met;
 - b. Infection control procedures and protocols are followed;
 - c. Adequate ventilation and functional dust extraction equipment is provided;
 - d. Appropriate safety equipment is provided to staff and relevant safety instructions are correctly displayed;
 - e. A first aid kit is provided (and First Aid Officer if required by WHS legislation);
 - f. Fire extinguishers are adequately provided and Fire Safety regulations are met.
6. The laboratory conducts its business from premises that meet all local, state and federal government regulations.
7. The laboratory holds a current public and product liability insurance policy. (Certificate of Currency is required).



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DECLARATION

I/We agree to meet all the conditions listed for ADTA Dental Laboratory Certification, including any amendments or updates to the certification document the Australian Dental Technicians Association (ADTA) may specify.

I/We acknowledge documental evidence and auditing may be requested by the ADTA to ensure compliance. And if the requests are not met, the ADTA may be required to deny or cancel certification.

I/We agree to allow a representative of ADTA to inspect the laboratory at a time convenient to both parties if and when needed.

The Australian Dental Technicians Association does not take any responsibility or accept any liability for the applicant of the ADTA Laboratory Certification program. All the information supplied to ADTA will be kept in strict confidence and will not be passed onto any third party.

Laboratory Name: _____

Laboratory ABN: _____

Address: _____

Laboratory Principal Name: _____

Signature: _____

Date: _____

Witness Name: _____

Signature: _____

Date: _____

RESOURCES

Safe Work Australia

<https://www.safeworkaustralia.gov.au/>

Fair Work Australia

<https://fairworkhelp.com.au/>

Therapeutic Goods Administration (TGA)

<https://www.tga.gov.au/medical-devices-ivds>

<https://www.tga.gov.au/sites/default/files/essential-principles-checklist-medical-devices.pdf>

<https://www.tga.gov.au/resource/personalised-medical-devices-including-3d-printed-devices>