ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 044841 0027 Rev. 00

Manufacturer: **Interacoustics A/S**
Audiometer Allé 1
5500 Middelfart
DENMARK

SRN Manufacturer: DK-MF-000001216

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 044841 0027 Rev. 00

Report No.: 713183048

Valid from: 2021-09-10
Valid until: 2026-09-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-09-10

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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(Class IIa and Class IIb Devices)

No. G10 044841 0027 Rev. 00

Classification:	IIa
Device Group:	Z121401 - AUDIOMETERS Z121403 - EVOKED POTENTIAL AUDIOMETRY INSTRUMENTS Z121404 - VESTIBULAR SYSTEM ANALYSIS INSTRUMENTS Z12149001 - AUDITORY FUNCTION SCREENING DEVICES Z12149004 - CALORIC IRRIGATION UNITS Z12149005 - MIDDLE EAR ANALYSERS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

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Product Service

Confirmation Statement related to the EU Certificate (MDR)

List of Sites involved in the Product Realisation Processes

No. GRS 044841 0029 Rev. 00

Manufacturer:

Interacoustics A/S
Audiometer Allé 1
5500 Middelfart
DENMARK

This List of Sites is only valid in combination with the following EU Certificate (MDR): **G10 044841 0027 Rev. 00**

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EU Certificate pursuant to the Regulation (EU) 2017/745 (MDR) on medical devices.

Report No.: 713183048

Valid until: 2026-09-09

Issue Date: 2021-11-19

R. Köhler

(Randolf Köhler)
PS-MHS-FA-0 – Foreign Affairs

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Product Service

Confirmation Statement related to the EU Certificate (MDR)

List of Sites involved in the Product Realisation Processes

No. GRS 044841 0029 Rev. 00

Sites:

Interacoustics A/S
Audiometer Allé 1, 5500 Middelfart, DENMARK

DGS Diagnostics Sp. z o. o.
ul. Zeusa 2, 72-006 Mierzyn, POLAND

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