



# Interacoustics

## CE Type list

The following Interacoustics products are CE marked and covered by the EC-Certificate G1 044841 0025 rev. 01

| Devices          |                                   |   |              |   |   |
|------------------|-----------------------------------|---|--------------|---|---|
| Product name     | Description                       | Product category                                | Class, rule  | GMDN/CND                                | Remarks   |
| AC40             | Clinical Audiometer               | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401                       |   |
| AD226            | Diagnostic Audiometer             | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401                       |   |
| AD229b           | Diagnostic Audiometer             | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401                       |   |
| AD229e           | Diagnostic Audiometer             | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401                       |   |
| AD629            | Diagnostic Audiometer             | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401                       |   |
| AD528            | Diagnostic Audiometer             | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401                       |   |
| PAS              | Screening Audiometer              | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401                       |   |
| AS608            | Screening Audiometer              | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401                       |   |
| Luna             | Screening Audiometer              | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401                       |   |
| AA222            | Audiometer and Tympanometer       | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401<br>and<br>Z12149005   |   |
| AT235            | Impedance Audiometer              | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z121401<br>and<br>Z12149005   |   |
| MT10             | Impedance Audiometer              | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z12149005                     |   |
| Titan            | Auditory analysis platform        | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z12149005<br>and<br>Z12149001 | Optional modules:<br>IMP440; WBT;<br>TEOAE440; DPOAE440                                     |
| Eclipse          | Medical PC Platform               | Audiometric Equipment                           | Ila, rule 10 | 63545/<br>Z12149001<br>and<br>Z121403   | Optional modules:<br>ABRIS; DPOAE20,<br>TEOAE25; VEMP; ASSR,<br>EP15; EP25;<br>IA OAE Suite |
| Affinity 2.0     | Universal Audio Analyzer Platform | Hearing Aid Analysers;<br>Audiometric Equipment | Ila, rule 10 | 45241/<br>Z121401                       | Optional modules:<br>AC440; REM440;<br>HIT440   |
| Affinity Compact | Universal Audio Analyzer Platform | Hearing Aid Analyzer                            | Ila, rule 10 | 45241/<br>Z12149001                     | Optional modules:<br>AC440; REM440;<br>HIT440   |
| Equinox 2.0      | Universal Audio Analyzer Platform | Audiometer Platform                             | Ila, rule 10 | 45241/<br>Z12149001                     | Optional modules:<br>AC440; REM440;<br>HIT440   |
| Callisto         | Audiometer Platform               | Hearing Aid Analysers;                          | Ila, rule 10 | 45241/                                  | Optional modules:   |

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| Product name | Description                                 | Product category             | Class, rule  | GMDN/CND                              | Remarks  |
|              |   | Audiometric Equipment        |              | Z121401                               | AC440; REM440; HIT440  |
| OtoRead      | Portable Otoacoustic Test Device            | Audiometric Equipment        | Ila, rule 10 | 63545/<br>Z12149001                   |  |
| Sera         | Auditory analysis platform                  | Audiometric Equipment        | Ila, rule 10 | 63545/<br>Z12149001<br>and<br>Z121403 | License:<br>ABRIS; DPOAE; TEOAE  |
| Lyra         | Portable otoacoustic Test Device            | Audiometric Equipment        | Ila, rule 10 | 63545/<br>Z12149001                   | Optional module:<br>IA OAE Suite   |
| EyeSeeCam    | Vestibular Examination Unit (Nystagmograph) | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404                     | Used with either the original EyeSeeCam software or a dedicated VisualEyes license |
| Air Fx       | Air Caloric irrigator                       | Vestibular Examination Units | Ila, rule 10 | 34891/<br>Z12149004                   | Stand alone and optional hardware for VisualEyes 515, 525                          |
| Aqua Stim    | Water Caloric irrigator                     | Vestibular Examination Units | Ila, rule 10 | 34891/<br>Z12149004                   | Stand alone and optional hardware for VisualEyes 515, 525                          |

| Software with medical purpose |  |                       |              |                     |   |
|-------------------------------|--|-----------------------|--------------|---------------------|---|
| Product name                  | Description                                    | Product category      | Class, rule  | GMDN/CND            | Remarks                                 |
| IMP440                        | Impedance Audiometer Module                    | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z12149005 | Optional module for: Titan              |
| WBT                           | Impedance Audiometer Module                    | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z12149005 | Optional functionality for Titan IMP440 |
| DPOAE440                      | Distortion Product OAE Module                  | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z12149001 | Optional module for: Titan              |
| TEOAE440                      | Transient OAE Module                           | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z12149001 | Optional module for: Titan              |
| ABRIS                         | Brain Stem Audiometer Module (Evoked response) | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z121403   | Optional module for: Eclipse            |
| EP15                          | Brain Stem Audiometer Module                   | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z121403   | Optional module for: Eclipse            |
| EP25                          | Brain Stem Audiometer Module                   | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z121403   | Optional module for: Eclipse            |
| ASSR                          | Diagnostic Module                              | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z121403   | Optional module for: Eclipse            |
| DPOAE20                       | Distortion Product OAE Module                  | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z12149001 | Optional module for: Eclipse            |
| TEOAE25                       | Transient OAE Module                           | Audiometric Equipment | Ila, rule 10 | 63545/<br>Z12149001 | Optional module for: Eclipse            |



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| Software with medical purpose |  |                              |              |                     |  |
|-------------------------------|--|------------------------------|--------------|---------------------|--|
| Product name                  | Description                                  | Product category             | Class, rule  | GMDN/ CND           | Remarks  |
| VEMP                          | Vestibular Evoked myogenic Potentials Module | Vestibular Examination Units | Ila, rule 10 | 63545/<br>Z121404   | Optional module for: Eclipse   |
| IA OAE Suite                  | Otoacoustic emissions software               | Audiometric Equipment        | Ila, rule 10 | 63545/<br>Z12149001 | Optional software for: Eclipse; Lyra   |
| AC440                         | Clinical Audiometer Module                   | Audiometric Equipment        | Ila, rule 10 | 45241/<br>Z121401   | Optional module for: Affinity 2.0; Callisto, Equinox   |
| REM440                        | Real Ear Measurement Module                  | Hearing Aid Analysers        | Ila, rule 10 | 45241/<br>Z121401   | Optional module for: Affinity 2.0; Callisto; Equinox; Affinity Compact   |
| VisualEyes 505                | Vestibular Examination Unit (Nystagmograph)  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   | Hardware options: 2D-VOGfw; BG4.0; USBM2.1, Vorteq   |
| VisualEyes 515                | Vestibular Examination Unit (Nystagmograph)  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   | Hardware options: 2D-VOGfw; BG4.0; USBM2.1, Vorteq, Datalink, Orion reclining  |
| VisualEyes 525                | Vestibular Examination Unit (Nystagmograph)  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   | Hardware options: 2D-VOGfw; BG4.0; USBM2.1, Vorteq, Datalink, Orion reclining, Orion Autotraverse, Orion Comprehensive |
| VisualEyes EyeSeeCam vHit     | Vestibular Examination Unit (Nystagmograph)  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   | Used with EyeSeeCam hardware   |
| Orion Comprehensive Basic     | Vestibular Examination Unit (Nystagmograph)  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   | Used with Orion Comprehensive chair  |
| Orion Autotraverse Basic      | Vestibular Examination Unit (Nystagmograph)  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   | Used with Orion Autotraverse chair   |
| VF405                         | Vestibular Examination Unit (Nystagmograph)  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   |  |
| VN415                         | Vestibular Examination Unit (Nystagmograph)  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   |  |
| VO425                         | Vestibular Examination Unit (Nystagmograph)  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   |  |

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| Medical device accessory |  |                              |              |                     |   |
|--------------------------|--|------------------------------|--------------|---------------------|---|
| Product name             | Description  | Product category             | Class, rule  | GMDN/CND            | Remarks   |
| 2D-VOG <sub>fw</sub>     | Vestibular Examination Unit  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   | Hardware for:<br>VisualEyes 505; 515;<br>525 and VF405, VN415,<br>VO425, Orion<br>Autotraverse Basic,<br>Orion Comprehensive<br>Basic |
| USBM2.1                  | Vestibular Examination Unit  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   | Hardware for:<br>VisualEyes 505; 515;<br>525, Orion<br>Autotraverse Basic,<br>Orion Comprehensive<br>Basic                            |
| BG4.0                    | Vestibular Examination Unit  | Vestibular Examination Units | Ila, rule 10 | 46390/<br>Z121404   | Hardware for:<br>VisualEyes 505; 515;<br>525, Orion<br>Autotraverse Basic,<br>Orion Comprehensive<br>Basic                            |
| Orion                    | Rotary Chair<br>Version: Reclining                                   | Vestibular Examination Units | Ila, rule 10 | 17217/<br>Z12140403 | Optional hardware for:<br>VisualEyes 515; 525   |
| Orion                    | Rotary Chair<br>Version: Autotraverse<br>(may include built-in EOG)  | Vestibular Examination Units | Ila, rule 10 | 17217/<br>Z12140403 | Optional hardware for:<br>VisualEyes 525, Orion<br>Autotraverse Basic   |
| Orion                    | Rotary Chair<br>Version: Comprehensive<br>(may include built-in EOG) | Vestibular Examination Units | Ila, rule 10 | 17217/<br>Z12140403 | Optional hardware for:<br>VisualEyes 525, Orion<br>Comprehensive Basic  |

Middelfart, 2020-12-14

*Erik Nielsen*

Erik Nielsen, Director, Regulatory & Compliance



# Interacoustics

## EC Declaration of Conformity

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It has been demonstrated that:

**Product:**

Product type: Pediatric Audiometer

Class: IIa

Trademark: Interacoustics

Type No.: PA5

**Manufactured by:**

Name: Interacoustics A/S

Address: Audiometer Allé 1

Area code/Area: 5500 Middelfart

Phone No.: (+45) 63713555

Country: Denmark

Fax No.: (+45) 63713522

**Is in conformity with the following Directives of the European Parliament and of the Council:**

- 93/42/EEC of 14 June 1993, including all amendments, concerning medical devices, fulfilling the essential requirements in appendix I through application of a full quality system according to appendix II.3
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

**The conformity is achieved by the fulfilling of the following main standards:**

- IEC 60601-1:2005 + A1 General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Electromagnetic compatibility – Requirements and tests

**Valid until:** 2023-09-30

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

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

Company: Interacoustics A/S

Address: Audiometer Allé 1

Address: 5500 Middelfart

Phone No.: (+45) 63713555

Country: Denmark

Fax No.: (+45) 63713522

Signature:

Name:

Title:

*Erik Nielsen*

**Erik Nielsen**

**Director, Regulatory & Compliance**

Date:

*2019-10-21*

(YYYY-MM-DD)



# Interacoustics

## EC Declaration of Conformity

It has been demonstrated that:

**Product:**

Product type: Impedance Audiometer

Class: Ila

Trademark: Interacoustics

Type No.: AT235

**Manufactured by:**

Name: **Interacoustics A/S**

Address: **Audiometer Allé 1**

Area code/Area: **5500 Middelfart**

Phone No.: **(+45) 63713555**

Country: **Denmark**

Fax No.: **(+45) 63713522**

Is in conformity with the following Directives of the European Parliament and of the Council:

- 93/42/EEC of 14 June 1993, including all amendments, concerning medical devices, fulfilling the essential requirements in appendix I through application of a full quality system according to appendix II.3
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The conformity is achieved by the fulfilling of the following main standards:

- IEC 60601-1:2005 + A1:2012 General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Electromagnetic disturbances – Requirements and tests

Valid until: 2023-09-30

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

This declaration is made on the sole responsibility of:

Company: **Interacoustics A/S**

Address: **Audiometer Allé 1**

Address: **5500 Middelfart**

Phone No.: **(+45) 63713555**

Country: **Denmark**

Fax No.: **(+45) 63713522**

Signature: *Erik Nielsen*

Name: **Erik Nielsen**

Title: **Director, Regulatory & Compliance**

Date: *2019-03-14*

(YYYY-MM-DD)

  
**Interacoustics**  
5500 Middelfart, Denmark  
[www.interacoustics.com](http://www.interacoustics.com)





# Certificate

No. Q5 044841 0028 Rev. 00

**Holder of Certificate:** **Interacoustics A/S**  
Audiometer Allé 1  
5500 Middelfart  
DENMARK

**Certification Mark:**



**Scope of Certificate:** **Design and development, manufacture, marketing, sales, service and calibration of audiometric equipment, hearing aid analysers, vestibular examination and rehabilitation units and related applied products**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 044841 0028 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 044841 0028 Rev. 00)

**Report No.:** 713213706

**Valid from:** 2021-08-01

**Valid until:** 2024-07-31

**Date,** 2021-07-29

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 044841 0028 Rev. 00

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** **Interacoustics A/S**  
Audiometer Allé 1, 5500 Middelfart, DENMARK

Design and development, production, marketing, sales, distribution,  
servicing and calibration of audiometric equipment, hearing aid analyzers,  
vestibular examination units and related applied products

**DGS Diagnostics Sp. z o. o.**  
ul. Zeusa 2, 72-006 Mierzyn, POLAND

Manufacturing, distribution, service and calibration of audiometric  
equipment, hearing aid analyzers, vestibular examination units and  
instrumentation for rehabilitation of patients with dizziness and balance  
disorders

**DGS Diagnostics A/S**  
Audiometer Allé 1, 5500 Middelfart, DENMARK

Production, servicing and calibration of audiometric equipment, hearing  
aid analyzers, and related applied products

**Micromedical Technologies Inc.**  
10 Kemp Drive, Chatham IL 62629, USA

Manufacture of Vestibular Examination Units: Rotary and Reclining Chairs  
with External Visual Fixation Sources, Caloric Irrigators, Active and  
Passive Head Position Sensors for the Assessment and Rehabilitation of  
Patients with Dizziness and Balance Disorders