







## **Certificate**

No. Q5 044841 0028 Rev. 04

**Holder of Certificate:** Interacoustics A/S

> Audiometer Allé 1 5500 Middelfart **DENMARK**

**Certification Mark:** 



Design and development, manufacture, Scope of Certificate:

sales and servicing of audiometric equipment, hearing aid analyzers, vestibular examination, assessment and

rehabilitation units for the area of audiology, balance and physiotherapy

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044841 0028 Rev. 04

Report No.: 713351753

Valid from: 2025-11-29 Valid until: 2028-11-28

2025-06-04

Christoph Dicks

Head of Certification/Notified Body





Date,





**Product Service** 

## **Certificate**

No. Q5 044841 0028 Rev. 04

ISO 13485:2016 Applied Standard(s):

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Interacoustics A/S

Audiometer Allé 1, 5500 Middelfart, DENMARK

Design and development, manufacture, sales and servicing of audiometric equipment, hearing aid analyzers, vestibular examination, assessment and rehabilitation units for the area of audiology, balance and physiotherapy

**DGS Diagnostics A/S** 

Audiometer Allé 1, 5500 Middelfart, DENMARK

Design and development, manufacture, sales and servicing of audiometric equipment and hearing aid analyzers, vestibular examination, assessment and rehabilitation units

DGS Diagnostics Sp. z o. o.

Rosówek 43, 72-001 Kolbaskowo, POLAND

Manufacture, distribution and servicing of audiometric equipment and hearing aid analyzers, vestibular examination, assessment and rehabilitation units

**Diagnostic Group LLC** 

10393 West 70th Street, Eden Prairie, Minnesota, 55344, USA

Manufacture, distribution and servicing of audiometric equipment and hearing aid analyzers, vestibular examination, assessment and rehabilitation units

VIRTUALIS SAS

78 Allée John Napier, 34000 Montpellier, FRANCE

Design and development, manufacture, sales and servicing of vestibular examination, assessment and rehabilitation units for the area of balance and physiotherapy