

## EU Declaration of Conformity

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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