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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 063429 0017 Rev. 03

Holder of Certificate: **MAICO Diagnostics GmbH**

Sickingenstr. 70-71
10553 Berlin
GERMANY

Certification Mark:

Scope of Certificate: **Design and development, manufacture, sales and servicing of audiometric equipment 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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 063429 0017 Rev. 03

Report No.: 713354791

Valid from: 2026-03-02
Valid until: 2029-03-01

Date, 2025-12-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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No. Q5 063429 0017 Rev. 03

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

Design and development, marketing and sales of audiometric equipment

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

Manufacture, distribution and servicing of audiometric equipment

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

Design and development, manufacture of audiometric equipment

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

Manufacture, distribution and servicing of audiometric equipment

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