

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This declaration is being made under clause 6.6 of Schedule 3 to the Regulations for a Class I non-sterile, non-measuring device.

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: I

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

ISO 13485:2016 – MDSAP Certificate No 2247210
Issued by DEKRA Certification B.V.

Design examination certificate (if applicable): Not applicable - Class I non-sterile, non-measuring device

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.

Devices included in this declaration:

Electrode Cable ABR-S	101001, A7i-101001
Electrode Cable ABR-L	101002, A7i-101002

Authorised signatory:



Digital unterschrieben
von
peters@pathme.de
Datum: 2025.06.18
13:40:43 +02'00'

Signature

Florian Peters, Quality Management Representative

Name, Position

18.06.2025

Date