

EC – Declaration of Conformity

Manufacturer: Beltone 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. 283130 MR2

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

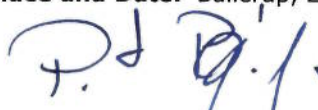
Declaration of Conformity expiry date: 2019-12-31

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
R&TTE: IEC 60601-2-66:2012, EN/(IEC) 62311:2008 (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, 25 January 2016



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



Lars Hagander
Vice President
Corporate Quality
GN ReSound A/S

Doc.: 0267020, Rev. F

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
Beltone	Ally	AY486-DW, AY386-DW, AY286-DW	M7080e00	02M7080e00	BTE	34671
Beltone	Ally	AY476-DW, AY376-DW, AY276-DW	M7080e00	02M7080e00	BTE	34671
Beltone	Ally	AY464-DRW, AY364-DRW	MRIEW00	02MRIEW00	BTE	47169
Beltone	Ally	AY466-DRW, AY366-DRW	M60W00	02M60W00	BTE	34671
Beltone	Ally	AY4ITE-DW UP, AY4ITE-DW HP, AY4ITE-DW MP AY3ITE-DW UP, AY3ITE-DW HP, AY3ITE-DW MP AY2ITE-DW UP, AY2ITE-DW HP, AY2ITE-DW MP AY4ITE-W UP, AY4ITE-W HP, AY4ITE-W MP AY3ITE-W UP, AY3ITE-W HP, AY3ITE-W MP AY2ITE-W UP, AY2ITE-W HP, AY2ITE-W MP	DA13i00/ DA312i00	02D011300/ 02D013100	FP/ITE	34672
Beltone	Ally	AY4ITC-DW UP, AY4ITC-DW HP, AY4ITC-DW MP, AY4ITC-DW LP, AY3ITC-DW UP, AY3ITC-DW HP, AY3ITC-DW MP, AY3ITC-DW LP, AY2ITC-DW UP, AY2ITC-DW HP, AY2ITC-DW MP, AY2ITC-DW LP, AY4ITC-W UP, AY4ITC-W HP, AY4ITC-W MP, AY4ITC-W LP, AY3ITC-W UP, AY3ITC-W HP, AY3ITC-W MP, AY3ITC-W LP, AY2ITC-W UP, AY2ITC-W HP, AY2ITC-W MP, AY2ITC-W LP	DA13i00/ DA312i00	02D011300/ 02D013100	FP/ITE	41209
Beltone	Boost	BOS1795-DW, BOS995-DW, BOS695-DW	LO9000	02LO9000	BTE	34671
Beltone	Boost Plus	BOP1795-DW, BOP995-DW, BOP695-DW	LO9000	02LO9000	BTE	34671
Beltone	Boost Plus	BOP1786-DW, BOP986-DW, BOP686-DW	BE8000	02B008000	BTE	34671
Beltone	First	F11763-DRW, F11763-DRPW, F11763-DRSW, F11763-DRUW, F1963-DRW, F1963-DRPW, F1963-DRSW, F1963-DRUW, F1663-DRW, F1663-DRPW, F1663-DRSW, F1663-DRUW	VE31200	02V031200	BTE	47169
Beltone	First	F11778-DW, F11778-DPW, F1978-DW, F1978-DPW, F1678-DW, F1678-DPW	LO8500	02LO8500	BTE	34671
Beltone	Legend	LND1786-DW, LND986-DW, LND686-DW	BE8000	02B008000	BTE	34671
Beltone	Legend	LND1776-DW, LND976-DW, LND676-DW	BE7000	02B007000	BTE	34671
Beltone	Legend	LND1764-DRW, LND964-DRW, LND664-DRW	BRIE00	02B00100	BTE	47169
Beltone	Legend	LND1763-DRW, LND963-DRW, LND663-DRW	VE31200	02V031200	BTE	47169
Beltone	Legend	LND17ITE-DW UP, LND17ITE-DW HP, LND17ITE-DW MP, LND9ITE-DW UP, LND9ITE-DW HP, LND9ITE-DW MP, LND6ITE-DW UP, LND6ITE-DW HP, LND6ITE-DW MP, LND17ITE-W UP, LND17ITE-W HP, LND17ITE-W MP, LND9ITE-W UP, LND9ITE-W HP, LND9ITE-W MP, LND6ITE-W UP, LND6ITE-W HP, LND6ITE-W MP	DA13i00	02D011300	FP/ITE	34672
Beltone	Legend	LND17ITC-DW UP, LND17ITC-DW HP, LND17ITC-DW MP, LND17ITC-DW LP, LND9ITC-DW UP, LND9ITC-DW HP, LND9ITC-DW MP, LND9ITC-DW LP, LND6ITC-DW UP, LND6ITC-DW HP, LND6ITC-DW MP, LND6ITC-DW LP, LND17ITC-W UP, LND17ITC-W HP, LND17ITC-W MP, LND17ITC-W LP, LND9ITC-W UP, LND9ITC-W HP, LND9ITC-W MP, LND9ITC-W LP, LND6ITC-W UP, LND6ITC-W HP, LND6ITC-W MP, LND6ITC-W LP	DA13i00/ DA312i00	02D011300/ 02D013100	FP/ITE	41209
Beltone	Legend	LND17MIH-W UP, LND17MIH-W HP, LND17MIH-W MP, LND17MIH-W LP, LND9MIH-W UP, LND9MIH-W HP, LND9MIH-W MP, LND9MIH-W LP, LND6MIH-W UP, LND6MIH-W HP, LND6MIH-W MP, LND6MIH-W LP	DA13r00/ DA312r00	02D001300/ 02D003100	FP/ITE	41209
Beltone	Promise	PSE1763-DRW, PSE1763-DRPW, PSE1763-DRSW, PSE963-DRW, PSE963-DRPW, PSE963-DRSW, PSE663-DRW, PSE663-DRPW, PSE663-DRSW	SY312e00	02SY312e00	BTE	47169
Beltone	Promise	PSE1764-DRW, PSE1764-DRPW, PSE1764-DRSW, PSE964-DRW, PSE964-DRPW, PSE964-DRSW, PSE664-DRW, PSE664-DRPW, PSE664-DRSW	MRIEW00	02MRIEW00	BTE	47169
Beltone	Promise	PSE1766-DW, PSE966-DW, PSE666-DW	M60W00	02M60W00	BTE	34671
Beltone	Promise	PSE1778-DW, PSE1778-DPW, PSE978-DW, PSE978-DPW, PSE678-DPW, PSE678-DW	M7080e00	02M7080e00	BTE	34671

Brand	Family Name	Models	Product Form Factor (PFF)	Brand PFF	Type	GMDN Code
Beltona	Promise	PSE1785-DGLW, PSE1785-DLW, PSE985-DGLW, PSE985-DLW	LO8500	02LO8500	BTE	34671
Beltona	Promise	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	02PH312W00	FP/ITE	41209
Beltona	Promise	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	02PH312W00/ 02PH13W00	FP/ITE	34672
Beltona	Promise	PSE1735-MW, PSE1735-MPW, PSE1735-MUW, PSE935-MW, PSE935-MPW, PSE935-MUW, PSE635-MW, PSE635-MPW, PSE635-MUW	BO312W00/ BO13W00	02BO312W00/ 02BO13W00	FP/ITE	41209
Beltona	True	TRU1763DW, TRU1763DW HPG, TRU663DW, TRU663DW HPG, TRU963DW, TRU963DW HPG, TRU363DW, TRU363DPW	SY31200	02SY31200	BTE	47169
Beltona	Silk	SLK1786-DW, SLK986-DW, SLK686-DW	BE8000	02B008000	BTE	34671
Beltona	Silk	SLK1776-DW, SLK976-DW, SLK676-DW	BE7000	02B007000	BTE	34671
Beltona	Silk	SLK1764-DRW, SLK964-DRW, SLK664-DRW	BRIE00	02B00100	BTE	47169
Beltona	Silk	SLK1763-DRW, SLK963-DRW, SLK663-DRW	VE31200	02V031200	BTE	47169
Beltona	Silk	SLK17ITE-DW UP, SLK17ITE-DW HP, SLK17ITE-DW MP, SLK9ITE-DW UP, SLK9ITE-DW HP, SLK9ITE-DW MP, SLK6ITE-DW UP, SLK6ITE-DW HP, SLK6ITE-DW MP, SLK17ITE-W UP, SLK17ITE-W HP, SLK17ITE-W MP, SLK9ITE-W UP, SLK9ITE-W HP, SLK9ITE-W MP, SLK6ITE-W UP, SLK6ITE-W HP, SLK6ITE-W MP	DA13i00	02D011300	FP/ITE	34672
Beltona	Silk	SLK17ITC-DW UP, SLK17ITC-DW HP, SLK17ITC-DW MP, SLK9ITC-DW UP, SLK9ITC-DW HP, SLK9ITC-DW MP, SLK6ITC-DW UP, SLK6ITC-DW HP, SLK6ITC-DW MP, SLK6ITC-DW LP, SLK17ITC-W UP, SLK17ITC-W HP, SLK17ITC-W MP, SLK9ITC-W UP, SLK9ITC-W HP, SLK9ITC-W MP, SLK6ITC-W UP, SLK6ITC-W HP, SLK6ITC-W MP, SLK6ITC-W LP	DA13i00 DA312i00	02D011300 02D013100	FP/ITE	41209
Beltona	Silk	SLK17MIH-W UP, SLK17MIH-W HP, SLK17MIH-W MP, SLK17MIH-W LP, SLK9MIH-W UP, SLK9MIH-W HP, SLK9MIH-W MP, SLK9MIH-W LP, SLK6MIH-W UP, SLK6MIH-W HP, SLK6MIH-W MP, SLK6MIH-W LP	DA13r00 DA312r00	02D001300 02D003100	FP/ITE	41209
Beltona	Taurus	TRS175D	M7080e00	02M7080e00	BTE	34671
Beltona	Taurus	TRS165D	M60W00	02M60W00	BTE	34671
Beltona	Taurus	TRS135P	PH312W00	02PH312W00	FP/ITE	41209
Beltona	True	TRU1764DW, TRU1764DPW, TRU964DW, TRU964DPW, TRU664DW, TRU664DPW	MRIEW00	02MRIEW00	BTE	47169
Beltona	True	TRU1766DW, TRU966DW, TRU666DW, TRU366DW	M60W00	02M60W00		34671
Beltona	True	TRU1778DW, TRU1778DPW, TRU978DW, TRU978DPW, TRU678DW, TRU678DPW, TRU378DW, TRU378DPW	M7080W00	02M7080W00	BTE	34671
Beltona	True	TRU1735W, TRU1735DW, TRU1735PW, TRU1735DPW, TRU935W, TRU935DW, TRU935PW, TRU935DPW, TRU635W, TRU635DW, TRU635PW, TRU635DPW	PH312W00	02PH312W00	FP/ITE	41209
Beltona	True	TRU1745W, TRU1745DW, TRU1745PW, TRU1745DPW, TRU945W, TRU945DW, TRU945PW, TRU945DPW, TRU645W, TRU645DW, TRU645PW, TRU645DPW	PH13W00	02PH13W00	FP/ITE	34671
Beltona	True	TRU1735MW, TRU1735MPW, TRU1735MUW, TRU935MW, TRU935MPW, TRU935MUW, TRU635MW, TRU635MPW, TRU635MUW	BO312W00	02BO312W00	FP/ITE	41209