

EU Declaration of Conformity

It has been demonstrated that:

Product:

| | |
|-------------------|-----------------------------------|
| Product name: | EROSCAN |
| Product type: | Portable Otoacoustics Test Device |
| Intended purpose: | Hearing assessment |
| Trademark: | MAICO |
| Class.: | Ila |
| Basic UDI-DI: | 426017612_8104863_25 |

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: 2021-07-28

Name:

Uwe Ledworuski

(YYYY-MM-DD)

Title:

Head of Quality & Regulatory