

EU Declaration of Conformity

It has been demonstrated that:

Product:

Product name: MA 1 -configurations covered see appendix A
Product type: Hearing Tester
Intended purpose: Hearing assessment
Trademark: MAICO
Class.: IIa
Basic UDI-DI: 426017612_8000183_WW

Manufactured by:

Name: MAICO Diagnostics GmbH SRN: DE-MF-000006145
Address: Sickingenstr. 70-71 Phone No.: (+49) 30 7071460
Area code/Area: 10553 Berlin Fax No.: (+49) 30 70714699
State/Country: Germany

Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

Conformity assessment: Annex IX (Quality system and technical documentation assessment)

EU-Certificate No.: G10 063429 0018 Rev. 00

Valid until: 2026-06-09

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstrasse 65, 80339 Munich / Germany
ID no. 0123

This declaration is issued on the sole responsibility of:

Company: MAICO Diagnostics GmbH
Address: Sickingenstr. 70-71
Address: 10553 Berlin
State/Country: Germany

Signature:  Place: Berlin
Date: 2023-02-24
Name: Uwe Ledworuski (YYYY-MM-DD)
Title: Head of Quality & Regulatory

EU Declaration of Conformity Appendix A

The following configurations are covered by this Declaration of Conformity:

- MA 1 with Audiometric headset DD45 from DGS Diagnostics A/S
- MA 1 with Audiometric headset DD65v2 from DGS Diagnostics A/S