



## EC - Declaration of Conformity

<b>Manufacturer:</b>	Beltonetm A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark	
<b>Conformity Assessment Procedure (MDD):</b>	Annex II of Medical Device Directive (MDD) 93/42/EEC	
<b>Conformity Assessment Procedure (RED):</b>	Annex II of Radio Equipment Directive (RED) 2014/53/EU	
<b>Identification of Notified Body (MDD):</b>	DQS Medizinprodukte GmbH August-Schanz-Str. 21, D-60433 Frankfurt am Main, Germany Notified Body EC Code No. 0297	
<b>Identification of the EC-certificate (MDD):</b>	DQS Med Certificate No. 283130 MR2	
<b>Identification of the Device:</b>	<b>Category:</b>	Hearing instrument
	<b>Brand:</b>	Refer to Appendix A
	<b>Model:</b>	Refer to Appendix A
<b>Declaration of Conformity expiry date:</b>	2022-12-23	
<b>Classification of the Device (MDD):</b>	<b>BTE:</b>	Class IIa, Rule 5 and 9

### Applied standards and normative standards:

MDD: EN/(IEC) 60118-0:2015, EN/(IEC) 60118-7:2005, EN 60601-1-2:2015,  
ISO 10993-1:2018, IEC 60118-13:2016, EN ISO 14971:2012

RED: Health & Safety: EN 62311:2008, EN 62479:2010;  
EMC: EN 301 489-17 V3.2.0, EN 301 489-1 V2.2.0;  
Spectrum: EN 300 328 V2.1.1, EN 300 422-4 V2.1.1

RoHS: EN 50581:2012, EN 62321-1:2013

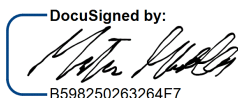
Other: ANSI 63.19-2011, ISO 14971:2007, IEC 60601-1-2: 2014, IEC 60118-13:2011

We, the manufacturer hereby declare that the above-mentioned devices comply with the relevant provisions of:

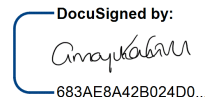
- EU Council Directive 93/42/EEC (MDD) Annex I - Essential Requirements;
- EU Council Directive 2014/53/EU (RED) Article 3 - Essential Requirements;
- EU Council Directive 2011/65/EU (RoHS);

and their relevant transpositions into national laws of the Member States in which the above-mentioned devices are distributed.

### Place and Date: Ballerup, 2020-08-14

DocuSigned by:  
  
B598250263264F7...

**Morten Henneveld**  
Senior Vice President  
Business Transformation & Strategy  
Beltonetm A/S

DocuSigned by:  
  
683AE8A42B024D0...

**Amarjit Kaur Gill**  
Vice President  
Corporate Quality  
Beltonetm A/S

Doc.: 0267020, Rev.R



## Appendix A

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

Receiver-In-The-Ear Hearing Aids as noted under GMDN code 47169 are compliant to the requirements stated on page 1 when receiver tube has been mounted on the device.

Brand	Family Name	Models	Product Form Factor (PFF)	Type	GMDN Code
Beltonetm	Ally	AY4ITE-W-UP, AY4ITE-W-MP, AY4ITE-W-HP, AY4ITE-DW-UP, AY4ITE-DW-MP, AY4ITE-DW-HP, AY4ITC-W-UP, AY4ITC-W-MP, AY4ITC-W-LP, AY4ITC-W-HP, AY4ITC-DW-UP, AY4ITC-DW-MP, AY4ITC-DW-LP, AY4ITC-DW-HP, AY3ITE-W-UP, AY3ITE-W-MP, AY3ITE-W-HP, AY3ITE-DW-UP, AY3ITE-DW-MP, AY3ITE-DW-HP, AY3ITC-W-UP, AY3ITC-W-MP, AY3ITC-W-LP, AY3ITC-W-HP, AY3ITC-DW-UP, AY3ITC-DW-MP, AY3ITC-DW-LP, AY3ITC-DW-HP, AY2ITE-W-UP, AY2ITE-W-MP, AY2ITE-W-HP, AY2ITE-DW-UP, AY2ITE-DW-MP, AY2ITE-DW-HP, AY2ITC-W-UP, AY2ITC-W-MP, AY2ITC-W-LP, AY2ITC-W-HP, AY2ITC-DW-UP, AY2ITC-DW-MP, AY2ITC-DW-LP, AY2ITC-DW-HP	DA13i 00/DA312i 00	ITE	34672
Beltonetm	Ally	AY466-DW, AY366-DW	M60 00	BTE	34671
Beltonetm	Ally	AY486-DW, AY476-DW, AY386-DW, AY376-DW, AY286-DW, AY276-DW	M7080E 00	BTE	34671
Beltonetm	Ally	AY464-DRW, AY364-DRW	MRIE 00	BTE	47169
Beltonetm	Amaze	AMZ966-DWT, AMZ666-DWT, AMZ1766-DWT	BEB60 02	BTE	34671
Beltonetm	Amaze	AMZ976-DWT, AMZ676-DWT, AMZ1776-DWT	BEB70 02	BTE	34671
Beltonetm	Amaze	AMZ986-DWT, AMZ686-DWT, AMZ1786-DWT	BEB80 02	BTE	34671
Beltonetm	Amaze	AMZ964-DRWT, AMZ964-DRW, AMZ664-DRWT, AMZ664-DRW, AMZ1764-DRWT, AMZ1764-DRW	BER13 02	BTE	47169
Beltonetm	Amaze	AMZ9ITC-DW-UP, AMZ9ITC-DW-MP, AMZ9ITC-DW-LP, AMZ9ITC-DW-HP, AMZ6ITC-DW-UP, AMZ6ITC-DW-MP, AMZ6ITC-DW-LP, AMZ6ITC-DW-HP, AMZ17ITC-DW-UP, AMZ17ITC-DW-MP, AMZ17ITC-DW-LP, AMZ17ITC-DW-HP	CSI12 02/CSI13 02	ITE	41209
Beltonetm	Amaze	AMZ9ITC-DWT-UP, AMZ9ITC-DWT-MP, AMZ9ITC-DWT-HP, AMZ6ITC-DWT-UP, AMZ6ITC-DWT-MP, AMZ6ITC-DWT-HP, AMZ17ITC-DWT-UP, AMZ17ITC-DWT-MP, AMZ17ITC-DWT-HP	CSI12 02	ITE	41209
Beltonetm	Amaze	AMZ9ITE-DWT-UP, AMZ9ITE-DWT-MP, AMZ9ITE-DWT-HP, AMZ6ITE-DWT-UP, AMZ6ITE-DWT-MP, AMZ6ITE-DWT-HP, AMZ17ITE-DWT-UP, AMZ17ITE-DWT-MP, AMZ17ITE-DWT-HP	CSI12 02/CSI13 02	ITE	34672
Beltonetm	Amaze	AMZ9ITE-DW-UP, AMZ9ITE-DW-MP, AMZ9ITE-DW-HP, AMZ6ITE-DW-UP, AMZ6ITE-DW-MP, AMZ6ITE-DW-HP, AMZ17ITE-DW-UP, AMZ17ITE-DW-MP, AMZ17ITE-DW-HP	CSI13 02	ITE	34672



Brand	Family Name	Models	Product Form Factor (PFF)	Type	GMDN Code
Beltone	Amaze	AMZ9CIC-W-UP, AMZ9CIC-W-MP, AMZ9CIC-W-LP, AMZ9CIC-W-HP, AMZ6CIC-W-UP, AMZ6CIC-W-MP, AMZ6CIC-W-LP, AMZ6CIC-W-HP, AMZ17CIC-W-UP, AMZ17CIC-W-MP, AMZ17CIC-W-LP, AMZ17CIC-W-HP	CSX10 02	ITE	41209
Beltone	Amaze	AMZ9MIH-WT-UP, AMZ9MIH-WT-MP, AMZ9MIH-WT-HP, AMZ9MIH-W-UP, AMZ9MIH-W-MP, AMZ9MIH-W-HP, AMZ6MIH-WT-UP, AMZ6MIH-WT-MP, AMZ6MIH-WT-HP, AMZ6MIH-W-UP, AMZ6MIH-W-MP, AMZ6MIH-W-HP, AMZ17MIH-WT-UP, AMZ17MIH-WT-MP, AMZ17MIH-WT-HP, AMZ17MIH-W-UP, AMZ17MIH-W-MP, AMZ17MIH-W-HP	CSX12 02/CSX13 02	ITE	41209
Beltone	Amaze	AMZ963-DRWC, AMZ663-DRWC, AMZ1763-DRWC	LXR45 02	BTE	47169
Beltone	Amaze	AMZ963-DRW, AMZ663-DRW, AMZ1763-DRW	VER12 02	BTE	47169
Beltone	Boost	BOS995-DW, BOS695-DW, BOS1795-DW	LO90 00	BTE	34671
Beltone	Boost Max	BBM986-DWH, BBM686-DWH, BBM1786-DWH	BE80 01	BTE	34671
Beltone	Boost Max	BBM995-DW, BBM695-DW, BBM1795-DW	LO90 01	BTE	34671
Beltone	Boost Plus	BOP986-DW, BOP686-DW, BOP1786-DW	BE80 00	BTE	34671
Beltone	Boost Plus	BOP995-DW, BOP695-DW, BOP1795-DW	LO90 00	BTE	34671
Beltone	Boost Ultra	BBU986-DWHT, BBU686-DWHT, BBU1786-DWHT	BEB80 02	BTE	34671
Beltone	Boost Ultra	BBU995-DWT, BBU695-DWT, BBU1795-DWT	LOB90 02	BTE	34671
Beltone	First	FI978-DW, FI978-DPW, FI678-DW, FI678-DPW, FI1778-DW, FI1778-DPW	LO85 00	BTE	34671
Beltone	First	FI963-DRW, FI963-DRUW, FI963-DRSW, FI963-DRPW, FI663-DRW, FI663-DRUW, FI663-DRSW, FI663-DRPW, FI1763-DRW, FI1763-DRUW, FI1763-DRSW, FI1763-DRPW	VE312 00	BTE	47169
Beltone	Imagine	<b>IMG963-DRW, IMG663-DRW, IMG463-DRW, IMG1763-DRW</b>	CAR12A 03	BTE	47169
Beltone	Imagine	<b>IMG964-DRW, IMG664-DRW, IMG464-DRW, IMG1764-DRW</b>	CAR13A 03	BTE	47169
Beltone	Imagine	<b>IMG963-DRWC, IMG663-DRWC, IMG463-DRWC, IMG1763-DRWC</b>	CAR46A 03	BTE	47169
Beltone	Legend	LND976-DW, LND676-DW, LND1776-DW	BE70 00	BTE	34671
Beltone	Legend	LND986-DW, LND686-DW, LND1786-DW	BE80 00	BTE	34671
Beltone	Legend	LND964-DRW, LND664-DRW, LND1764-DRW	BRIE 00	BTE	47169
Beltone	Legend	LND9ITE-W UP, LND9ITE-W MP, LND9ITE-W HP, LND9ITE-DW UP, LND9ITE-DW MP, LND9ITE-DW HP, LND6ITE-W UP, LND6ITE-W MP, LND6ITE-W HP, LND6ITE-DW UP, LND6ITE-DW MP, LND6ITE-DW HP, LND17ITE-W MP, LND17ITE-W HP, LND17ITE-DW UP, LND17ITE-DW MP, LND17ITE-DW HP, LND17ITE-W UP	DA13i 00	ITE	34672
Beltone	Legend	LND9ITC-W UP, LND9ITC-W MP, LND9ITC-W LP, LND9ITC-W HP, LND9ITC-DW UP, LND9ITC-DW MP, LND9ITC-DW LP, LND9ITC-DW HP, LND6ITC-W UP, LND6ITC-W MP, LND6ITC-W LP, LND6ITC-W HP,	DA13i 00/DA312i 00	ITE	41209



Brand	Family Name	Models	Product Form Factor (PFF)	Type	GMDN Code
		LND6ITC-DW UP, LND6ITC-DW MP, LND6ITC-DW LP, LND6ITC-DW HP, LND17ITC-W UP, LND17ITC-W MP, LND17ITC-W LP, LND17ITC-W HP, LND17ITC-DW UP, LND17ITC-DW MP, LND17ITC-DW LP, LND17ITC-DW HP			
Beltone	Legend	LND9MIH-W UP, LND9MIH-W MP, LND9MIH-W LP, LND9MIH-W HP, LND6MIH-W UP, LND6MIH-W MP, LND6MIH-W LP, LND6MIH-W HP, LND17MIH-W UP, LND17MIH-W MP, LND17MIH-W LP, LND17MIH-W HP	DA13r 00/DA312r 00	ITE	41209
Beltone	Legend	LND963-DRW, LND663-DRW, LND1763-DRW	VE312 00	BTE	47169
Beltone	Promise	PSE935-MW, PSE935-MUW, PSE935-MPW, PSE635-MW, PSE635-MUW, PSE635-MPW, PSE1735-MW, PSE1735-MUW, PSE1735-MPW	BO312 00/BO13 00	FP/ITE	41209
Beltone	Promise	PSE985-DLW, PSE985-DGLW, PSE1785-DLW, PSE1785-DGLW	LO85 00	BTE	34671
Beltone	Promise	PSE966-DW, PSE666-DW, PSE1766-DW	M60 00	BTE	34671
Beltone	Promise	PSE978-DW, PSE978-DPW, PSE678-DW, PSE678-DPW, PSE1778-DW, PSE1778-DPW	M7080E 00	BTE	34671
Beltone	Promise	PSE964-DRW, PSE964-DRSW, PSE964-DRPW, PSE664-DRW, PSE664-DRSW, PSE664-DRPW, PSE1764-DRW, PSE1764-DRSW, PSE1764-DRPW	MR1E 00	BTE	47169
Beltone	Promise	PSE935-W, PSE935-PW, PSE935-DW, PSE935-DPW, PSE635-PW, PSE635-DW, PSE635-DPW, PSE1735-W, PSE1735-PW, PSE1735-DW, PSE1735-DPW	PH312 00	FP/ITE	41209
Beltone	Promise	PSE945-W, PSE945-PW, PSE945-DW, PSE945-DPW, PSE645-W, PSE645-PW, PSE645-DW, PSE645-DPW, PSE1745-W, PSE1745-PW, PSE1745-DW, PSE1745-DPW	PH312 00/PH13 00	FP/ITE	34672
Beltone	Promise	PSE963-DRW, PSE963-DRSW, PSE963-DRPW, PSE663-DRW, PSE663-DRSW, PSE663-DRPW, PSE1763-DRW, PSE1763-DRSW, PSE1763-DRPW	SY312E 00	BTE	47169
Beltone	Silk	SLK976-DW, SLK676-DW, SLK1776-DW	BE70 00	BTE	34671
Beltone	Silk	SLK986-DW, SLK686-DW, SLK1786-DW	BE80 00	BTE	34671
Beltone	Silk	SLK964-DRW, SLK664-DRW, SLK1764-DRW	BRIE 00	BTE	47169
Beltone	Silk	SLK9ITE-W UP, SLK9ITE-W MP, SLK9ITE-W HP, SLK9ITE-DW UP, SLK9ITE-DW MP, SLK9ITE-DW HP, SLK6ITE-W UP, SLK6ITE-W MP, SLK6ITE-W HP, SLK6ITE-DW UP, SLK6ITE-DW MP, SLK6ITE-DW HP, SLK17ITE-W MP, SLK17ITE-W HP, SLK17ITE-DW UP, SLK17ITE-DW MP, SLK17ITE-DW HP, SLK17IITE-W UP	DA13i 00	ITE	34672
Beltone	Silk	SLK9ITC-W UP, SLK9ITC-W MP, SLK9ITC-W LP, SLK9ITC-W HP, SLK9ITC-DW UP, SLK9ITC-DW MP, SLK9ITC-DW LP, SLK9ITC-DW HP, SLK6ITC-W UP, SLK6ITC-W MP, SLK6ITC-W LP, SLK6ITC-W HP, SLK6ITC-DW UP, SLK6ITC-DW MP,	DA13i 00/DA312i 00	ITE	41209



Brand	Family Name	Models	Product Form Factor (PFF)	Type	GMDN Code
		SLK6ITC-DW LP, SLK6ITC-DW HP, SLK17ITC-W UP, SLK17ITC-W MP, SLK17ITC-W LP, SLK17ITC-W HP, SLK17ITC-DW UP, SLK17ITC-DW MP, SLK17ITC-DW LP, SLK17ITC-DW HP			
Beltone	Silk	SLK9MIH-W UP, SLK9MIH-W MP, SLK9MIH-W LP, SLK9MIH-W HP, SLK6MIH-W UP, SLK6MIH-W MP, SLK6MIH-W LP, SLK6MIH-W HP, SLK17MIH-W UP, SLK17MIH-W MP, SLK17MIH-W LP, SLK17MIH-W HP	DA13r 00/DA312r 00	ITE	41209
Beltone	Silk	SLK963-DRW, SLK663-DRW, SLK1763-DRW	VE312 00	BTE	47169
Beltone	Taurus	TRS165D	M60 00	BTE	34671
Beltone	Taurus	TRS175D	M7080E 00	BTE	34671
Beltone	Taurus	TRS135P	PH312 00	FP/ITE	41209
Beltone	True	TRU935MW, TRU935MUW, TRU935MPW, TRU635MW, TRU635MUW, TRU635MPW, TRU1735MW, TRU1735MUW, TRU1735MPW	BO312 00	FP/ITE	41209
Beltone	True	TRU966DW, TRU666DW, TRU366DW, TRU1766DW	M60 00	BTE	34671
Beltone	True	TRU978DW, TRU978DPW, TRU678DW, TRU678DPW, TRU378DW, TRU378DPW, TRU1778DW, TRU1778DPW	M7080 00	BTE	34671
Beltone	True	TRU964DW, TRU964DPW, TRU66DPW, TRU664DW, TRU1764DW, TRU1764DPW	MRIE 00	BTE	47169
Beltone	True	TRU945W, TRU945PW, TRU945DW, TRU945DPW, TRU645W, TRU645PW, TRU645DW, TRU645DPW, TRU1745W, TRU1745PW, TRU1745DW, TRU1745DPW	PH13 00	FP/ITE	34672
Beltone	True	TRU935W, TRU935PW, TRU935DW, TRU935DPW, TRU635W, TRU635PW, TRU635DW, TRU635DPW, TRU1735W, TRU1735PW, TRU1735DW, TRU1735DPW	PH312 00	FP/ITE	41209
Beltone	True	TRU963DW HPG, TRU963DW, TRU663DW HPG, TRU663DW, TRU363DW, TRU363DPW, TRU1763DW HPG, TRU1763DW	SY312 00	BTE	47169
Beltone	Trust	TST966-DW, TST666-DW, TST1766-DW	BE60 01	BTE	34671
Beltone	Trust	TST976-DW, TST676-DW, TST1776-DW	BE70 01	BTE	34671
Beltone	Trust	TST986-DW, TST686-DW, TST1786-DW	BE80 01	BTE	34671
Beltone	Trust	TST964-DRW, TST664-DRW, TST1764-DRW	BRIE 01	BTE	47169
Beltone	Trust	TST9ITE-W-UP, TST9ITE-W-MP, TST9ITE-W-HP, TST9ITE-DW-UP, TST9ITE-DW-MP, TST9ITE-DW-HP, TST6ITE-W-UP, TST6ITE-W-MP, TST6ITE-W-HP, TST6ITE-DW-UP, TST6ITE-DW-MP, TST6ITE-DW-HP, TST17ITE-W-UP, TST17ITE-W-MP, TST17ITE-W-HP, TST17ITE-DW-UP, TST17ITE-DW-MP, TST17ITE-DW-HP	DA13i 01	ITE	34672
Beltone	Trust	TST9ITC-W-UP, TST9ITC-W-MP, TST9ITC-W-LP, TST9ITC-W-HP, TST9ITC-DW-UP, TST9ITC-DW-MP, TST9ITC-DW-LP, TST9ITC-DW-HP, TST6ITC-W-UP, TST6ITC-W-MP,	DA13i 01/DA312i 01	ITE	41209



Brand	Family Name	Models	Product Form Factor (PFF)	Type	GMDN Code
		TST6ITC-W-LP, TST6ITC-W-HP, TST6ITC-DW-UP, TST6ITC-DW-MP, TST6ITC-DW-LP, TST6ITC-DW-HP, TST17ITC-W-UP, TST17ITC-W-MP, TST17ITC-W-LP, TST17ITC-W-HP, TST17ITC-DW-UP, TST17ITC-DW-MP, TST17ITC-DW-LP, TST17ITC-DW-HP			
Beltone	Trust	TST9MIH-W-UP, TST9MIH-W-MP, TST9MIH-W-LP, TST9MIH-W-HP, TST6MIH-W-UP, TST6MIH-W-MP, TST6MIH-W-LP, TST6MIH-W-HP, TST17MIH-W-UP, TST17MIH-W-MP, TST17MIH-W-LP, TST17MIH-W-HP	DA13r 01/DA312r 01	ITE	41209
Beltone	Trust	TST963-DRWZ UP, TST963-DRWZ MP, TST963-DRWZ LP, TST963-DRWZ HP, TST963-DRW, TST663-DRWZ UP, TST663-DRWZ MP, TST663-DRWZ LP, TST663-DRWZ HP, TST663-DRW, TST1763-DRWZ UP, TST1763-DRWZ MP, TST1763-DRWZ LP, TST1763-DRWZ HP, TST1763-DRW	VE312 01	BTE	47169
MicroAudio	Ally	AY4ITE-W-UP, AY4ITE-W-MP, AY4ITE-W-HP, AY4ITE-DW-UP, AY4ITE-DW-MP, AY4ITE-DW-HP, AY3ITE-W-UP, AY3ITE-W-MP, AY3ITE-W-HP, AY3ITE-DW-UP, AY3ITE-DW-MP, AY3ITE-DW-HP, AY2ITE-W-UP, AY2ITE-W-MP, AY2ITE-W-HP, AY2ITE-DW-UP, AY2ITE-DW-MP, AY2ITE-DW-HP	DA13i 00	ITE	34672
MicroAudio	Ally	AY4ITC-W-UP, AY4ITC-W-MP, AY4ITC-W-HP, AY4ITC-DW-UP, AY4ITC-DW-MP, AY4ITC-DW-HP, AY3ITC-W-UP, AY3ITC-W-MP, AY3ITC-W-HP, AY3ITC-DW-UP, AY3ITC-DW-MP, AY3ITC-DW-HP, AY2ITC-W-UP, AY2ITC-W-MP, AY2ITC-W-HP, AY2ITC-DW-UP, AY2ITC-DW-MP, AY2ITC-DW-HP	DA312i 00	ITE	41209
MicroAudio	Ally	AY466-DW, AY366-DW	M60 00	BTE	34671
MicroAudio	Ally	AY486-DW, AY476-DW, AY386-DW, AY376-DW, AY286-DW, AY276-DW	M7080E 00	BTE	34671
MicroAudio	Ally	AY464-DRW, AY364-DRW	MRIE 00	BTE	47169
MicroAudio	Boost Max	BBM1786-DWH, BBM686-DWH	BE80 01	BTE	34671
MicroAudio	Boost Max	BBM1795-DW, BBM695-DW	LO90 01	BTE	34671
MicroAudio	Trust	TST1766-DW, TST666-DW	BE60 01	BTE	34671
MicroAudio	Trust	TST1776-DW, TST676-DW	BE70 01	BTE	34671
MicroAudio	Trust	TST1786-DW, TST686-DW	BE80 01	BTE	34671
MicroAudio	Trust	TST1764-DRW, TST664-DRW	BRIE 01	BTE	47169
MicroAudio	Trust	TST6ITE-W-UP, TST6ITE-W-MP, TST6ITE-W-HP, TST6ITE-DW-UP, TST6ITE-DW-MP, TST6ITE-DW-HP, TST17ITE-W-UP, TST17ITE-W-MP, TST17ITE-W-HP, TST17ITE-DW-UP, TST17ITE-DW-MP, TST17ITE-DW-HP	DA13i 01	ITE	34672
MicroAudio	Trust	TST6ITC-W-UP, TST6ITC-W-MP, TST6ITC-W-HP, TST6ITC-DW-UP, TST6ITC-DW-MP, TST6ITC-DW-HP, TST17ITC-W-UP, TST17ITC-W-MP, TST17ITC-W-HP, TST17ITC-DW-UP, TST17ITC-DW-MP, TST17ITC-DW-HP	DA312i 01	ITE	41209
MicroAudio	Trust	TST1763-DRW, TST663-DRW	VE312 01	BTE	47169