



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



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](http://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

**Issue date:** 2021-09-10

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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**

**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 -



Product Service

## Confirmation Statement related to the EU Certificate (MDR)

List of Sites involved in the Product Realisation Processes

**No. GRS 044841 0029 Rev. 01**

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

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

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.:** 713297268

**Valid until:** 2026-09-09

**Issue Date:** 2023-03-28

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Sign Affairs



Product Service

## Confirmation Statement related to the EU Certificate (MDR)

List of Sites involved in the Product Realisation Processes

**No. GRS 044841 0029 Rev. 01**

### Sites:

**Interacoustics A/S**

Audiometer Allé 1, 5500 Middelfart, DENMARK

**DGS Diagnostics Sp. z o. o.**

Rosówek 43, 72-001 Kolbaskowo, POLAND

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