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

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

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TÜV®

CE Type List

Following MAICO products are CE marked and covered by the
EU Quality Management System Certificate (MDR) G10 063429 0018, Rev. 00

Product Name	Product category	Description	Class, rule	GMDN / CND
MA 1	Audiometric Equipment	Hearing Tester	IIa, rule 10	63545 / Z121401
MA 25	Audiometric Equipment	Screening Audiometer	IIa, rule 10	63545 / Z121401
MA 27	Audiometric Equipment	Screening Audiometer	IIa, rule 10	63545 / Z121401
MA 28	Audiometric Equipment	Screening Audiometer	IIa, rule 10	63545 / Z121401
MA 42	Audiometric Equipment	Diagnostic Audiometer	IIa, rule 10	63545 / Z121401
PILOT TEST	Audiometric Equipment	Screening Audiometer	IIa, rule 10	63545 / Z121401
MA 33	Audiometric Equipment	PC Audiometer	IIa, rule 10	63545 / Z121401
RA660	Audiometric Equipment	PC Audiometer	IIa, rule 10	63545 / Z121401
Product Name	**Product category**	**Description**	**Class, rule**	**GMDN / CND**
Product name: touchTymp *Versions:* MI 24 MI 26 MI 34 MI 36	Audiometric Equipment	 Tympanometer Audio-Tymp Middle Ear Analyzer Audio-Tymp	IIa, rule 10	63545 / Z12149005 and Z121401 (MI 26 & 36)
Product name: easyTymp *Versions:* Basic Plus Pro	Audiometric Equipment	 Tympanometer Tympanometer Tympanometer	IIa, rule 10	63545 / Z12149005

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EU Quality Management System Certificate (MDR) G10 063429 0018, Rev. 00

Product Name	Product category	Description	Class, rule	GMDN / CND
ERO•SCAN™	Audiometric Equipment	OAE Test System	IIa, rule 10	63545 / Z12149001
MB 11 BERAphone	Audiometric Equipment	ABR Test System	IIa, rule 10	63545 / Z121403
MB 11 Classic	Audiometric Equipment	ABR Test System	IIa, rule 10	63545 / Z121403
easyScreen	Audiometric Equipment	OAE / ABR Test System	IIa, rule 10	63545 / Z12149001 and Z121403

Berlin, 2021-06-10

Uwe Ledworuski, Head of Quality & Regulatory

MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
Tel:+49 30 70 71 46-50 Fax: +49 30 70 71 46-99

Vertimas iš anglų kalbos į lietuvių

CE sertifikatas

Pagal Reglamento (ES) 2017/745 dėl medicinos prietaisų IX priedo I ir III skyrius
(IIa ir IIb klasės prietaisai)

Nr. G10 063429 0018 Rev. 00

Gamintojas

Pavadinimas: MAICO Diagnostika GmbH
Adresas: Sickingenstr. 70-71
10553 Berlynas
Vokietija

SRN Gamintojas: DE-MF-000006145

„TUV SUD Product Service GmbH“ sertifikavimo įstaiga patvirtina, kad gamintojas sukūrė, patvirtino dokumentais ir įgyvendino kokybės valdymo sistemą, kaip aprašyta Reglamento (ES) 2017/745 dėl medicinos prietaisų 10 straipsnio 9 dalyje. Išsami informacija apie prietaisų kategorijas, kurioms taikoma kokybės valdymo sistema, aprašyta kitame (-iuose) puslapyje (-iuose). Toliau nurodomoje ataskaitoje apibendrinami vertinimo rezultatai ir pateikiama nuoroda į atitinkamas CS, darniuosius standartus ir bandymų ataskaitas. Atitikties vertinimas buvo atliktas pagal šio reglamento IX priedo I ir III skyrius, o rezultatas buvo teigiamas.
Sertifikuotą kokybės valdymo sistemą periodiškai prižiūri TUV SUD prduct Service GmbH. Priežiūros vertinimas taip pat apima ir atitinkamo prietaiso ar prietaisų techninių dokumentų vertinimą, remiantis kitais tipiniais pavyzdžiais. Turi būti laikomasi visų taikomų „TUV SUD Group“ bandymų ir sertifikavimo taisyklių reikalavimų.

Ataskaitos Nr. 713185782

Galioja nuo: 2021-06-10
Galioja iki: 2026-06-09

Data, 2021-06-10 /PARAŠAS/
Christoph Dicks

Klasė: IIa
Preitaisų grupė: Audiometrai
audiometrijos instrumentai
klausos tikrinimo prietaisai
vidurinės ausies analizatoriai

TUV SUD Produktų Servisas GmbH notifikavimas su identifikacija Nr. 0123