



Certificate

No. Q5 063429 0017 Rev. 00

Holder of Certificate:



MAICO Diagnostics GmbH

Sickingenstr. 70-71
10553 Berlin
GERMANY

Certification Mark:



Scope of Certificate:

Design and development, manufacture, sales, distribution, servicing and calibration of audiometric equipment and related applied products

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 and certification regulation of 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. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_063429_0017_Rev_00)

Report No.: 713185782

Valid from: 2021-01-28

Valid until: 2023-07-08

Date, 2021-01-28

Christoph Dicks

Head of Certification/Notified Body



Product Service

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Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies): MAICO Diagnostics GmbH
 Sickingenstr. 70-71, 10553 Berlin, GERMANY

Design and development, manufacture, sales, distribution,
 servicing and calibration of audiometric equipment and related
 applied products

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

Manufacturing, distribution, servicing and calibration of audiometric
 equipment

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

Manufacturing, distribution, servicing and calibration of audiometric
 equipment