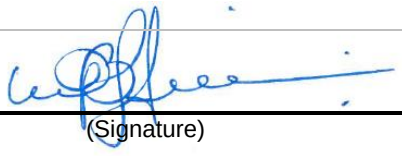
Declaration of Conformity

Technical Documentation File	TD 8-2
Manufacturer	Medtronic Xomed, Inc. 6743 Southpoint Drive North Jacksonville, FL 32216 USA
European Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Product Family	**ENT Invasive Implant Materials & Devices**
Product List	See **Table 1** for Model Number(s), Product Description, Classification and Rule, and Conformity Assessment Annex.
EC Certificate(s)	*EC Certification under Annex II, Cert. No. **G1 041921 0035** Rev. 00 issued by TÜV SÜD Product Service GmbH on 2020-05-05 (expiring 2024-05-26)* *EC Certification under Annex V, Cert. No. **G2S 041921 0034** Rev. 00 issued by TÜV SÜD Product Service GmbH on 2020-01-27 (expiring 2024-05-26)*
Quality System Certificate	*ISO 13485:2016, Cert. No. **QS6 041921 0033** Rev. 05* *issued by TÜV SÜD America Inc. on 2023-11-01 (expiring 2026-10-20)* *EN ISO 13485:2016, Cert. No. **Q6 077608 0100 **** Rev. 01* *issued by TÜV SÜD Product Service GmbH on 2022-10-12 (expiring 2024-12-04)*
Notified Body/ID#	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstr. 65 80339 Munich, Germany ID# 0123
Declaration Statement	Medtronic Xomed, Inc., hereby confirms in our sole responsibility that the products described herein meet the applicable essential requirements of Council Directive 93/42/EEC including amendments issued. This declaration is supported by the EC Quality System Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward. *I, the undersigned declare that the Medical Device(s) specified below in Table 2 comply with Article 120 of the Regulation (EU) 2017/745 as amended by Regulation (EU) 2023/607 and 93/42/EEC (MDD) or 90/385/EEC (AIMD).* *This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of 93/42/EEC (MDD) or 90/385/EEC (AIMD), and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607.* *The validity of the certificates listed on this DoC are valid through 31 December 2028.*
Person Authorized to Sign	 December 1, 2023 (Signature) (Date) Gabriela Moreira, Regulatory Affairs Management Representative
Date of Validity	*From signature date above.*

******* Only applicable to devices contract manufactured at SIMA facility.*

Table 1: Product List

CFN	Product Description	CE Date	Class	Rule	Annex	GMDN Code	RoHS Compliant (Yes/No)
15000 **	ALAR 15000 Nasal Valve Stent 0.5 X 16 X 19 2/BX	4/10/2013	IIa	5 & 7	II	62718	N/A
117200 **	PULEC ENDOLYMPHATIC SHUNT C-FLEX 1/EA	2/23/1998	IIb	8	II	16033	N/A
400561	SILICONE SPLINT PAIRS 10/PK	5/24/1998	I	5	V & VII	31919	N/A
400562	SPLINT KIT 5/BX	5/3/1999	I	5	V & VII	31919	N/A
600500 **	BOOMERANG 5/BX	5/24/1998	I	5	V & VII	31919	N/A
1156404	AUSTIN ENDOLYMPHATIC SHUNT 1/EA	2/23/1998	IIb	8	II	16033	N/A
1156505	AUSTIN ENDOLYMPHATIC SHUNT C-FLEX 1/EA	11/16/1999	IIb	8	II	16033	N/A
1425015	PACKING STRIPS PTFE LONG 2984 6/PK	5/24/1998	IIb	8	II	33310	N/A
1425020	STRIPS PTFE REG, 6/PK	5/24/1998	IIb	8	II	33310	N/A
1428005 **	SILVERST STRIPS POLY LG 2904 6/PK	5/24/1998	IIb	8	II	33310	N/A
1428010 **	SILVERST STRIPS POLY REG 2905 6/PK	5/24/1998	IIb	8	II	33310	N/A
1515000	FRONTAL SINUS STENT (PARELL T) 6/BX	5/24/1998	IIa	5	II	63599	N/A
1516000 **	GOODE MAGN NASAL SPLINT-SIL PAIR 1/SET	5/24/1998	IIa	5	II	31919	N/A
1516010 **	GOODE MAGNE SPLINT-LARGE, 1 PR/BX	5/24/1998	IIa	5	II	31919	N/A
1522000	SIMPLESPLINTS, PAIRS 20/PK	5/24/1998	I	5	V & VII	31919	N/A
1523000 **	OVAL SEPTAL SPLINT PAIRS 10/PK	5/24/1998	IIa	5	II	31919	N/A
1524050 **	DOYLE II NASAL SEPTAL SPLINT, SIL., 5PR/BX	5/24/1998	I	5	V & VII	31919	N/A
1524055 **	DOYLE II NASAL SEPTAL SPLINT, SIL., 1/PR	5/24/1998	I	5	V & VII	31919	N/A
1524060 **	GOLDSMITH INFLATABLE AIRWAY SPLINT 1PR/BX	5/24/1998	I	5	V & VII	31919	N/A
1524075 **	DOYLE BIVALVE SEPTAL SPLINT, C-FLEX 1/BX	5/24/1998	I	5	V & VII	31919	N/A
1524105 **	NASAL SEPTAL BUTTONS 1400 1/EA	5/24/1998	IIa	5	II	46397	N/A
1524110 **	2 PART SILICONE SEPTAL BUTTON 1/EA	5/24/1998	IIa	5	II	46397	N/A
1526701	GASKINS NASAL PAK 1/EA	5/24/1998	I	5	V & VII	62718	N/A
1526702	RICE DOUBLE KEEL PACK 1/EA	5/24/1998	I	5	V & VII	62718	N/A
1526800	NASAL POSTPAC 5/BX	5/24/1998	I	5	V & VII	12699	N/A
1527000	REUTER NASAL SPLINT PAIRS, STD THIN 10/PK	5/24/1998	I	5	V & VII	31919	N/A
1527005	NASAL SPLINT PAIRS, STD THICK 10/PK	5/24/1998	I	5	V & VII	31919	N/A
1527010	REUTER NASAL SPLINT PAIRS, LG THIN 10/PK	5/24/1998	I	5	V & VII	31919	N/A
1527015	NASAL SPLINT PAIRS, LG THK 10/PK	5/24/1998	I	5	V & VII	31919	N/A

CFN	Product Description	CE Date	Class	Rule	Annex	GMDN Code	RoHS Compliant (Yes/No)
1527020	NASAL SPLINT PAIRS, LGE THK 10/PK	5/24/1998	I	5	V & VII	31919	N/A
1527025	REUTER NASAL SPLINT PAIRS, LG THIN 10/PK	5/24/1998	I	5	V & VII	31919	N/A
1527031 **	XOMED EPISTAT SINGLE 1/EA	5/24/1998	I	5	V & VII	18716	N/A
1532500	SILICONE SHEET 2 X 2 X .010 10/BX	5/24/1998	IIb	8	II	61557	N/A
1532505 **	SILICONE SHEET 2 X 2 X .005 10/BX	5/24/1998	IIb	8	II	61557	N/A
1532510 **	SILICONE SHEET 2 X 2 X .020 10/BX	5/24/1998	IIb	8	II	61557	N/A
1532520 **	SILICONE SHEET 2 X 2 X .040 10/BX	5/24/1998	IIb	8	II	61557	N/A
1532530 **	SILICONE SHEET 2 X 2 X .062 10/BX	5/24/1998	IIb	8	II	61557	N/A
1532540	SILICONE SHEET 2 X 2 X .125 10/BX	5/24/1998	IIb	8	II	61557	N/A
9124105 **	SEPTAL BUTTON, NASAL, 6 CM DIA., 1/EA	1/24/2003	IIa	5	II	46397	N/A
76310200M	MEDTRONIC XOMED, INC. AIRVANCE G2 BONE SCREW	8/20/2009	IIb	8	II	33957	N/A
76353200M	MEDTRONIC XOMED, INC. AIRVANCE BONE SCREW SYSTEM	8/20/2009	IIb	8	II	33957	YES
PDS3000M	IMPLANT PDS3000M 6PK PILLAR PALATAL	11/4/2008	IIb	8	II	33957	N/A
PDS3000ME	IMPLANT PDS3000ME PILLAR PALATAL	11/4/2008	IIb	8	II	33957	N/A

Table 2: Product List for Extension per Regulation (EU) 2023/607

CFN	Product Description	Class	Rule	Annex	Basic UDI-DI	EMDN
400561	SPLINT 400561 10PK PAIR SILICONE	I(s)	5	IX	0763000B00025798U	P020203
400562	SPLINT KIT 400562 5PK SILICONE	I(s)	5	IX	0763000B00025798U	P020203
1522000	SPLINT 1522000 20PK PAIR SIMPLESPLINTS	I(s)	5	IX	0763000B000255186	P020203
1524050	SPLINT 1524050 5PK PAIR DOYLE II SEPTAL	I(s)	5	IX	0763000B00025538A	P020203
1524055	SPLINT 1524055 DOYLE II INTRANASAL AIRWAY	I(s)	5	IX	0763000B00025538A	P020203
1527000	SPLINT 1527000 10PK PAIR REUTER NASAL TH	I(s)	5	IX	0763000B000255186	P020203
1527005	SPLINT 1527005 10PK PAIR NASAL STD THICK	I(s)	5	IX	0763000B000255186	P020203
1527010	SPLINT 1527010 10PK PAIR REUTER LARGE TH	I(s)	5	IX	0763000B000255186	P020203
1527015	SPLINT 1527015 10PK PAIR REUTER LARGE TH	I(s)	5	IX	0763000B000255186	P020203
1527020	SPLINT 1527020 10PK PAIR REUTER LARGE TH	I(s)	5	IX	0763000B000255186	P020203
1527025	SPLINT 1527025 10PK PAIR REUTER LARGE TH	I(s)	5	IX	0763000B000255186	P020203
1527031	CATHETER 1527031 EPISTAT NASAL	I(s)	5	IX	0763000B000255288	Q030201
1532500	Silicone Sheet, 0.25 mm	IIa	7	IX	0763000B00008198B	M030505
1532505	Silicone Sheet, 0.13 mm	IIa	7	IX	0763000B00008198B	M030505
1532510	Silicone Sheet, 0.51 mm	IIa	7	IX	0763000B00008198B	M030505
1532520	Silicone Sheet, 1.02 mm	IIa	7	IX	0763000B00008198B	M030505
1532530	Silicone Sheet, 1.57 mm	IIa	7	IX	0763000B00008198B	M030505