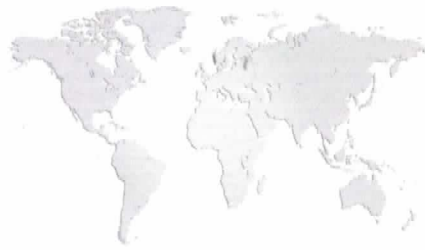


EC CERTIFICATE

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

Certified location:

Landsberger Straße 65, 82110 Germering, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 51260-Z2-00, the decision dated 16.12.2014 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification: 18.12.2009

Date of the last recertification: 18.12.2014

This certificate is valid until: 17.12.2017

Certificate registration No.: 51260-16-01
duplicate



DEKRA Certification GmbH
Stuttgart, 16.12.2014

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

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid.

Annex to the EC Certificate 51260-16-01 dated 16.12.2014

Duplicate

Revision status: 0

Date: 18.12.2014

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Devices/device categories included in the certificate

Class II a:

Audiometer, + diagnostic device for otoacoustic emissions (OAE), + diagnostic device for auditory evoked potentials (AEP), + tympanometer

Device types:

- | | | |
|---------------------------|-----------------|---|
| - 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 |

Accessories for audiometer, + OAE diagnostic device, + AEP diagnostic device, + tympanometry diagnostic device:

- | | |
|---------------------|-------------------------------------|
| - Ear Probe | - Type: EP-TE, EP-DP, EP-VIP, EP-TY |
| - Ear coupler cable | - Type: ECC |
| - Electrode cable | |

