



America

CERTIFICATE

No. QS6 063429 0015 Rev. 01

Certificate Holder:



MAICO Diagnostics GmbH
 Sickingenstr. 70-71
 10553 Berlin
 GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Manufacture, Distribution and Service of Instruments to Measure Pure-Tone and Speech Audiometry, OAE, ABR, Aural Acoustic Impedance/Admittance and Hearing Tester

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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert

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

DUNS No:

34-486-3550

Effective Date:

2020-10-09

Expiry Date:

2022-01-13

Page 1 of 3

Date of Issue: 2021-02-26

(Tina Israel)
 Manager, US Certification Body,
 Medical and Health Services



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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. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

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

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

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

Facility(ies):

MAICO Diagnostics GmbH
 Sickingenstr. 70-71, 10553 Berlin, GERMANY

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

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

Page 2 of 3

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Facility Scopes:

MAICO Diagnostics GmbH

Sickingenstr. 70-71, 10553 Berlin, GERMANY

Design and Development, Manufacture, Distribution and Service of Instruments to Measure Pure-Tone and Speech Audiometry, OAE, ABR, Aural Acoustic Impedence / Admittance and Hearing Tester
DUNS No: 34-486-3550

DGS Diagnostics A/S

Audiometer Allé 1, 5500 Middelfart, DENMARK

Manufacture, Distribution and Service of Audiometric Equipment, Hearing Aid Analyzers, Vestibular Examination Units and related Applied Products
DUNS No: 30-360-8354

DGS Diagnostics Sp z.o.o.

ul. Zeusa 2, 72-006 Mierzyn, POLAND

Manufacture, Distribution and Service of Audiometric Equipment, Hearing Aid Analyzers, Vestibular Examination Units and related Applied Products
DUNS No: 42-543-8180

Page 3 of 3

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