

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		