



EC – Declaration of Conformity

Manufacturer: GN Hearing A/S
Lautrupbjerg 7
DK-2750 Ballerup
Denmark

Conformity Assessment Procedure: Annex II of Medical Device Directive (MDD) 93/42/EEC
Annex III of Radio and Telecommunications Terminal
Equipment (R&TTE) 1999/5/EC

Identification of Notified Body (MDD): DQS Medizinprodukte GmbH
August-Schanz-Str. 21,
D-60433 Frankfurt am Main, Germany
Notified Body EC Code No. 0297

Identification of EC-certificate (MDD): DQS Med Certificate No. 514627 MR2

Identification of the Device: **Category:** Hearing Instrument
Brand: GN Hearing
Model: Refer to Appendix A

Declaration of Conformity expiry date: 2019-12-31

Classification of the Device (MDD): Class IIa, Rule 9, MDD 93/42/EEC

Applied standards and normative standards:
US: ANSI 63.19-2011, IEC 60601-1-2:2007
MDD: IEC 60118-0:83+A1:94, IEC 60118-7:2005, IEC 60118-13:2011, IEC 60601-2-66:2012
ISO 10993-5:2009, ISO 10993-10:2010, ISO 14971:2007, EN ISO 14971:2012
R&TTE: IEC 60601-2-66:2012, EN/IEC 62479:2010 (Health & Safety)
EN 301 489-17 2.2.1 (EMC), EN 300-328 V1.8.1 (Spectrum)

We, the manufacturer hereby declare that the above-mentioned devices comply with the relevant provisions of the EU Council Directive 93/42/EEC (MDD) Annex I - Essential Requirements and the essential requirements and other relevant requirements of the R&TTE Directive 1999/5/EC and their relevant transpositions into national laws of the Member States in which the above mentioned medical devices are distributed.

Place and Date: Ballerup, 7 July 2016


Peter Bjørnskov-Johansen
Senior Vice President
Global Marketing
GN ReSound A/S


Lars Hagander
Vice President
Corporate Quality
GN ReSound A/S

Doc.: 0270780, Rev. E



Appendix A

The following listed models are compliant to the requirements stated on page 1.

Brand	Family Name	Models	Product Form Factor (PFF)	Brand PFF	Type	GMDN Code
GN Hearing	Merge	PSE1763-DRW, PSE1763-DRPW, PSE1763-DRSW, PSE963-DRW, PSE963-DRPW, PSE963-DRSW, PSE663-DRW, PSE663-DRPW, PSE663-DRSW	SY312e00	05SY312e00	BTE	47169
GN Hearing	Merge	PSE1764-DRW, PSE1764-DRPW, PSE1764-DRSW, PSE964-DRW, PSE964-DRPW, PSE964-DRSW, PSE664-DRW, PSE664-DRPW, PSE664-DRSW	MRIEW00	05MRIEW00	BTE	47169
GN Hearing	Merge	PSE1766-DW, PSE966-DW, PSE666-DW	M60W00	05M60W00	BTE	34671
GN Hearing	Merge	PSE1778-DW, PSE1778-DPW, PSE1778-DPGW, PSE978-DW, PSE978-DPW, PSE978-DPGW, PSE678-DPW, PSE678-DW, PSE678-DPGW	M7080e00	05M7080e00	BTE	34671
GN Hearing	Merge	PSE1785-DGLW, PSE1785-DLW, PSE985-DGLW, PSE985-DLW	LO8500	05LO8500	BTE	34671
GN Hearing	Merge	PSE1735-W, PSE1735-DW, PSE1735-DPW, PSE1735-PW, PSE935-W, PSE935-DW, PSE935-DPW, PSE935-PW, PSE635-W, PSE635-DW, PSE635-DPW, PSE635-PW	PH312W00	05PH312W00	FP/ITE	41209
GN Hearing	Merge	PSE1745-W, PSE1745-DW, PSE1745-DPW, PSE1745-PW, PSE945-W, PSE945-DW, PSE945-DPW, PSE945-PW, PSE645-W, PSE645-DW, PSE645-DPW, PSE645-PW	PH312W00/ PH13W00	05PH312W00/ 05PH13W00	FP/ITE	34672
GN Hearing	Merge	PSE1735-MW, PSE1735-MPW, PSE1735-MUW, PSE935-MW, PSE935-MPW, PSE935-MUW, PSE635-MW, PSE635-MPW, PSE635-MUW	BO312W00/ BO13W00	05BO312W00/ 05BO13W00	FP/ITE	41209
GN Hearing	Merge	TRU363DW, TRU363DPW	SY31200	05SY31200	BTE	47169
GN Hearing	Merge	TRU366DW	M60W00	05M60W00		34671
GN Hearing	Intela-Hear/ ATOM	9288-DW, 7288-DW, 5288-DW	BE8000	05BE8000	BTE	34671
GN Hearing	Intela-Hear/ ATOM	9277-DW, 7277-DW, 5277-DW	BE7000	05BE7000	BTE	34671
GN Hearing	Intela-Hear/ ATOM	9262-DRW, 7262-DRW, 5262-DRW	BRIE00	05BRIE00	BTE	47169
GN Hearing	Intela-Hear/ ATOM	9261-DRW, 7261-DRW, 5261-DRW	VE31200	05VE31200	BTE	47169
GN Hearing	Intela-Hear/ ATOM	92ITE-DW UP, 92ITE-DW HP, 92ITE-DW MP, 72ITE-DW UP, 72ITE-DW HP, 72ITE-DW MP, 52ITE-DW UP, 52ITE-DW HP, 52ITE-DW MP, 92ITE-W UP, 92ITE-W HP, 92ITE-W MP, 72ITE-W UP, 72ITE-W HP, 72ITE-W MP, 52ITE-W UP, 52ITE-W HP, 52ITE-W MP	DA13100	05DAI1300	FP/ITE	34672
GN Hearing	Intela-Hear/ ATOM	92ITC-DW UP, 92ITC-DW HP, 92ITC-DW MP, 92ITC-DW LP, 92ITC-DWE HP, 72ITC-DW UP, 72ITC-DW HP, 72ITC-DW MP, 72ITC-DW LP, 52ITC-DW UP, 52ITC-DW HP, 52ITC-DW MP, 52ITC-DW LP, 92ITC-W UP, 92ITC-W HP, 92ITC-W MP, 72ITC-W LP, 72ITC-W UP, 72ITC-W HP, 72ITC-W MP, 52ITC-W UP, 52ITC-W HP, 52ITC-W MP, 52ITC-W LP	DA13100/ DA312100	05DAI1300/ 05DAI3100	FP/ITE	41209
GN Hearing	Intela-Hear/ ATOM	92MIH-W UP, 92MIH-W HP, 92MIH-W MP, 92MIH-W LP, 72MIH-W UP, 72MIH-W HP, 72MIH-W MP, 72MIH-W LP, 52MIH-W UP, 52MIH-W HP, 52MIH-W MP, 52MIH-W LP	DA13r00/ DA312r00	05DAR1300/ 05DAR3100	FP/ITE	41209
GN Hearing	eMeritus	9288-DW, 7288-DW, 5288-DW	BE8000	05BE8000	BTE	34671
GN Hearing	eMeritus	9277-DW, 7277-DW, 5277-DW	BE7000	05BE7000	BTE	34671
GN Hearing	eMeritus	9262-DRW, 7262-DRW, 5262-DRW	BRIE00	05BRIE00	BTE	47169
GN Hearing	eMeritus	9261-DRW, 7261-DRW, 5261-DRW	VE31200	05VE31200	BTE	47169
GN Hearing	eMeritus	92ITE-DW UP, 92ITE-DW HP, 92ITE-DW MP, 72ITE-DW UP, 72ITE-DW HP, 72ITE-DW MP, 52ITE-DW UP, 52ITE-DW HP, 52ITE-DW MP, 92ITE-W UP, 92ITE-W HP, 92ITE-W MP,	DA13100	05DAI1300	FP/ITE	34672



Brand	Family Name	Models	Product Form Factor (PFF)	Brand PFF	Type	GMDN Code
		72ITE-W UP, 72ITE-W HP, 72ITE-W MP, 52ITE-W UP, 52ITE-W HP, 52ITE-W MP				
GN Hearing	eMeritus	92ITC-DW UP, 92ITC-DW HP, 92ITC-DW MP, 92ITC-DW LP, 92ITC-DWE HP, 72ITC-DW UP, 72ITC-DW HP, 72ITC-DW MP, 72ITC-DW LP, 52ITC-DW UP, 52ITC-DW HP, 52ITC-DW MP, 52ITC-DW LP, 92ITC-W UP, 92ITC-W HP, 92ITC-W MP, 92ITC-W LP, 72ITC-W UP, 72ITC-W HP, 72ITC-W MP, 72ITC-W LP, 52ITC-W UP, 52ITC-W HP, 52ITC-W MP, 52ITC-W LP	DA13i00/ DA312i00	05DAI1300/ 05DAI3100	FP/ITE	41209
GN Hearing	eMeritus	92MIH-W UP, 92MIH-W HP, 92MIH-W MP, 92MIH-W LP, 72MIH-W UP, 72MIH-W HP, 72MIH-W MP, 72MIH-W LP, 52MIH-W UP, 52MIH-W HP, 52MIH-W MP, 52MIH-W LP	DA13r00/ DA312r00	05DAR1300/ 05DAR3100	FP/ITE	41209
GN Hearing	Auris/Øre	9288-DW, 7288-DW, 5288-DW	BE8000	05BE8000	BTE	34671
GN Hearing	Auris/Øre	9277-DW, 7277-DW, 5277-DW	BE7000	05BE7000	BTE	34671
GN Hearing	Auris/Øre	9262-DRW, 7262-DRW, 5262-DRW	BRIE00	05BRIE00	BTE	47169
GN Hearing	Auris/Øre	9261-DRW, 7261-DRW, 5261-DRW	VE31200	05VE31200	BTE	47169
GN Hearing	Auris/Øre	92ITE-DW UP, 92ITE-DW HP, 92ITE-DW MP, 72ITE-DW UP, 72ITE-DW HP, 72ITE-DW MP, 52ITE-DW UP, 52ITE-DW HP, 52ITE-DW MP, 92ITE-W UP, 92ITE-W HP, 92ITE-W MP, 72ITE-W UP, 72ITE-W HP, 72ITE-W MP, 52ITE-W UP, 52ITE-W HP, 52ITE-W MP	DA13i00	05DAI1300	FP/ITE	34672
GN Hearing	Auris/Øre	92ITC-DW UP, 92ITC-DW HP, 92ITC-DW MP, 92ITC-DW LP, 92ITC-DWE HP, 72ITC-DW UP, 72ITC-DW HP, 72ITC-DW MP, 72ITC-DW LP, 52ITC-DW UP, 52ITC-DW HP, 52ITC-DW MP, 52ITC-DW LP, 92ITC-W UP, 92ITC-W HP, 92ITC-W MP, 92ITC-W LP, 72ITC-W UP, 72ITC-W HP, 72ITC-W MP, 72ITC-W LP, 52ITC-W UP, 52ITC-W HP, 52ITC-W MP, 52ITC-W LP	DA13i00/ DA312i00	05DAI1300/ 05DAI3100	FP/ITE	41209
GN Hearing	Auris/Øre	92MIH-W UP, 92MIH-W HP, 92MIH-W MP, 92MIH-W LP, 72MIH-W UP, 72MIH-W HP, 72MIH-W MP, 72MIH-W LP, 52MIH-W UP, 52MIH-W HP, 52MIH-W MP, 52MIH-W LP	DA13r00/ DA312r00	05DAR1300/ 05DAR3100	FP/ITE	41209
GN Hearing	Concept/ Complete	9288-DW, 7288-DW, 5288-DW	BE8000	05BE8000	BTE	34671
GN Hearing	Concept/ Complete	9277-DW, 7277-DW, 5277-DW	BE7000	05BE7000	BTE	34671
GN Hearing	Concept/ Complete	9262-DRW, 7262-DRW, 5262-DRW	BRIE00	05BRIE00	BTE	47169
GN Hearing	Concept/ Complete	9261-DRW, 7261-DRW, 5261-DRW	VE31200	05VE31200	BTE	47169
GN Hearing	Concept/ Complete	92ITE-DW UP, 92ITE-DW HP, 92ITE-DW MP, 72ITE-DW UP, 72ITE-DW HP, 72ITE-DW MP, 52ITE-DW UP, 52ITE-DW HP, 52ITE-DW MP, 92ITE-W UP, 92ITE-W HP, 92ITE-W MP, 72ITE-W UP, 72ITE-W HP, 72ITE-W MP, 52ITE-W UP, 52ITE-W HP, 52ITE-W MP	DA13i00	05DAI1300	FP/ITE	34672
GN Hearing	Concept/ Complete	92ITC-DW UP, 92ITC-DW HP, 92ITC-DW MP, 92ITC-DW LP, 92ITC-DWE HP, 72ITC-DW UP, 72ITC-DW HP, 72ITC-DW MP, 72ITC-DW LP, 52ITC-DW UP, 52ITC-DW HP, 52ITC-DW MP, 52ITC-DW LP, 92ITC-W UP, 92ITC-W HP, 92ITC-W MP, 92ITC-W LP, 72ITC-W UP, 72ITC-W HP, 72ITC-W MP, 72ITC-W LP, 52ITC-W UP, 52ITC-W HP, 52ITC-W MP, 52ITC-W LP	DA13i00/ DA312i00	05DAI1300/ 05DAI3100	FP/ITE	41209
GN Hearing	Concept/ Complete	92MIH-W UP, 92MIH-W HP, 92MIH-W MP, 92MIH-W LP, 72MIH-W UP, 72MIH-W HP, 72MIH-W MP, 72MIH-W LP, 52MIH-W UP, 52MIH-W HP, 52MIH-W MP, 52MIH-W LP	DA13r00/ DA312r00	05DAR1300/ 05DAR3100	FP/ITE	41209
GN Hearing	Optima/ Deuce	9288-DW, 7288-DW, 5288-DW	BE8000	05BE8000	BTE	34671



Brand	Family Name	Models	Product Form Factor (PFF)	Brand PFF	Type	GMDN Code
GN Hearing	Optima/Deuce	9277-DW, 7277-DW, 5277-DW	BE7000	05BE7000	BTE	34671
GN Hearing	Optima/Deuce	9262-DRW, 7262-DRW, 5262-DRW	BRIE00	05BRIE00	BTE	47169
GN Hearing	Optima/Deuce	9261-DRW, 7261-DRW, 5261-DRW	VE31200	05VE31200	BTE	47169
GN Hearing	Optima/Deuce	92ITE-DW UP, 92ITE-DW HP, 92ITE-DW MP, 72ITE-DW UP, 72ITE-DW HP, 72ITE-DW MP, 52ITE-DW UP, 52ITE-DW HP, 52ITE-DW MP, 92ITE-W UP, 92ITE-W HP, 92ITE-W MP, 72ITE-W UP, 72ITE-W HP, 72ITE-W MP, 52ITE-W UP, 52ITE-W HP, 52ITE-W MP	DA13i00	05DAI1300	FP/ITE	34672
GN Hearing	Optima/Deuce	92ITC-DW UP, 92ITC-DW HP, 92ITC-DW MP, 92ITC-DW LP, 92ITC-DWE HP, 72ITC-DW UP, 72ITC-DW HP, 72ITC-DW MP, 72ITC-DW LP, 52ITC-DW UP, 52ITC-DW HP, 52ITC-DW MP, 52ITC-DW LP, 92ITC-W UP, 92ITC-W HP, 92ITC-W MP, 92ITC-W LP, 72ITC-W UP, 72ITC-W HP, 72ITC-W MP, 72ITC-W LP, 52ITC-W UP, 52ITC-W HP, 52ITC-W MP, 52ITC-W LP	DA13i00/ DA312i00	05DAI1300/ 05DAI3100	FP/ITE	41209
GN Hearing	Optima/Deuce	92MIH-W UP, 92MIH-W HP, 92MIH-W MP, 92MIH-W LP, 72MIH-W UP, 72MIH-W HP, 72MIH-W MP, 72MIH-W LP, 52MIH-W UP, 52MIH-W HP, 52MIH-W MP, 52MIH-W LP	DA13r00/ DA312r00	05DAR1300/ 05DAR3100	FP/ITE	41209
GN Hearing	Chime	CH961-DRW	SY312e00	05SY31200	BTE	47169
GN Hearing	Chime	CH962-DRW, CH562-DVIRW	MRIEW00	05MRIEW00	BTE	47169
GN Hearing	Chime	CH967-DW, CH567-DIW	M60W00	05M60W00	BTE	34671
GN Hearing	Chime	CH977-DW, CH988-DW	M7080e00	05M7080e00	BTE	34671
GN Hearing	Chime	CH930-MW, CH930-MPW, CH930-MUW	BO312W00/ BO13W00	05BO312W00/ 05BO13W00	FP/ITE	41209
GN Hearing	Chime	CH950-DW, CH950-DPW, CH950-PW, CH950-W	PH312W00/ PH13W00	05PH312W00/ 05PH13W00	FP/ITE	34672
GN Hearing	Chime	CH561-DRW	SY31200	05SY31200	BTE	47169
GN Hearing	Chime	CH577/88-DVIW	M7080W00	05M7080W00	BTE	34671
GN Hearing	Chime	CH540-DPW, CH540-DW, CH540-PW, CH540-W	PH312W00	05PH312W00	FP/ITE	34672
GN Hearing	Chime	CH550-DPW, CH550-DW, CH550-PW, CH550-W	PH13W00	05PH13W00	FP/ITE	34672
GN Hearing	Chime	CH530-MUW, CH530-MPW, CH530-MW	BO312W00	05BO312W00	FP/ITE	41209
GN Hearing	Chime	CH550-MUW, CH550-MPW, CH550-MW	BO13W00	05BO13W00	FP/ITE	41209