

EC - Declaration of Conformity

Manufacturer:	Interton A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark
Conformity Assessment Procedure (MDD):	Annex II of Medical Device Directive (MDD) 93/42/EEC
Conformity Assessment Procedure (RED):	Annex II of Radio Equipment Directive (RED) 2014/53/EU
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 the EC-certificate (MDD):	DQS Med Certificate No. 410524 MR2
Identification of the Device:	Category: Hearing instrument Brand: Refer to Appendix A Model: Refer to Appendix A
Declaration of Conformity expiry date:	2019-12-31
Classification of the Device (MDD):	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, EN ISO 10993-5:2009, EN ISO 10993-10:2013, 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, 2018-10-19


Helen Ljungdahl Round
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Appendix A

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

Brand	Family Name	Models	Product Form Factor (PFF)	Type	GMDN Code
Interton	Centro	CT661-DRW, CT461-DRW, CT261-DRW	VE31200	BTE	47169
Interton	Cosmo	C650-MW, C650-MUW, C650-MPW, C450-MW, C450-MUW, C450-MPW	BO13W00	FP/ITE	34672
Interton	Cosmo	C630-MW, C630-MUW, C630-MPW, C430-MW, C430-MUW, C430-MPW	BO312W00	FP/ITE	41209
Interton	Cosmo	C661-DRW NP, C661-DRW HP, C661-DRW, C461-DRW NP, C461-DRW HP, C461-DRW	SY31200	BTE	47169
Interton	Crisp	CI365-DIW, CI265-DIW	M60W00	BTE	34671
Interton	Crisp	CI370/80-DVIW, CI270/80-DVIW	M7080W00	BTE	34671
Interton	Crisp	CI360-DVIRW NP, CI360-DVIRW HP, CI360-DVIRW, CI260-DVIRW NP, CI260-DVIRW HP, CI260-DVIRW	MRIEW00	BTE	47169
Interton	Crisp	CI350-W, CI350-PW, CI350-DW, CI350-DPW, CI250-W, CI250-PW, CI250-DW, CI250-DPW	PH13W00	FP/ITE	34672
Interton	Crisp	CI330-W, CI330-PW, CI330-DW, CI330-DPW, CI230-W, CI230-PW, CI230-DW, CI230-DPW	PH312W00	FP/ITE	41209
Interton	Ready	RD670-DW, RD470-DW, RD370-DW, RD270-DW	BE7001	BTE	34671
Interton	Ready	RD680-DW, RD480-DW, RD380-DW, RD280-DW	BE8001	BTE	34671
Interton	Ready	RD662-DRW, RD462-DRW, RD362-DRW, RD262-DRW	BRIE01	BTE	47169
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	DA13i01	FP/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	DA312i01	FP/ITE	34672
Interton	Ready	RD661-DRW, RD461-DRW, RD361-DRW, RD261-DRW	VE31201	BTE	47169
Interton	Step	ST665-DW, ST465-DW, ST265-DW	M60W00	BTE	34671
Interton	Step	ST680-DW, ST670-DW, ST480-DW HP, ST480-DW, ST470-DW, ST280-DW HP, ST280-DW, ST270-DW	M7080e00	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	MRIEW00	BTE	47169
Interton	Step	ST450-W, ST450-PW, ST450-DW, ST450-DPW, ST250-W, ST250-PW, ST250-DW, ST250-DPW	PH13W00	FP/ITE	34672
Interton	Step	ST650-W, ST650-PW, ST650-DW, ST650-DPW	PH13W00/ PH312W00	FP/ITE	34672

Brand	Family Name	Models	Product Form Factor (PFF)	Type	GMDN Code
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	PH312W00	FP/ITE	41209