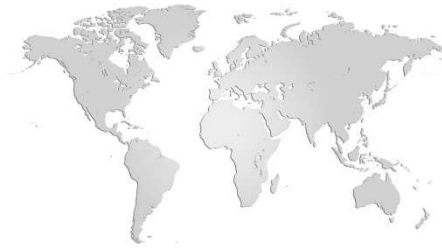


# EC CERTIFICATE

## for the Quality Assurance System



### according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company  
**PATH medical GmbH**

Landsberger Straße 65, 82110 Germering, Germany

**Certified location:**

Landsberger Straße 65, 82110 Germering, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 51260-Z4-00, the decision dated 2020-12-11 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-12-18 to 2022-12-17

Registration No.: 51260-16-03



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2020-12-11  
Notified Body ID-number: 0124



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
**ZLG-BS-295.10.02**

# Annex to the EC Certificate No. 51260-16-03

Valid from 2020-12-18 to 2022-12-17

Revision status of the annex: 0 dated 2020-12-11

Devices/device categories included in the certificate:

## Class II a:

- MD1301
  - Audiometer, + Diagnostic Device for otoacoustic emissions (OAE), + Diagnostic Device for auditory evoked potentials (AEP), + Tympanometer
    - Senti Model number: SIH100097
    - Senti (Type Desktop) Model number: SID100419 (Vero)  
SID100433 (Vero Flex)
    - Sentiero Model number: SOH100098
    - Sentiero Advanced Model number: SOH100360
    - Sentiero (Type Desktop) Model number: SOD100497
  - Hearing Screener
    - AABR Newborn Hearing Screener ALGO7i Model number: 101049 (A7i)
  - Accessories for Audiometer, + Diagnostic Device for otoacoustic emissions (OAE), + Diagnostic Device for auditory evoked potentials (AEP), + Tympanometer
    - Ear Probe Type: EP-TE, EP-DP, EP-VIP, EP-TY
    - Headphone, Insert Phone Type: HP, IP
    - Bone Conductor Type: BC
    - Ear Coupler Cable Type: ECC, ATA (A7i)
  - Tympanometer
    - nanoTymp Model number: TU100948 (TY-MU)



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2020-12-11  
Notified Body ID-number: 0124