



America

CERTIFICATE

No. QS6 044841 0024 Rev. 06

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

Certification Mark:



Scope of Certificate: Design and Development, Manufacture, Distribution and Servicing of Audiometric Equipment, Hearing Aid Analyzers, Vestibular Examination and Rehabilitation Units for the area of Audiology

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_044841_0024_Rev.06

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F001685
Report No.: 713281977
Effective Date: 2023-05-04
Expiry Date: 2025-08-14

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Date of Issue: 2023-05-22

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
 - RDC ANVISA n. 551/2021
 - RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

Interacoustics A/S

Audiometer Allé 1, 5500 Middelfart, DENMARK

DGS Diagnostics Sp. z o. o.

Rosówek 43, 72-001 Kolbaskowo, POLAND

DGS Diagnostics A/S

Audiometer Allé 1, 5500 Middelfart, DENMARK

Micromedical Technologies Inc.

10 Kemp Drive, Chatham IL 62629, USA

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Facility Scopes:

Interacoustics A/S

Audiometer Allé 1, 5500 Middelfart, DENMARK

Design and Development, Servicing and Distribution of Audiometric Equipment, Hearing Aid Analyzers, Vestibular Examination and Rehabilitation Units
REPs Facility ID: F001685

DGS Diagnostics Sp. z o. o.

Rosówek 43, 72-001 Kolbaskowo, POLAND

Manufacture, Distribution and Servicing of Audiometric Equipment, Hearing Aid Analyzers and Vestibular Examination and Rehabilitation Units
REPs Facility ID: F005394

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
REPs Facility ID: F005395

Micromedical Technologies Inc.

10 Kemp Drive, Chatham IL 62629, USA

Manufacture of Vestibular Examination and Rehabilitation Units
REPs Facility ID: F005504

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