

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/ Z121401	
AD226	Diagnostic Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401	
AD229b	Diagnostic Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401	
AD229e	Diagnostic Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401	
AD629	Diagnostic Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401	
AD528	Diagnostic Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401	
PAS	Screening Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401	
AS608	Screening Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401	
Luna	Screening Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401	
AA222	Audiometer and Tympanometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401 and Z12149005	
AT235	Impedance Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z121401 and Z12149005	
MT10	Impedance Audiometer	Audiometric Equipment	Ila, rule 10	63545/ Z12149005	
Titan	Auditory analysis platform	Audiometric Equipment	Ila, rule 10	63545/ Z12149005 and Z12149001	Optional modules: IMP440; WBT; TEOAE440; DPOAE440
Eclipse	Medical PC Platform	Audiometric Equipment	Ila, rule 10	63545/ Z12149001 and Z121403	Optional modules: ABRIS; DPOAE20, TEOAE25; VEMP; ASSR, EP15; EP25; IA OAE Suite
Affinity 2.0	Universal Audio Analyzer Platform	Hearing Aid Analysers; Audiometric Equipment	Ila, rule 10	45241/ Z121401	Optional modules: AC440; REM440; HIT440
Affinity Compact	Universal Audio Analyzer Platform	Hearing Aid Analyzer	Ila, rule 10	45241/ Z12149001	Optional modules: AC440; REM440; HIT440
Equinox 2.0	Universal Audio Analyzer Platform	Audiometer Platform	Ila, rule 10	45241/ Z12149001	Optional modules: AC440; REM440; 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/ Z12149001	
Sera	Auditory analysis platform	Audiometric Equipment	Ila, rule 10	63545/ Z12149001 and Z121403	License: ABRIS; DPOAE; TEOAE
Lyra	Portable otoacoustic Test Device	Audiometric Equipment	Ila, rule 10	63545/ Z12149001	Optional module: IA OAE Suite
EyeSeeCam	Vestibular Examination Unit (Nystagmograph)	Vestibular Examination Units	Ila, rule 10	46390/ 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/ Z12149004	Stand alone and optional hardware for VisualEyes 515, 525
Aqua Stim	Water Caloric irrigator	Vestibular Examination Units	Ila, rule 10	34891/ 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/ Z12149005	Optional module for: Titan
WBT	Impedance Audiometer Module	Audiometric Equipment	Ila, rule 10	63545/ Z12149005	Optional functionality for Titan IMP440
DPOAE440	Distortion Product OAE Module	Audiometric Equipment	Ila, rule 10	63545/ Z12149001	Optional module for: Titan
TEOAE440	Transient OAE Module	Audiometric Equipment	Ila, rule 10	63545/ Z12149001	Optional module for: Titan
ABRIS	Brain Stem Audiometer Module (Evoked response)	Audiometric Equipment	Ila, rule 10	63545/ Z121403	Optional module for: Eclipse
EP15	Brain Stem Audiometer Module	Audiometric Equipment	Ila, rule 10	63545/ Z121403	Optional module for: Eclipse
EP25	Brain Stem Audiometer Module	Audiometric Equipment	Ila, rule 10	63545/ Z121403	Optional module for: Eclipse
ASSR	Diagnostic Module	Audiometric Equipment	Ila, rule 10	63545/ Z121403	Optional module for: Eclipse
DPOAE20	Distortion Product OAE Module	Audiometric Equipment	Ila, rule 10	63545/ Z12149001	Optional module for: Eclipse
TEOAE25	Transient OAE Module	Audiometric Equipment	Ila, rule 10	63545/ 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/ Z121404	Optional module for: Eclipse
IA OAE Suite	Otoacoustic emissions software	Audiometric Equipment	Ila, rule 10	63545/ Z12149001	Optional software for: Eclipse; Lyra
AC440	Clinical Audiometer Module	Audiometric Equipment	Ila, rule 10	45241/ Z121401	Optional module for: Affinity 2.0; Callisto, Equinox
REM440	Real Ear Measurement Module	Hearing Aid Analysers	Ila, rule 10	45241/ Z121401	Optional module for: Affinity 2.0; Callisto; Equinox; Affinity Compact
VisualEyes 505	Vestibular Examination Unit (Nystagmograph)	Vestibular Examination Units	Ila, rule 10	46390/ Z121404	Hardware options: 2D-VOGfw; BG4.0; USBM2.1, Vorteq
VisualEyes 515	Vestibular Examination Unit (Nystagmograph)	Vestibular Examination Units	Ila, rule 10	46390/ 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/ 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/ Z121404	Used with EyeSeeCam hardware
Orion Comprehensive Basic	Vestibular Examination Unit (Nystagmograph)	Vestibular Examination Units	Ila, rule 10	46390/ Z121404	Used with Orion Comprehensive chair
Orion Autotraverse Basic	Vestibular Examination Unit (Nystagmograph)	Vestibular Examination Units	Ila, rule 10	46390/ Z121404	Used with Orion Autotraverse chair
VF405	Vestibular Examination Unit (Nystagmograph)	Vestibular Examination Units	Ila, rule 10	46390/ Z121404	
VN415	Vestibular Examination Unit (Nystagmograph)	Vestibular Examination Units	Ila, rule 10	46390/ Z121404	
VO425	Vestibular Examination Unit (Nystagmograph)	Vestibular Examination Units	Ila, rule 10	46390/ Z121404	

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

Middelfart, 2020-12-14

Erik Nielsen

Erik Nielsen, Director, Regulatory & Compliance

EC Declaration of Conformity

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: IIa

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:

Name:

Erik Nielsen

Title:

Director, Regulatory & Compliance

Date: 2019-03-14

(YYYY-MM-DD)


Interacoustics
5500 Middelfart, Denmark
www.interacoustics.com



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 044841 0025 Rev. 01

Manufacturer:

Interacoustics A/S

Audiometer Allé 1
5500 Middelfart
DENMARK

Facility(ies):

Interacoustics A/S
Audiometer Allé 1, 5500 Middelfart, DENMARK

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

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

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

Product Category(ies): Audiometric Equipment, Hearing Aid Analysers, Vestibular Examination Units

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713157269

Valid from: 2019-11-22

Valid until: 2023-09-30

Date, 2019-11-22

Christoph Dicks
Head of Certification/Notified Body



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

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