





Product Service

Certificate

No. Q5 044841 0028 Rev. 02

Holder of Certificate: Interacoustics A/S

Audiometer Allé 1 5500 Middelfart DENMARK

Certification Mark:



Scope of Certificate: Design and development, manufacture,

sales and servicing of audiometric equipment, hearing aid analyzers,

vestibular examination and rehabilitation

units for the area of audiology

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 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:Q5-044841-0028-Rev. 02

Report No.: 713274285

 Valid from:
 2023-03-01

 Valid until:
 2025-11-28

Date, 2023-03-01 Christoph Dicks

Head of Certification/Notified Body





Certificate

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EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Interacoustics A/S

Audiometer Allé 1, 5500 Middelfart, DENMARK

Design and development, marketing, sales and servicing of audiometric equipment, hearing aid analyzers, vestibular

examination and rehabilitation units

DGS Diagnostics A/S

Audiometer Allé 1, 5500 Middelfart, DENMARK

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