

## EC - Declaration of Conformity

<b>Manufacturer:</b>	Interton 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. 410524 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>	Class IIa, Rule 5 and 9
<b>Applied standards and normative standards:</b>	
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, 2021-01-25**

DocuSigned by:  
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**Christoph Schmid**  
Vice President  
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**Amarjit Kaur Gill**  
Vice President  
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Doc.: 0267040, Rev.H

## 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
Interton	Centro	CT661-DRW, CT461-DRW, CT261-DRW	VE312 00	BTE	47169
Interton	Cosmo	C650-MW, C650-MUW, C650-MPW, C450-MW, C450-MUW, C450-MPW	BO13 00	FP/ITE	34672
Interton	Cosmo	C630-MW, C630-MUW, C630-MPW, C430-MW, C430-MUW, C430-MPW	BO312 00	FP/ITE	41209
Interton	Cosmo	C661-DRW NP, C661-DRW HP, C661-DRW, C461-DRW NP, C461-DRW HP, C461-DRW	SY312 00	BTE	47169
Interton	Crisp	CI365-DIW, CI265-DIW	M60 00	BTE	34671
Interton	Crisp	CI370/80-DVIW, CI270/80-DVIW	M7080 00	BTE	34671
Interton	Crisp	CI360-DVIRW NP, CI360-DVIRW HP, CI360-DVIRW, CI260-DVIRW NP, CI260-DVIRW HP, CI260-DVIRW	MRIE 00	BTE	47169
Interton	Crisp	CI350-W, CI350-PW, CI350-DW, CI350-DPW, CI250-W, CI250-PW, CI250-DW, CI250-DPW	PH13 00	FP/ITE	34672
Interton	Crisp	CI330-W, CI330-PW, CI330-DW, CI330-DPW, CI230-W, CI230-PW, CI230-DW, CI230-DPW	PH312 00	FP/ITE	41209
Interton	Move	<b>MV665-DW, MV465-DW, MV365-DW, MV265-DW</b>	<b>BEB60 02</b>	<b>BTE</b>	<b>34671</b>
Interton	Move	<b>MV670-DW, MV470-DW, MV370-DW, MV270-DW, MV170-DW</b>	<b>BEB70 02</b>	<b>BTE</b>	<b>34671</b>
Interton	Move	<b>MV680-DWH, MV480-DWH, MV380-DWH, MV280-DWH, MV180-DWH</b>	<b>BEB80 02</b>	<b>BTE</b>	<b>34671</b>
Interton	Move	<b>MV662-DRW, MV462-DRW, MV362-DRW, MV262-DRW</b>	<b>BER13 02</b>	<b>BTE</b>	<b>47169</b>
Interton	Move	<b>MV6ITC-DW-UP, MV6ITC-DW-MP, MV6ITC-DW-HP, MV4ITC-DW-UP, MV4ITC-DW-MP, MV4ITC-DW-HP, MV3ITC-DW-UP, MV3ITC-DW-MP, MV3ITC-DW-HP</b>	<b>CSI12 02</b>	<b>ITE</b>	<b>41209</b>
Interton	Move	<b>MV6ITE-DW-UP, MV6ITE-DW-MP, MV6ITE-DW-HP, MV4ITE-DW-UP, MV4ITE-DW-MP, MV4ITE-DW-HP, MV3ITE-DW-UP, MV3ITE-DW-MP, MV3ITE-DW-HP</b>	<b>CSI12 02 &amp; CSI13 02</b>	<b>ITE</b>	<b>34672</b>
Interton	Move	<b>MV6CIC-W-MP, MV6CIC-W-LP, MV6CIC-W-HP, MV4CIC-W-MP, MV4CIC-W-LP, MV4CIC-W-HP, MV3CIC-W-MP, MV3CIC-W-LP, MV3CIC-W-HP</b>	<b>CSX10 02</b>	<b>ITE</b>	<b>41209</b>
Interton	Move	<b>MV690-DW, MV490-DW, MV390-DW, MV290-DW</b>	<b>LOB90 02</b>	<b>BTE</b>	<b>34671</b>
Interton	Move	<b>MV661-DRWC, MV461-DRWC</b>	<b>LXR45 02</b>	<b>BTE</b>	<b>47169</b>
Interton	Move	<b>MV661-DRW, MV461-DRW, MV361-DRW, MV261-DRW</b>	<b>VER12 02</b>	<b>BTE</b>	<b>47169</b>
Interton	Ready	<b>RD670-DW, RD470-DW, RD370-DW, RD270-DW</b>	<b>BE70 01</b>	<b>BTE</b>	<b>34671</b>
Interton	Ready	<b>RD680-DW, RD480-DW, RD380-DW, RD280-DW</b>	<b>BE80 01</b>	<b>BTE</b>	<b>34671</b>
Interton	Ready	<b>RD662-DRW, RD462-DRW, RD362-DRW, RD262-DRW</b>	<b>BRIE 01</b>	<b>BTE</b>	<b>47169</b>

Brand	Family Name	Models	Product Form Factor (PFF)	Type	GMDN Code
Interton	Ready	RD6ITE-DW-UP, RD6ITE-DW-MP, RD6ITE-DW-HP, RD4ITE-DW-UP, RD4ITE-DW-MP, RD4ITE-DW-HP, RD3ITE-DW-UP, RD3ITE-DW-MP, RD3ITE-DW-HP, RD2ITE-DW-UP, RD2ITE-DW-MP, RD2ITE-DW-HP	DA13i 01	ITE	34672
Interton	Ready	RD6ITC-W-UP, RD6ITC-W-MP, RD6ITC-W-HP, RD6ITC-DW-UP, RD6ITC-DW-MP, RD6ITC-DW-HP, RD4ITC-W-UP, RD4ITC-W-MP, RD4ITC-W-HP, RD4ITC-DW-UP, RD4ITC-DW-MP, RD4ITC-DW-HP, RD3ITC-W-UP, RD3ITC-W-MP, RD3ITC-W-HP, RD3ITC-DW-UP, RD3ITC-DW-MP, RD3ITC-DW-HP, RD2ITC-W-UP, RD2ITC-W-MP, RD2ITC-W-HP, RD2ITC-DW-UP, RD2ITC-DW-MP, RD2ITC-DW-HP	DA312i 01	ITE	34672
Interton	Ready	RD661-DRW, RD461-DRW, RD361-DRW, RD261-DRW	VE312 01	BTE	47169
Interton	Step	ST665-DW, ST465-DW, ST265-DW	M60 00	BTE	34671
Interton	Step	ST680-DW, ST670-DW, ST480-DW HP, ST480-DW, ST470-DW, ST280-DW HP, ST280-DW, ST270-DW	M7080E 00	BTE	34671
Interton	Step	ST660-DRW, ST460-DRW S, ST460-DRW NP, ST460-DRW HP, ST460-DRW, ST260-DRW S, ST260-DRW NP, ST260-DRW HP, ST260-DRW	MR1E 00	BTE	47169
Interton	Step	ST450-W, ST450-PW, ST450-DW, ST450-DPW, ST250-W, ST250-PW, ST250-DW, ST250-DPW	PH13 00	FP/ITE	34672
Interton	Step	ST650-W, ST650-PW, ST650-DW, ST650-DPW	PH13 00/PH312 00	FP/ITE	34672
Interton	Step	ST630-W, ST630-PW, ST630-DW, ST630-DPW, ST430-W, ST430-PW, ST430-DW, ST430-DPW, ST230-W, ST230-PW, ST230-DW, ST230-DPW	PH312 00	FP/ITE	41209