

# 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.: 51260-60-00-01

Certificate valid from:

2026-01-13

Certificate valid to:

2028-01-16

Previous certificate no. 51260-60-00-00, issued on 2025-01-20



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)

BS-MDR-092

DEKRA Certification GmbH, Stuttgart 2026-01-13  
Notified Body ID number: 0124

# Annex to the EU Certificate no. 51260-60-00-01

Following devices/device categories are included in this certificate:

## Class IIa

MDA0204

- Audiometer, +Diagnostic Device for otoacoustic emissions (OAE), + Diagnostic Device for auditory evoked Potentials (AEP), + Tympanometer
  - nanoAudio Model Number NA101414
  - 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 101049 (A7i)
  - QScreen: OAE and AEP Screener Model number 101199 (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)

Change(s) to previous certificate: Product nanoAudio included.