



America

CERTIFICATE

No. QS6 063429 0015 Rev. 00

Certificate Holder:
 MAICO

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 <https://www.tuev-sued.de/product-testing/certificates>

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

DUNS No:

34-486-3550

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Page 1 of 2

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(Arie Henkin)
Manager, Certification Body MHS

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