

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	PATH MEDICAL GmbH
Business address:	PATH MEDICAL GmbH Landsberger Str. 65 82110 Germering Germany
Medical device(s):	see attached schedule for multiple products
Classification:	IIa
GMDN code and term:	35747 Audiometer, auditory evoked response
Scope of application:	All products to which the full quality assurance procedures have been applied.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:	EN ISO 13485:2016 Quality System Certificate No 51260- 21-00_EN Issued by DEKRA Certification GmbH Notified Body Number 0124
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ISO 13485:2016 – MDSAP Certificate No 2247210
Issued by DEKRA Certification B.V.

Design examination certificate (if applicable):	EC Certificate of Quality Assurance; Certificate No: 51260-60-00-00 Issued by DEKRA Certification GmbH Notified Body Number 0124 Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III
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Standards applied:	ISO 13485:2016 – Medical Devices- Quality Management Systems EN ISO 14971:2019 – Medical Products – application of risk management to medical products IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety (Ed.: 3.0) IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020 Medical Electrical Equipment Part 1.2 – General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and tests.
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Devices included in this declaration:

ALGO 7i	A101049, 101049
ATA-S	101003
ATA-L	101004

Authorised signatory:



Signature

Florian Peters, Quality Management Representative
Name, Position

18.06.2025
Date