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:	37503 Audiometer, pure-tone 41188 Audiometer, speech 58019 Otoacoustic emission system, battery powered 35747 Audiometer, auditory evoked response 36717 Audiometer, impedance
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):	**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**
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:

Senti (Type Desktop)	Modell: SID100433 (Vero Flex)
Sentiero (Type Handheld)	Modell: SOH100098
Sentiero Advanced (Type Handheld)	Modell: SOH100360
Sentiero (Type Desktop)	Modell: SOD100497
nanoTymp / TY-MU	Modell: TU100948
Headphone DD 45 Headphone HB7/DD 45	HP-06 / 100306 HP-06 / 100306-US
Headphone DD 45-contra	HP-16 / 100725
Headphone DD 65 v2	HP-18 / 101044
Headphone DD 450	HP-19 / 101335
Bone Conductor B 71, grey	Modell: BC-01 / 100392
Bone Conductor B 71, red	Modell: BC-01 / 100344
Bone Conductor B 71, grey, incl. patient response button	Modell: BC-RE1 / 100214
Bone Conductor B 81, grey	Modell: BC-03 / 100909
Bone Conductor B 81, red	Modell: BC-03 / 100888
Bone Conductor B 81, grey, incl. patient response button	Modell: BC-RE2 / 100910
Insert Earphone	Model: IP-05/ 100860, 100860-BL
Insert Earphone monaural	Model: IP-05M/ 100867, 100867-BL
PATH Ear coupler cable	Model: PECC-01 / 100477
PATH Ear coupler cable (High Power)	Model: PECC-HP / 100970
Earprobe	100028-US (red) 100530-US (blue)
Earprobe	Model: EP-VIP 100540-US (red) 100539-US (blue)
Earprobe	Model: EP-TY 100188-US 100947 (TY-MA)
Earprobe	Model: EP-LT 101021 101023
Probe Tips	100013 100014 100014-W 101014

Accessory Boxes	100135 (A) 100207 (E) 100261 (P), 100261-BL 100587 (Tymp), 100587-AD 100676 (Screening) 100902 (Starter Kit Newborn/Baby) 101043 (Zubehörbox EP-LT)

Authorised signatory:

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von peters@pathme.de
Datum: 2025.07.03
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Signature

Florian Peters, Quality Management Representative	3/07/2025
Name, Position	Date