



Interacoustics

EU-MDR Declaration of Conformity

It has been demonstrated that:

Product:

Product name: BG4.0
Product type: Vestibular Examination Unit
Trademark: Interacoustics
Class.: Ila, accessory
Basic UDI-DI: 5711117_8510760_68
Configurations covered: See appendix A

Manufactured by:

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

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*
Name: Erik Nielsen
Title: Director, Regulatory & Compliance

Place: Middelfart

Date: *2021-10-22*
(YYYY-MM-DD)

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Appendix A

The following configurations are covered by this Declaration of Conformity:

Optional Hardware for : VisualEyes 505
 VisualEyes 515
 VisualEyes 525
 Orion Autotraverse Basic
 Orion Comprehensive Basic