PATH MEDICAL GmbH
Landsberger Str. 65
D-82110 Germering
Germany
Tel. +49 / 89 / 80076502
Email: info@pathme.de
Internet: www.pathme.de

Manufacturers Declaration of Conformity

Australian Therapeuthic Goods (Medical Devices) Regulations 2002

DECLARATION OF CONFORMITY PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 Part 1 to the Therapeutic Goods (Medical Device) Regulations 2002.

Manufacturers Name: **PATH MEDICAL GmbH**

Business Address: **Landsberger Strasse 65, 82110 Germering, Germany**

Medical Device: Accessories to Sentiero Devices, as Electrode Cables, Ear Coupler, Ear Tips.
Classification: Class I

GMDN Codes and Term:
37503 Audiometer, pure-tone
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, including Sentiero devices marketed with Bio-Logic branding.
Each kind of medical device to which the Declaration of Conformity Procedure applies, the production quality assurance procedures have also been applied to the device. Each kind of medical device to which the Technical Documentation applies complies with the applicable provision of the essential principles, the classification rules, and these procedures.

Full Quality Management System Certificate:
ISO 13485:2016 Quality System Certificate No 51260- 14-01
Issued by DEKRA Certification GmbH
Notified Body Number 0124

Standards Applied:
ISO 13485:2016 – Medical Devices- Quality Management Systems
EN ISO 14971:2019 – Medical Products – application of risk management to medical products
EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety (Ed.: 3.0)
EN 60601-1-2 Medical Electrical Equipment Part 1.2 – General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and tests.

Authorized Signatory:

Dr. Hans Oswald, General Management

Date: 2022-07-14