



# Certificate

No. Q5 044841 0028 Rev. 00

**Holder of Certificate:** **Interacoustics A/S**  
Audiometer Allé 1  
5500 Middelfart  
DENMARK

**Certification Mark:**



**Scope of Certificate:** **Design and development, manufacture, marketing, sales, service and calibration of audiometric equipment, hearing aid analysers, vestibular examination and rehabilitation units and related applied products**

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. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_044841_0028_Rev._00)

**Report No.:** 713213706

**Valid from:** 2021-08-01  
**Valid until:** 2024-07-31

**Date,** 2021-07-29



Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** EN ISO 13485:2016  
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, production, marketing, sales, distribution,  
servicing and calibration of audiometric equipment, hearing aid analyzers,  
vestibular examination units and related applied products

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

Manufacturing, distribution, service and calibration of audiometric  
equipment, hearing aid analyzers, vestibular examination units and  
instrumentation for rehabilitation of patients with dizziness and balance  
disorders

**DGS Diagnostics A/S**  
Audiometer Allé 1, 5500 Middelfart, DENMARK

Production, servicing and calibration of audiometric equipment, hearing  
aid analyzers, and related applied products

**Micromedical Technologies Inc.**  
10 Kemp Drive, Chatham IL 62629, USA

Manufacture of Vestibular Examination Units: Rotary and Reclining Chairs  
with External Visual Fixation Sources, Caloric Irrigators, Active and  
Passive Head Position Sensors for the Assessment and Rehabilitation of  
Patients with Dizziness and Balance Disorders