



# Interacoustics

## EU-MDR Declaration of Conformity

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It has been demonstrated that:

**Product:**

Product name: Affinity 2.0  
Product type: Universal Audio Analyzer Platform  
Trademark: Interacoustics  
Class.: Ila  
Basic UDI-DI: 5711117\_8000274\_2L  
Configurations covered: See appendix A

**Manufactured by:**

Name:	<b>Interacoustics A/S</b>	SRN:	<b>DK-MF-000001216</b>
Address:	<b>Audiometer Allé 1</b>	Phone No.:	<b>(+45) 63713555</b>
Area code/Area:	<b>5500 Middelfart</b>	Fax No.:	<b>(+45) 63713522</b>
State/Country:	<b>Denmark</b>		

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)  
**MDR-Certificate No.:** G10 044841 0027  
**Valid until:** 2026-09-09

**Notified Body:** TÜV SÜD Product Service GmbH  
Ridlerstrasse 65, D-80339 Munich / Germany  
ID No.: 0123

**This declaration is issued on the sole responsibility of:**

Company: **Interacoustics A/S**  
Address: **Audiometer Allé 1**  
Address: **5500 Middelfart**  
State/Country: **Denmark**

Signature: *Erik Nielsen* Place: **Middelfart**  
Name: **Erik Nielsen** Date: **2021-10-22**  
Title: **Director, Regulatory & Compliance** (YYYY-MM-DD)

# EC Declaration of Conformity

## Appendix A

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The following configurations are covered by this Declaration of Conformity:

Optional modules:           AC440  
                                      REM440  
                                      HIT440