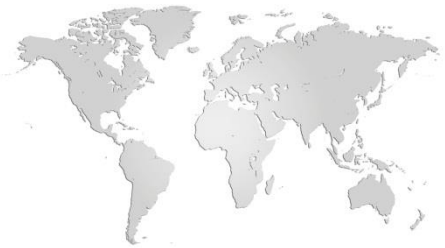
EU Certificate

for the assessment of the quality management system



according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the manufacturer

PATH medical GmbH

Single Registration Number (SRN): SRN: DE-MF-000006935
Landsberger Straße 65, 82110 Germering, Germany

applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo51260-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 51260-60-00-00

Certificate valid from: 2025-01-20
Certificate valid to: 2028-01-16

Elena Schröder
Digitally signed by Elena Schröder
Date: 2025-01-20 16:34:49+01:00

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

DEKRA Certification GmbH, Stuttgart 2025-01-20
Notified Body ID number: 0124

Annex to the EU Certificate no. 51260-60-00-00

Following devices categories are included in this certificate:

Class IIa

MDA0204

- Audiometer, +Diagnostic Device for otoacoustic emissions (OAE), + Diagnostic Device for auditory evoked Potentials (AEP), + Tympanometer
  - Senti (Type Desktop Flex) Model number SID100433
  - Sentiero Model number SOH100098
  - Sentiero Advanced Model number SOH100360
  - Sentiero (Type Desktop) Model number SOD100497

- Hearing screener
  - AABR Newborn Hearing Screener ALGO 7i Model number A7i-101049
  - QScreen: OAE and AEP Screener Model number PM1610

- Accessories to Audiometer, +Diagnostic Device for otoacoustic emissions (OAE), + Diagnostic Device for auditory evoked Potentials (AEP), + Tympanometer
  - Ear Probe Type: EP-TE, EP-DP, EP-LT, EP-VIP, EP-TY
  - Headphone, Insert Earphone Type: HP, IP
  - Bone Conductor Type: BC
  - Ear Coupler Cable Type: ECC, ATA (A7i)

- Tympanometer
  - nanoTymp Model number TU100948 (TY-MU)