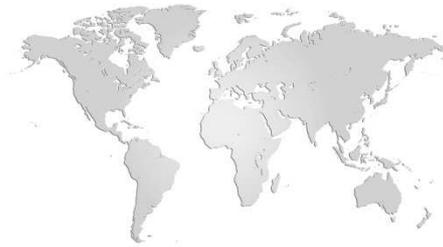


EC CERTIFICATE

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
ZLG-BS-295.10.02

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

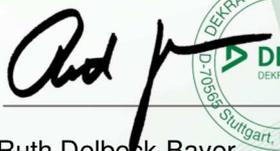
Valid from 2020-12-18 to 2022-12-17

Revision status of the annex: 1 dated 2021-05-25

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)
 - QSCREEN: OAE and ABR Hearing Screener Model Number: 101199 (PM1610)
 - 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-LT, 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, 2021-05-25
Notified Body ID-number: 0124