



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 063429 0018 Rev. 00

Manufacturer:

MAICO Diagnostics GmbH

Sickingenstr. 70-71
10553 Berlin
GERMANY

SRN Manufacturer:

DE-MF-000006145

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 063429 0018 Rev. 00

Report No.:

713185782

Valid from:

2021-06-10

Valid until:

2026-06-09

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2021-06-10



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No. G10 063429 0018 Rev. 00

Classification:

IIa

Device Group:

Z121401 - AUDIOMETERS

Z121403 - EVOKED POTENTIAL AUDIOMETRY INSTRUMENTS

Z12149001 - AUDITORY FUNCTION SCREENING DEVICES

Z12149005 - MIDDLE EAR ANALYSERS

Intended Purpose:

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**The validity of this certificate
depends on conditions and/or
is limited to the following:**

-none-