

EC – Declaration of Conformity

Manufacturer: Interton 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. 410524 MR2

Identification of the Device: **Category:** Hearing Instrument
Brand: Interton
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) 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, 26 April 2016


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


Lars Hagander
Vice President
Corporate Quality
GN ReSound A/S

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
Interton	Centro	CT261-DRW , CT661-DRW, CT461-DRW	VE31200	03VE31200	BTE	47169
Interton	Cosmo	C461-DRW, C461-DRW HP, C461-DRW NP, C661-DRW, C661-DRW HP, C661-DRW NP	SY31200	03SY31200	BTE	47169
Interton	Cosmo	C430-MPW, C430-MUW, C430-MW, C630-MPW, C630-MUW, C630-MW	BO312W00	03BO312W00	FP/ITE	41209
Interton	Cosmo	C450-MPW, C450-MUW, C450-MW, C650-MPW, C650-MUW, C650-MW	BO13W00	03BO13W00	FP/ITE	34672
Interton	Crisp	CI260-DVIRW, CI260-DVIRW NP, CI260-DVIRW HP, CI360-DVIRW, CI360-DVIRW NP, CI360-DVIRW HP	MRIEW00	03MRIEW00	BTE	47169
Interton	Crisp	CI365-DIW, CI265-DIW, ST665-DW	M60W00	03M60W00	BTE	34671
Interton	Crisp	CI370/80-DVIW, CI270/80-DVIW	M7080W00	03M7080W00	BTE	34671
Interton	Crips	CI330-W, CI330-DW, CI330-DPW, CI330-PW, CI230-W, CI230-DW, CI230-DPW, CI230-PW	PH312W00	03PH312W00	FP/ITE	41209
Interton	Crisp	CI250-W, CI250-DW, CI250-DPW, CI250-PW, CI350-W, CI350-DW, CI350-DPW, CI350-PW	PH13W00	03PH13W00	FP/ITE	34672
Interton	Step	ST260-DRW, ST260-DRW NP, ST260-DRW HP, ST260-DRW S, ST460-DRW, ST460-DRW NP, ST460-DRW HP, ST460-DRW S, ST660-DRW	MRIEW00	03MRIEW00	BTE	47169
Interton	Step	ST465-DW, ST265-DW	M60W00	03M60W00	BTE	34671
Interton	Step	ST270-DW, ST280-DW, ST280-DW HP, ST470-DW, ST480-DW, ST480-DW HP, ST870-DW , ST680-DW	M7080e00	03M7080e00	BTE	34671
Interton	Step	ST230-W, ST230-DW, ST230-DPW, ST230-PW, ST430-W, ST430-DW, ST430-DPW, ST430-PW, ST630-W , ST630-DW , ST630-DPW , ST630-PW	PH312W00	03PH312W00	FP/ITE	41209
Interton	Step	ST250-W, ST250-DW, ST250-DPW, ST250-PW, ST450-W, ST450-DW, ST450-DPW, ST450-PW, ST650-W , ST650-DW , ST650-DPW , ST650-PW	PH13W00/ PH312W00	03PH13W00	FP/ITE	34672