



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



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. 01

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, 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:G10 063429 0018 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G10_063429_0018_Rev._01)

Report No.: 713407506
Preceding Certificate No.: G10 063429 0018 Rev. 00
Valid from: 2026-06-10
Valid until: 2031-06-09
Date of Initial Issuance: 2021-06-10

Christoph Dicks
 Head of Certification/Notified Body

Issue date: 2026-05-26



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Classification: Class IIa
Device Group: Z121401 - AUDIOMETERS
 Z121403 - EVOKED POTENTIAL AUDIOMETRY INSTRUMENTS
 Z12149001 - OTOACOUSTIC EMISSIONS EQUIPMENT
 Z12149005 - IMPEDANCE METERS FOR THE AUDITORY
 SYSTEM

Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2021-06-10	713185782	-
01	2026-06-10	713407506	Renewal of certificate