

EU-MDR Declaration of Conformity

Product:

Product name: See Appendix A
Product type: Ear tip
Trademark: Sanibel™
Class: I (Rule 1)
Basic UDI-DI: 5711117_P-0000501_R5

Manufactured by:

| | | | |
|-----------------|----------------------------|------------|-----------------------|
| Name: | DGS Diagnostics A/S | SRN: | To be assigned |
| Address: | Audiometer Allé 1 | Phone No.: | (+45) 63713555 |
| Area code/Area: | 5500 Middelfart | | |
| State/Country: | Denmark | Fax No.: | (+45) 63713522 |

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

This declaration is made on the sole responsibility of:

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

Signature: 
Name: **Flemming Vinding**
Title: **Vice President, Global Quality**

Place: Middelfart

Date: **2022-01-17**
(YYYY-MM-DD)

Appendix A

Ear tips covered by this Declaration of Conformity:

| Product | Item no. |
|------------------------------------|---|
| Preemie Ear tip | 8529255 / 8502837 (25) / 8502838 (100)/ 8517439 (blister pack 10 pcs) |
| OAE ear tip OAE and MT4 ear tip | 8105249 (39422-35-025) / 8105237 (39422-35-100) 8105238 (39422-47-100) / 8105250 (39422-47-025) 8105239 (39422-58-100) / 8105251 (39422-58-025) 8105240 (39422-07-100) / 8105252 (39422-07-025) 8105241 (39422-08-100) 8105253 (39422-08-025) 8105242 (39422-09-100) / 8105254 (39422-09-025) 8105243 (39422-10-100) / 8105255 (39422-10-025) 8105244 (39422-11-100) / 8105256 (39422-11-025) 8105245 (39422-12-100) / 8105257 (39422-12-025) 8105246 (39422-13-100) / 8105258 (39422-13-025) 8105247 (39422-14-100) / 8105259 (39422-14-025) 8105248 (39422-15-100) / 8105260 (39422-15-025) 8105687 (39422-19-100) / 8105688 (39422-19-025) |
| 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 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) 8102679 (100) |
| ANA ear tip | 8529258 / 8106362 (50) / 8529256 / 8106363 (50) / 8529257 / 8106364 (50) / 8529263 / 8106365 (50) / 8529262 / 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 Infant ear tip C | 8508199 / 8522758 (100) / 8522759 (25) 8509180 / 8522760 (100) / 8522761 (25) |
| 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 |
| Assortment BET55 Complete | 8104678 |