

DGS Diagnostics

Declaration of Conformity

We hereby declare that:

Product:

Product name: Ear tip – see details in Appendix A
Intended purpose: Audiometric ear tip
Brand name: Sanibel™
Class.: I
Basic UDI-DI: 5711117_P-0000501_R5

Manufactured by:

Name: DGS Diagnostics A/S
Address: Audiometer Allé 1
Area code/Area: 5500 Middelfart
State/Country: Denmark

SRN: DK-MF-000020570
Phone No.: (+45) 63713555
Fax No.: (+45) 63713522

Is in conformity with the European Regulation (EU) 2017/745.

This declaration is issued on the sole responsibility of:

Company: DGS Diagnostics A/S
Address: Audiometer Allé 1
Address: 5500 Middelfart
State/Country: Denmark
y:

Signature: 
Name: Mette Ambirk
Title: Compliance & Regulatory Affairs Manager

Place: Middelfart

Date: 2023-12-11
(YYYY-MM-DD)

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Appendix A

Ear tips covered by this Declaration of Conformity:

Product name	Catalogue number / REF
Preemie Ear tip	8502837 (25) / 8502838 (100)/ 8517439 (blister pack 10 pcs)
Pediatric OAE ear tips	8102679 (100)
Ear tip, flanged	8012963 (25) / 8012964 (100) / 8100826 (750) 8517442 (blister pack 10 pcs) 8012965 (25) / 8012966 (100) / 8100827 (750) 8517443 (blister pack 10 pcs) 8012967 (25) / 8012968 (100) / 8100828 (750) 8517444 (blister pack 10 pcs)
Ear tip, mushroom	8013001 (25) / 8013002 (100) / 8100816 (750) / 8517446 (blister pack 10 pcs) 8013003 (25) / 8013004 (100) / 8100817 (750) 8012969 (25) / 8012970 (100) / 8100818 (750) / 8529247 (blisterpack 10 pcs) 8012971 (25) / 8012972 (100) / 8100819 (750) 8012973 (25) / 8012974 (100) / 8100820 (750) / 8517448 (blisterpack 10 pcs) 8012975 (25) / 8012976 (100) / 8100821 (750) 8012977 (25) / 8012978 (100)/ 8100822 (750) / / 8517449 (blisterpack 10 pcs) 8012979 (25) / 8012980 (100)/ 8100823 (750) 8012981 (25) / 8012982 (100) / 8100824 (750) 8012983 (25) / 8012984 (100) / 8100825 (750)
Ear tip, umbrella	8012985 (25 pcs) / 8012986 (100 pcs) 8012987 (25 pcs) / 8012988 (100 pcs) 8012989 (25) / 8012990 (100) 8012991 (25) / 8012992 (100) 8012993 (25) / 8012994 (100) 8012995 (25) / 8012996 (100) 8012997 (25) / 8012998 (100) 8012999 (25) / 8013000 (100)
Ear tip, OAE-3 Ear tip, OAE-4	8013005 (25) / 8013006 (100) / 8103437 (750) 8517445 (blister pack 10 pcs) 8002035 (100) / 8002036 (25) / 8103438 (750)
AuDX ear tip	8107885 (100) / 8515505 (20) 8107889 (100) / 8515506 (20) 8107887 (100) / 8515507 (20)
ANA ear tip	8106362 (50) / 8106363 (50) / 8106364 (50)/ 8106365 (50) / 8106366 (50)
AOT ear tip	8106367 (50) / 8516544 (250) 8106368 (50) / 8516545 (250) 8106369 (50) / 8516546 (250) 8106370 (50) / 8516547 (250) 8106371 (50) / 8516548 (250)
Ear tip, infant	8104998 (25) / 8105016 (100) / 8105034 (750) 8104999 (25) / 8105017 (100) / 8105035 (750) 8105000 (25)/8105018 (100)/8105036 (750)
Infant ear tip A	8522758 (100) / 8522759 (25)/ 8522760 (100) / 8522761 (25)

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Infant ear tip C	
Ear tip (3.7 mm, 4 mm, 4.5 mm, 5 mm 4-7 mm)	8105019 (100) / 8105037 (750) / 8105001 (25) 8105002 (25) / 8105020 (100) / 8105038 (750) 8105003 (25) / 8105021 (100) / 8105039 (750) 8105004 (25) / 8105022 (100) / 8105040 (750) 8105005 (25) / 8105023 (100) / 8105041 (750)
Sanibel™ ADI Ear Tip Kit	8511445
Sanibel ADI Scre. Ear Tip Kit	8501572
Assortment Box BET25	8012838
SnapPROBE™ Accessories box	8522461
ADI eartip sample kits	8106925 8522207 8524062