



Free Sales Certificate

The Danish Medicines Agency hereby certifies that the company has its registered place of business in Denmark:

Interacoustics A/S
Audiometer Allé 1,
5500 Middelfart
Denmark

Medical devices specified in the attached list which are CE marked in conformity with the Medical Device Regulation (Council Regulation 2017/745) may be marketed in Denmark/EU and exported without any approval from the Danish Medicines Agency.



Valid from: 9 April 2025
Valid to: 9 September 2026

Lise Roving Kristiansen
Student Assistant

Axel Heides Gade 1
DK-2300 København S

T +45 44 88 95 95
F +45 44 88 95 99

med-udstyr@dkma.dk
www.medicinskudstyr.dk



Udstyrsliste/Product list

We have been informed that the products specified below, are manufactured at the site:

DGS Diagnostics Sp. z o. o.
Rosówek 43
72-001 Kolbaskowo
Poland

or

DGS Diagnostics A/S
Audiometer Allé 1
5500 Middelfart
Denmark

On behalf of

Interacoustics A/S
Audiometer Allé 1
5500 Middelfart
Denmark

Product name	Optional modules	Description	Basic UDI number	Notified body certificate number
AC40	N/A	Clinical Audiometer	5711117_8000644_2Z	No. G10 044841 0027 Rev. 00
AD226	N/A	Diagnostic Audiometer	5711117_80000646_37	No. G10 044841 0027 Rev. 00
AD629	N/A	Diagnostic Audiometer	5711117_8519654_9B	No. G10 044841 0027 Rev. 00
AD528	N/A	Diagnostic Audiometer	5711117_8510944_6Q	No. G10 044841 0027 Rev. 00



Udstyrsliste/Product list

PA5	N/A	Screening Audiometer	5711117_80000352_2B	No. G10 044841 0027 Rev. 00
AS608	N/A	Screening Audiometer	5711117_80000355_2L	No. G10 044841 0027 Rev. 00
Luna	N/A	Screening Audiometer	5711117_8522960_7R	No. G10 044841 0027 Rev. 00
Equinox Evo	N/A	Clinical Audiometer	5711117_8533212_6D	No. G10 044841 0027 Rev. 00
AA222	N/A	Audiometer and Tympanometer	5711117_8107329_5F	No. G10 044841 0027 Rev. 00
AT235	N/A	Impedance Audiometer	5711117_8525798_9K	No. G10 044841 0027 Rev. 00
MT10	N/A	Impedance Audiometer	5711117_8100116_26	No. G10 044841 0027 Rev. 00
Titan	IMP440; WBT; TEOAE440; DPOAE440	Auditory analysis platform	5711117_8514941_7T	No. G10 044841 0027 Rev. 00
Eclipse	IA OAE suite (DPOAE20/ TEOAE25); ABRIS; ASSR; EP15/EP25 (VEMP; Aided)	Medical PC Platform	5711117_8507420_6X	No. G10 044841 0027 Rev. 00
Affinity Compact	AC440; REM440; HIT440	Universal Audio Analyzer Platform	Version 1: 5711117_8511426_5U Version 2: 5711117_8511427_5X Version 3: 5711117_8511428_62 Version 4: 5711117_8511429_65	No. G10 044841 0027 Rev. 00



Udstyrsliste/Product list

Callisto	AC440; REM440; HIT 440	Audiometer Platform	5711117_8000361_2D	No. G10 044841 0027 Rev. 00
OtoRead	N/A	Portable Otoacoustic Test Device	5711117_8504335_6B	No. G10 044841 0027 Rev. 00
Sera	ABRIS; DPOAE; TEOAE	Auditory analysis platform	5711117_8107006_47	No. G10 044841 0027 Rev. 00
Lyra	IA OAE Suite	Portable Otoacoustic Test Device	5711117_8507549_8B	No. G10 044841 0027 Rev. 00
EyeSeeCam	N/A	Vestibular Examination Unit (Nystagmograph)	5711117_8508003_6D	No. G10 044841 0027 Rev. 00
Air Fx	N/A	Air Caloric irrigator	5711117_8511044_54	No. G10 044841 0027 Rev. 00
Aqua Stim	N/A	Water Caloric irrigator	5711117_8512136_5P	No. G10 044841 0027 Rev. 00
VisualEyes 505	N/A	Vestibular Examination Unit (Nystagmograph)	5711117_8523237_6R	No. G10 044841 0027 Rev. 00
VisualEyes 515	N/A	Vestibular Examination Unit (Nystagmograph)	5711117_8523238_6U	No. G10 044841 0027 Rev. 00
VisualEyes 525	N/A	Vestibular Examination Unit (Nystagmograph)	5711117_8523241_6C	No. G10 044841 0027 Rev. 00
VisualEyes EyeSeeCam vHIT	N/A	Vestibular Examination Unit (Nystagmograph)	5711117_8523272_6W	No. G10 044841 0027 Rev. 00
Orion Comprehensive Basic	N/A	Vestibular Examination Unit (Nystagmograph)	5711117_8523243_6J	No. G10 044841 0027 Rev. 00



Udstyrsliste/Product list

Orion Autotraverse Basic	N/A	Vestibular Examination Unit (Nystagmograph)	5711117_8523243_6J	No. G10 044841 0027 Rev. 00
2D-VOGfw	N/A	Accessory for vestibular examination unit	5711117_8014831_4S	No. G10 044841 0027 Rev. 00
USBM2.1	N/A	Accessory for vestibular examination unit	5711117_8504096_6P	No. G10 044841 0027 Rev. 00
BG4.0	N/A	Accessory for vestibular examination unit	5711117_8510760_68	No. G10 044841 0027 Rev. 00
Orion Reclining	N/A	Accessory for vestibular examination unit	5711117_8512671_6X	No. G10 044841 0027 Rev. 00
Orion Autotraverse	N/A	Accessory for vestibular examination unit	5711117_8515102_5V	No. G10 044841 0027 Rev. 00
Orion Comprehensive	N/A	Accessory for vestibular examination unit	5711117_8515102_5V	No. G10 044841 0027 Rev. 00
Datalink	N/A	Accessory for vestibular examination unit	5711117_8503756_79	N/A
Vorteq	N/A	Accessory for vestibular examination unit	5711117_8517237_7Q	N/A
TRV	N/A	Rehabilitation chair	5711117_8524196_7Q	N/A
Viot Suite	N/A	Video Otopscope	5711117_8501364_5N	N/A
Touch Keyboard	N/A	Accessory for audiometer	5711117_8534050_6Q	N/A

