ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
Medical Device Single Audit Program

America

CERTIFICATE

No. QS6 063429 0015 Rev. 06

Certificate Holder:
MAICO

MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture, Distribution and Servicing of Audiometric Equipment for the area of Audiology**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. 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 063429 0015 Rev. 06
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002417**
Report No.: **713354791**
Effective Date: **2025-12-13**
Expiry Date: **2028-12-12**

Date of Issue: 2025-10-15

(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):

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.
Rosówek 43, 72-001 Kolbaskowo, POLAND

Diagnostic Group LLC
10393 West 70th Street, Eden Prairie, Minnesota, 55344, USA

Date of Issue: 2025-10-15

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Facility Scopes:

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

Design and Development and Distribution of Audiometric Equipment

REPs Facility ID: F002417

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

Design and Development, Manufacture of Audiometric Equipment

REPs Facility ID: F005395

DGS Diagnostics Sp. z o. o.
Rosówek 43, 72-001 Kolbaskowo, POLAND

Manufacture, Distribution and Servicing of Audiometric Equipment

REPs Facility ID: F005394

Diagnostic Group LLC
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Manufacture, Distribution and Servicing of Audiometric Equipment

REPs Facility ID: F007315

Date of Issue: 2025-10-15

(Renee Walker)
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