

CONFIRMATION OF CERTIFICATION

Frankfurt a. M.,
2021-01-28

To whom it may concern,

DQS Medizinprodukte GmbH hereby confirms that the company:

***Interton A/S
Lautrupbjerg 7
2750 Ballerup
Denmark***

has implemented and maintains a Quality Management System that conforms to EN ISO 13485:2016 + AC: 2016 . The current certificate has the registration number of 410524 MP2016, and the unique ID number of 170762883. The certificate was issued on 2021-01-01 and is valid until 2023-12-31.

Therefore, it is confirmed that the products shown on the certificate with the registration number of 410524 MR2, and the unique ID 170770361 (issued on 2020-06-26 and valid until 2024-05-26), have been designed and manufactured within a Quality Assurance System that fulfils the requirements of MDD 93/42/EEC and can be placed on the market within the European Union bearing CE-0297 under the responsibility of Interton A/S.

This document certifies that the below mentioned models may be placed on the market in the EU.

The manufacturing plant in which the devices are produced is subject to periodic inspections.



The following devices with the stated Product Form Factors (PFF) and associated models are covered by the scope of the certification:

Brand	Family Name	Models	PFF	Type
Interton	Avio 1	A150-D HPG, A150-D, A150 HPG, A150, A140-D HPG, A140-D, A140 HPG, A140, A130-D HPG, A130-D, A130 HPG, A130, A110 PB HPG, A110 PB, A110 HPG, A110	CCS 00	FP/ITE
Interton	Avio 1	A165-D	PA60 00	BTE
Interton	Avio 1	A170-D	PA70 00	BTE
Interton	Avio 3	A350-D HPG, A350-D, A350 HPG, A350, A340-D HPG, A340-D, A340 HPG, A340, A330-D HPG, A330-D, A330 HPG, A330, A310 PB HPG, A310 PB, A310 HPG, A310	CCS 00	FP/ITE
Interton	Avio 3	A365-D	PA60 00	BTE
Interton	Avio 3	A370-D	PA70 00	BTE
Interton	Avio 5	A550-D HPG, A550-D, A550 HPG, A550, A540-D HPG, A540-D, A540 HPG, A540, A530-D HPG, A530-D, A530 HPG, A530, A510 PB HPG, A510 PB, A510 HPG, A510	CCS 00	FP/ITE
Interton	Avio 5	A565-D	PA60 00	BTE
Interton	Avio 5	A570-D	PA70 00	BTE
Interton	Centro	CT661-DRW, CT461-DRW, CT261-DRW	VE312 00	BTE
Interton	Cosmo	C650-MW, C650-MUW, C650-MPW, C450-MW, C450-MUW, C450-MPW	BO13 00	FP/ITE
Interton	Cosmo	C630-MW, C630-MUW, C630-MPW, C430-MW, C430-MUW, C430-MPW	BO312 00	FP/ITE
Interton	Cosmo	C662-DR NP, C662-DR HP, C662-DR	SY10 00	BTE
Interton	Cosmo	C661-DRW NP, C661-DRW HP, C661-DRW, C461-DRW NP, C461-DRW HP, C461-DRW	SY312 00	BTE
Interton	Crisp	CI365-DIW, CI265-DIW	M60 00	BTE
Interton	Crisp	CI370/80-DVIW, CI270/80-DVIW	M7080 00	BTE
Interton	Crisp	CI360-DVIRW NP, CI360-DVIRW HP, CI360-DVIRW, CI260-DVIRW NP, CI260-DVIRW HP, CI260-DVIRW	MRIE 00	BTE
Interton	Crisp	CI310-P, CI310, CI210-P, CI210	PH10 00	FP/ITE
Interton	Crisp	CI350-W, CI350-PW, CI350-P, CI350-DW, CI350-DPW, CI350-DP, CI350-D, CI350, CI250-W, CI250-PW, CI250-P, CI250-DW, CI250-DPW, CI250-DP, CI250-D, CI250	PH13 00	FP/ITE
Interton	Crisp	CI330-W, CI330-PW, CI330-P, CI330-DW, CI330-DPW, CI330-DP, CI330-D, CI330, CI230-W, CI230-PW, CI230-P, CI230-DW, CI230-DPW, CI230-DP, CI230-D, CI230	PH312 00	FP/ITE
Interton	Crisp	CI362-DR NP, CI362-DR HP, CI362-DR	SY10 00	BTE
Interton	Danavox Hear Now	DXHN00	CCS 00	FP/ITE
Interton	ELIPSE	EL90-VI	Viking 00	BTE
Interton	Gain	GAN390-DVI, GAN290-DVI	DE90 00	BTE
Interton	Hear Now	HN00, HN01A	CCS 00	FP/ITE
Interton	Micro	M610-MP, M610-M, M410-MP, M410-M	BO10 00	FP/ITE
Interton	Micro	M650-MU, M650-MP, M650-M, M450-MU, M450-MP, M450-M	BO13 00	FP/ITE
Interton	Micro	M630-MU, M630-MP, M630-M, M430-MU, M430-MP, M430-M	BO312 00	FP/ITE
Interton	Move	MV665-DW, MV465-DW, MV365-DW, MV265-DW	BEB60 02	BTE
Interton	Move	MV670-DW, MV470-DW, MV370-DW, MV270-DW, MV170-DW	BEB70 02	BTE
Interton	Move	MV680-DWH, MV480-DWH, MV380-DWH, MV280-DWH, MV180-DWH	BEB80 02	BTE
Interton	Move	MV662-DRW, MV462-DRW, MV362-DRW, MV262-DRW	BER13 02	BTE
Interton	Move	MV6ITC-DW-UP, MV6ITC-DW-MP, MV6ITC-DW-HP, MV4ITC-DW-UP, MV4ITC-DW-MP,	CSI12 02	ITE

		MV4ITC-DW-HP, MV3ITC-DW-UP, MV3ITC-DW-MP, MV3ITC-DW-HP		
Interton	Move	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	CSI12 02 & CSI13 02	ITE
Interton	Move	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	CSX10 02	ITE
Interton	Move	MV690-DW, MV490-DW, MV390-DW, MV290-DW	LOB90 02	BTE
Interton	Move	MV661-DRWC, MV461-DRWC	LXR45 02	BTE
Interton	Move	MV661-DRW, MV461-DRW, MV361-DRW, MV261-DRW	VER12 02	BTE
Interton	Ready	RD670-DW, RD470-DW, RD370-DW, RD270-DW	BE70 01	BTE
Interton	Ready	RD680-DW, RD480-DW, RD380-DW, RD280-DW	BE80 01	BTE
Interton	Ready	RD662-DRW, RD462-DRW, RD362-DRW, RD262-DRW	BRIE 01	BTE
Interton	Ready	RD6CIC-UP, RD6CIC-MP, RD6CIC-LP, RD6CIC-HP, RD4CIC-UP, RD4CIC-MP, RD4CIC-LP, RD4CIC-HP, RD3CIC-UP, RD3CIC-MP, RD3CIC-LP, RD3CIC-HP, RD2CIC-UP, RD2CIC-MP, RD2CIC-LP, RD2CIC-HP	DA10 01	ITE
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
Interton	Ready	RD6ITC-W-UP, RD6ITC-W-MP, RD6ITC-W-HP, RD6ITC-UP, RD6ITC-MP, RD6ITC-HP, RD6ITC-DW-UP, RD6ITC-DW-MP, RD6ITC-DW-HP, RD6ITC-D-UP, RD6ITC-D-MP, RD6ITC-D-HP, RD4ITC-W-UP, RD4ITC-W-MP, RD4ITC-W-HP, RD4ITC-UP, RD4ITC-MP, RD4ITC-HP, RD4ITC-DW-UP, RD4ITC-DW-MP, RD4ITC-DW-HP, RD4ITC-D-UP, RD4ITC-D-MP, RD4ITC-D-HP, RD3ITC-W-UP, RD3ITC-W-MP, RD3ITC-W-HP, RD3ITC-UP, RD3ITC-MP, RD3ITC-HP, RD3ITC-DW-UP, RD3ITC-DW-MP, RD3ITC-DW-HP, RD3ITC-D-UP, RD3ITC-D-MP, RD3ITC-D-HP, RD2ITC-W-UP, RD2ITC-W-MP, RD2ITC-W-HP, RD2ITC-UP, RD2ITC-MP, RD2ITC-HP, RD2ITC-DW-UP, RD2ITC-DW-MP, RD2ITC-DW-HP, RD2ITC-D-UP, RD2ITC-D-MP, RD2ITC-D-HP	DA312i 01	ITE
Interton	Ready	RD661-DRW, RD461-DRW, RD361-DRW, RD261-DRW	VE312 01	BTE
Interton	Scope 4	S450-D HPG, S450-D, S450 HPG, S450, S440-D HPG, S440-D, S440 HPG, S440, S430-D HPG, S430-D, S430 HPG, S430, S410 PB HPG, S410 PB, S410 HPG, S410	CCS 00	FP/ITE
Interton	Scope 4	S465-D	PA60 00	BTE
Interton	Scope 4	S470-D	PA70 00	BTE
Interton	Scope 4	S480-D	PA80 00	BTE
Interton	Scope 6	S650-D HPG, S650-D, S650 HPG, S650, S640-D HPG, S640-D, S640 HPG, S640, S630-D HPG, S630-D, S630 HPG, S630, S610 PB HPG, S610 PB, S610 HPG, S610	CCS 00	FP/ITE
Interton	Scope 6	S665-D	PA60 00	BTE
Interton	Scope 6	S670-D	PA70 00	BTE
Interton	Scope 6	S680-D	PA80 00	BTE
Interton	Share	SR1365-DI	DE60 00	BTE

Interton	Share	SR1380-DVI, SR1370-DVI, SR1280-DVI, SR1270-DVI, SR1180-VI, SR1170-VI	DE7080 00	BTE
Interton	Share	SR1360-DVR NP, SR1360-DVIR HP, SR1360-DVIR	MRIE 00	BTE
Interton	Share	SR1310-P, SR1310, SR1210-P, SR1210, SR1110-P, SR1110	PH10 00	FP/ITE
Interton	Share	SR1350-P, SR1350-DP, SR1350-D, SR1350, SR1250-P, SR1250-DP, SR1250-D, SR1250, SR1150-P, SR1150	PH13 00	FP/ITE
Interton	Share	SR1330-P, SR1330-DP, SR1330-D, SR1330, SR1230-P, SR1230-DP, SR1230-D, SR1230, SR1130-P, SR1130	PH312 00	FP/ITE
Interton	Stage	ISG43-P, ISG343-P, ISG33-P, ISG33, ISG233-U, ISG233-P, ISG233, ISG23-P, ISG223-U, ISG13-P, ISG123-P, ISG113-P	CCS 00	FP/ITE
Interton	Stage	ISG383-V, ISG373-V, ISG283-V, ISG273-V, ISG173-V	Shang 00	BTE
Interton	Stage	ISG393-VI	Viking 00	BTE
Interton	START	SA50-D HPG, SA50-D, SA50 HPG, SA50, SA40-D HPG, SA40-D, SA40 HPG, SA40, SA30-D HPG, SA30-D, SA30 HPG, SA30, SA10 HPG, SA10	CCS 00	FP/ITE
Interton	Step	ST665-DW, ST465-DW, ST265-DW	M60 00	BTE
Interton	Step	ST680-DW, ST670-DW, ST480-DW HP, ST480-DW, ST470-DW, ST280-DW HP, ST280-DW, ST270-DW	M7080E 00	BTE
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	MRIE 00	BTE
Interton	Step	ST610-P, ST610, ST410-P, ST410, ST210-P, ST210	PH10 00	FP/ITE
Interton	Step	ST450-W, ST450-PW, ST450-P, ST450-DW, ST450-DPW, ST450-DP, ST450-D, ST450, ST250-W, ST250-PW, ST250-P, ST250-DW, ST250-DPW, ST250-DP, ST250-D, ST250	PH13 00	FP/ITE
Interton	Step	ST650-W, ST650-PW, ST650-P, ST650-DW, ST650-DPW, ST650-DP, ST650-D, ST650	PH13 00/ PH312 00	FP/ITE
Interton	Step	ST630-W, ST630-PW, ST630-P, ST630-DW, ST630-DPW, ST630-DP, ST630-D, ST630, ST430-W, ST430-PW, ST430-P, ST430-DW, ST430-DPW, ST430-DP, ST430-D, ST430, ST230-W, ST230-PW, ST230-P, ST230-DW, ST230-DPW, ST230-DP, ST230-D, ST230	PH312 00	FP/ITE

Yours Sincerely,
DQS Medizinprodukte GmbH



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