

MANUFACTURER'S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
DECLARATION OF CONFORMITY PROCEDURES

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name: Advanced Medical Devices (AMD) Pty LTD

Business address: Warehouse 3 / 4-8 Inglewood Place, Baulkham Hills, NSW, 2153, Australia

Medical device(s): Advanced Medical Devices – P2 Surgical/medical respirator, single-use

Classification: Class I

GMDN code and term: 57794 – Surgical/medical respirator, single-use

Scope of application: These Declaration of Conformity procedures apply to all batches of the above product

Each kind of medical device to which the technical documentation applies, complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Standards applied: EN1716:2012
ISO 9001:2015

Authorised signatory:



Signature



Ed Lee, Director

Name, Position

15/June 2020

Date