

Declaration of Conformity

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2019-10-07 - 14:12
Reviewed:	QA	John Wennborg - JOHWEN	2019-10-07 - 14:27
Approved:	OP	Martin Richardson - MARRIC	2019-10-07 - 15:17
Released:	QA	Ulrika Svensson - SEHRBHNU	2019-10-09 - 12:58

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We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

The FreeVent Accessories

REF	Name	Class	GMDN code
1502	Stoma Oil 100ml	IIb	57897
1601	FreeVent Tracheal Tube Detergent Powder	I	63385
1602	FreeVent Tracheal Tube Cleansing Jar	I	62628
FreeVent TubeBrush			
1205	FreeVent TubeBrush Sz 6	I	34883
1206	FreeVent TubeBrush Sz 8	I	34883
1207	FreeVent TubeBrush Sz 10	I	34883
1208	FreeVent TubeBrush Sz 12	I	34883
1209	FreeVent TubeBrush Sz 14	I	34883
1210	FreeVent TubeBrush Set 1x8, 1x10, 1x12mm	I	34883
FreeVent Cloths Stoma Cover			
1400	Clothing cover White 3ply velcro closure	I	31065
14001	Clothing cover Beige 3ply velcro closure	I	31065
140011	Clothing cover blue 3ply velcro closure	I	31065
1401	Clothing cover White 4ply velcro closure	I	31065
14011	Clothing cover Blue 4ply velcro closure	I	31065
14012	Clothing cover Beige 4ply velcro closure	I	31065
1402	Clothing cover White 8ply velcro closure	I	31065
14022	Clothing cover Beige 8ply velcro closure	I	31065
14023	Clothing cover Blue 8ply velcro closure	I	31065
1403	Clothing cover White 12ply velcro closure	I	31065
14033	Clothing cover Beige 12ply velcro closure	I	31065
14034	Clothing cover Blue 12ply velcro closure	I	31065
1412R1	Clothing round neck, white	I	31065
1412R2	Clothing round neck beige cotton	I	31065
1412R3	Clothing round neck, light blue cotton	I	31065
1412R4	Clothing round neck, blue cotton	I	31065
1412R5	Clothing round neck, brown cotton	I	31065
1412R6	Clothing round neck vine red	I	31065
1412R7	Clothing round neck green	I	31065
1412R8	Clothing round neck grey	I	31065
1412R9	Clothing round neck, black cotton	I	31065

Notified Body: *Intertek Semko AB, Sweden. Identification no. 0413
EC-certificate no. 41310296-01*

Competent Authority: *Medical Products Agency, Sweden*

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1413RSR1	Clothing round T-shirt w zip lock white		31065
1413RSR11	Clothing round neck, T-shirt, zip grey		31065
1413RSR15	Clothing round Tshirt w zip lock d.brown		31065
1413RSR2	Clothing round T-shirt w zip lock beige		31065
1413RSR3	Clothing round Tshirt w zip lock yellow		31065
1413RSR4	Clothing T-shirt w zip lock light blue		31065
1413RSR6	Clothing round T-shirt w zip lock red		31065
1413RSR7	Clothing round Tshirt w zip lock d.green		31065
1413RSR8	Clothing round T-shirt w zip lock blue		31065
1413RSR9	Clothing round T-shirt w zip lock black		31065
1414RS1	Clothing round neck T-shirt form white		31065
1414RS2	Clothing round neck t-shirt form beige		31065
1414RS3	Clothing round T-shirt form light blue		31065
1414RS4	Clothing round neck green		31065
1414RS5	Clothing round neck T-shirt form blue		31065
1414RS6	Clothing round neck T-shirt form black		31065
1410A15BP	Clothing scarf, dark blue cotton/polyses		31065
1410A15TG	Clothing scarf, dark blue trevira-georg		31065
1410A1TG	Clothing scarf, blue with white dots TG		31065
1410A21BP	Clothing scarf, grey Cotton/Polyester		31065
1410A3BP	Clothing scarf, white cotton/polyester		31065
1410A3TG	Clothing scarf, white trevira-georgette		31065
1410A4BP	Clothing scarf, black cotton/polyester		31065
1410A4TG	Clothing scarf, black trevira-georgette		31065
1410A5BP	Clothing scarf, vine red cotton/polyst		31065
1410A5TG	Clothing scarf, vine red trevira-george		31065
1410A7BP	Clothing scarf, beige Cotton/Polyester		31065
1410A9TG	Clothing scarf speckled black'n white TG		31065
FreeVent Dressings			
1425	FreeVent Tracheostomy dressing AL coated		63324
14251	FreeVent Trach dressing AL coated w slit		63324
14251-PED	FreeVent Trachcompr PED, slit 65x70 AL		63324
18008-001	FreeVent Tracheostomy dressing AL, mini		63324
14250	FreeVent Trachcompr w slit 90x100mm wh		63324
14250-PED	FreeVent Trachcomp PED w slit 65x70 wh		63324
1425921	Tracheostomy dressing white with slit		63324
1425923	Trach dressing white with slit, long		63324
1425932	Tracheostomy dressing white/AL with slit		63324
1425933	Trach dressing white/AL with slit long		63324
14253	FreeVent Trach. dress.combi white w slit		63324
14255	Tracheostomy dressing combi, white		63324
14253H	FreeVent Trach. dress.combi w slit beige		63324
14255H	FreeVent Tracheostomy dress.combi beige		63324
14257	FreeVentTrach dress.combi w slit long wh		63324
14259	FreeVentTrach dress.combi long white		63324

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14259H	FreeVentTrach.dres.comb.beig o/slit long		63324
14253H-PED	FreeVentTrach.dres.combi PED w slit beig		63324
14253-PED	FreeVent Trach.dres. combi PED w slit wh		63324
14254	FreeVent Trach dressing combi, AL w slit		63324
14256	FreeVent Tracheostomy dressing combi, AL		63324
14256H	FreeVent Trach. dress. combi, AL beige		63324
14258	FreeVent Trach dress comb AL w slit long		63324
142510	FreeVent Tracheostomy dress double white		63324
142512	FreeVent Trach dressing double w slit wh		63324
142514	FreeVent Trach.dress. double white long		63324
142516	FreeVent Trach dres double, slit long wh		63324
142512-PED	FreeVent Trach double compr. PED w slit		63324
142511	FreeVent Tracheostomy dress.double AL		63324
142513	FreeVent Trach dressing double AL w slit		63324
142515	FreeVent Trachdress. double AL slit long		63324
8034	FREEVENT Dressing Softfoam L		15624
8035	FREEVENT Dressing Softfoam S		15624
8036	FREEVENT Dressing Softfoam Slim L		15624
FreeVent TracheoFix			
1427	FreeVentTracheoFix one strip ivory 55x60		63378
1428	FreeVentTracheoFix 7 x 7 cm, 1 strip,wit		63378
1435	FreeVent TracheoFix, two strips, ivory		63378
1429H	FreeVent TracheoFix foam 1 stripe beige		63378
1430H	FreeVent TracheoFix foam 1 stripe beige		63378
1432H	FreeVent TracheoFix foam 2 stripes beige		63378
1433H	FreeVent TracheoFix foam 2 stripes beige		63378
1434H	FreeVent TracheoFix foam 1 stripe beige		63378
FreeVent Pads			
142800	FreeVent Pad, Adult, 65x45mm		63324
142700-D	FreeVent Pad, Adult, 90x100mm, w slit		63324
142700-PED	FreeVent Pad, PED, 65x70 mm w. slit		63324
1431	FreeVent TracheoFix with hole		63324
FreeVent Neckbands			
1699	FreeVent Flexi-Klett Tube-Holder beige		63438
1599	FreeVent Flexi-Klett Tube-Holder		63438
1588	FreeVent Flexi-Klett extension 25cm		63438
1577	FreeVent Flexi-Klett Tube-Holder f. kids		63438
1651	FREEVENT Neckband, one-piece, small		63438
1661	FREEVENT Neckband, one-piece, large		63438
1652	FREEVENT Neckband, two-piece, small		63438
1662	FREEVENT Neckband, two-piece, large		63438
1751	FREEVENT Neckband, one-piece, small		63438
1752	FREEVENT Neckband, two-piece, small		63438
1761	FREEVENT Neckband, one-piece, large		63438

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1762	FREEVENT Neckband, two-piece, large	I	63438
FreeVent NeckStraps			
1520-01	FreeVent NeckStrap. Beige, Hook (1 pc)	I	35752
1520-04	FreeVent NeckStrap. Beige, Hook (4 pcs)	I	35752
1530-01	FreeVent NeckStrap. White, Hook (1 pc)	I	35752
1530-04	FreeVent NeckStrap. White, Hook (4 pcs)	I	35752
1580-01	FreeVent NeckStrap White, Velcro (1 pc)	I	35752
1580-04	FreeVent NeckStrap White, Velcro (4 pcs)	I	35752
1590-01	FreeVent NeckStrap. Beige, Velcro (1 pc)	I	35752
1590-04	FreeVent NeckStrap. Beige Velcro (4 pcs)	I	35752

Each kind of medical device to which the system has been applied complies with the applicable provisions of the Essential Principles and Essential Requirements, the classification rules, applicable standards and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Valid Certificates are controlled and filed by QA/RA Department. For standards applied see Applicable Standards & Essential Requirements for each product.

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Approved:	DD	Mikael Melefors - SEHRBSGM	2019-10-15 - 13:02
Released:	QA	Ulrika Svensson - SEHRBHNU	2019-10-15 - 13:09

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We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

The ProTrach DualCare System

REF	Name	Class	GMDN code
7740	ProTrach DualCare Set 22	I	36071
7741	ProTrach DualCare Set 15	I	36071
7742	ProTrach HME 15 Regular	I	36071
7743	ProTrach HME 15 Regular (BigPack)	I	36071
7744	ProTrach DualCare Speaking Valve	I	36071
7745	Removal Aid	I	58705
7746	ProTrach Connection strap	I	36071
7747	ProTrach HME 22 Regular	I	36071
7755	ProTrach DualCare Speaking Valve Blue	I	36071
7756	HME DigiTop O2	IIa	58705
7766	ProTrach HME 15 XtraMoist	I	36071

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Released:	QA	Ulrika Svensson - SEHRBHNU	2019-10-15 - 13:10

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The ProTrach XtraCare System

REF	Name	Class	GMDN code
7767	ProTrach XtraCare White 30 pcs	I	58705
7768	ProTrach XtraCare Blue 30 pcs	I	58705
7788	ProTrach XtraCare Blue 5 pcs	I	58705
7789	ProTrach XtraCare White 5 pcs	I	58705
7769	ProTrach O2 Adaptor 10 pcs	IIa	58705

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Approved:	OP	Martin Richardson - MARRIC	2019-10-10 - 17:49
Released:	QA	Ulrika Svensson - SEHRBHNU	2019-10-11 - 08:08

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The Provox Accessories

REF	Name	Class	GMDN code
7122	Provox Dilator 17	IIa	62125
7123	Provox Dilator 20	IIa	62125
7211	Provox Dilator	IIa	11263
7204	Provox Brush	I	62095
7225	Provox Brush XL	I	62095
8109	Provox Flush	I	62096
7205	Provox Plug	IIa	62119
8119	Provox Vega Plug 17	IIa	62119
8129	Provox Vega Plug 20	IIa	62119
8139	Provox Vega Plug 22.5	IIa	62119
7215	Provox Guide Wire	IIa	45623
7210	Provox Pharynx Protector	I	45919
7203	Provox Trocar	I	45919
7270	Provox Measure	I	42533
7271	Provox Measure Flanges	I	42533
7275	Provox XtraFlange 22.5	IIb	42533
7276	Provox XtraFlange 20	IIb	42533
7277	Provox XtraFlange 17	IIb	42533
7385	Provox Protector Small White	I	31065
7386	Provox Protector Large White	I	31065
7387	Provox Protector Slim Small White	I	31065
7388	Provox Protector Slim Small Blue	I	31065
7389	Provox Protector Slim Large White	I	31065
7390	Provox Protector Slim Large Blue	I	31065
7391	Provox Protector Air Small White	I	31065
7392	Provox Protector Air Small Blue	I	31065
7393	Provox Protector Air Large White	I	31065
7394	Provox Protector Air Large Blue	I	31065
7794	Provox Capsule 16Fr	I	62134
7795	Provox Capsule 17Fr	I	62134
7796	Provox Capsule 20Fr	I	62134
7797	Provox Capsule 22.5Fr	I	62134

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8017	Provox Insertion System 17Fr	I	62127
8018	Provox Insertion System 20Fr	I	62127
8019	Provox Insertion System 22.5Fr	I	62127
8030	Provox TwistLock 17Fr	I	63307
8031	Provox TwistLock 20Fr	I	63307
8032	Provox TwistLock 22,5Fr	I	63307
1427	Provox Tracheofix 1 strip ivory 55x60	I	63378
1428	Provox Tracheofix 1 strip ivory 70x70	I	63378
1435	Provox Tracheofix 2 strips ivory 70x70	I	63378
1429H	Provox Tracheofix 1 strip beige 55x60	I	63378
1430H	Provox Tracheofix 1 strip beige 70x70	I	63378
1432H	Provox Tracheofix 2 strips beige 55x60	I	63378
1433H	Provox Tracheofix 2 strips beige 70x70	I	63378
1434H	Provox Tracheofix 1 strip beige 38x63	I	63378

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Released:	QA	Ulrika Svensson - SEHRBHNU	2019-09-24 - 07:34

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We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

The Provox ActiValve System

REF	Name	Class	GMDN code
7150	Provox ActiValve Light 4.5 mm	IIb	62094
7151	Provox ActiValve Light 6 mm	IIb	62094
7152	Provox ActiValve Light 8 mm	IIb	62094
7153	Provox ActiValve Light 10 mm	IIb	62094
7154	Provox ActiValve Light 12.5 mm	IIb	62094
7160	Provox ActiValve Strong 4.5 mm	IIb	62094
7161	Provox ActiValve Strong 6 mm	IIb	62094
7162	Provox ActiValve Strong 8 mm	IIb	62094
7163	Provox ActiValve Strong 10 mm	IIb	62094
7164	Provox ActiValve Strong 12.5 mm	IIb	62094
7165	Provox ActiValve XtraStrong 4.5 mm	IIb	62094
7166	Provox ActiValve XtraStrong 6 mm	IIb	62094
7167	Provox ActiValve XtraStrong 8 mm	IIb	62094
7168	Provox ActiValve XtraStrong 10 mm	IIb	62094
7169	Provox ActiValve XtraStrong 12.5 mm	IIb	62094
7149	ActiValve Lubricant	IIb	62094

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Approved:	DD	Mikael Melefors - SEHRBSGM	2019-10-15 - 13:03
Released:	QA	Ulrika Svensson - SEHRBHNU	2019-10-15 - 13:10

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The Provox FreeHands HME

REF	Name	Class	GMDN code
7710	Provox FreeHands HME	I	36071
7711	Provox FreeHands HME Cassette, 30 pcs	I	58705
7712	Provox FreeHands HME Cassette, 20 pcs	I	58705
7713	Provox FreeHands HME Speech Valve Membrane Light	I	36071
7714	Provox FreeHands HME Speech Valve Membrane Medium	I	36071
7715	Provox FreeHands HME Speech Valve Membrane Strong	I	36071
7716	Provox FreeHands HME Replacement Device, light	I	36071
7717	Provox FreeHands HME Replacement Device, medium	I	36071
7718	Provox FreeHands HME Cleaning and Storage Box	I	36071
7719	Provox FreeHands HME Adjustment Kit	I	36071
7720	Provox Silicone Glue	I	58978
7721	Provox FreeHands HME Replacement Device, strong	I	36071
7722	Provox FreeHands HME Replacement Device	I	36071
7730	Provox HME Cap	I	58705
8020	Provox FreeHands Support Starter Set	I	62155
8021	Provox FreeHands Support Flat	I	62155
8022	Provox FreeHands Support Medium	I	62155
8023	Provox FreeHands Support Deep	I	62155
8024	Provox FreeHands Support Adhesive (15 pcs)	I	62175
7757	Provox FreeHands FlexiVoice Set Plus	I	36071
7760	Provox FreeHands FlexiVoice Set	I	36071
8161	Provox FreeHands FlexiVoice Light	I	36071
8162	Provox FreeHands FlexiVoice Medium	I	36071
8163	Provox FreeHands FlexiVoice Strong	I	36071
8166	Provox FreeHands FlexiVoice XtraStrong	I	36071
8165	Provox FreeHands FlexiVoice Arch	I	36071
8220	Provox FreeHands HME Moist (30 pcs)	I	58705
8221	Provox FreeHands HME Flow (30 pcs)	I	58705
8222	Provox FreeHands HME Moist (20 pcs)	I	58705
8223	Provox FreeHands HME Flow (20 pcs)	I	58705
7401	Provox Life FreeHands Adhesive	I	62175

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We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

The Provox HME Accessories

REF	Name	Class	GMDN code
7244	Provox Cleaning Towel	I	46205
7246	Provox HME CassetteAdaptor	I	58705
7251	Provox Adhesive Regular Round	I	62175
7252	Provox Adhesive Regular Oval	I	62175
7330	Provox Adhesive Regular Plus	I	62175
7253	Provox Adhesive FlexiDerm Round	I	62175
7254	Provox Adhesive FlexiDerm Oval	I	62175
7331	Provox Adhesive FlexiDerm Plus	I	62175
7255	Provox Adhesive OptiDerm Round	I	62175
7256	Provox Adhesive OptiDerm Oval	I	62175
7332	Provox Adhesive OptiDerm Plus	I	62175
7251ES	Provox Adhesive Regular Round	I	62175
7252ES	Provox Adhesive Regular Oval	I	62175
7253ES	Provox Adhesive FlexiDerm Round	I	62175
7254ES	Provox Adhesive FlexiDerm Oval	I	62175
7260	Provox ShowerAid	I	62047
7263	Provox BasePlate Adaptor	I	58705
7265	Provox XtraBase Adhesive base plate	I	62175
7289	Provox StabiliBase (15 pcs)	I	62175
7299	Provox StabiliBase (3 pcs)	I	62175
7318	Provox StabiliBase OptiDerm (15 pcs)	I	62175
7328	Provox StabiliBase OptiDerm (3 pcs)	I	62175
7405	Provox Life Standard Adhesive	I	62175
7406	Provox Life Sensitive Adhesive	I	62175
8011	Provox Skin Barrier	I	58978
8012	Provox Adhesive Remover	I	60494
8014	Provox Luna Adhesive	I	62175
8015	Provox Adhesive Strip	I	62175
8016	Provox Luna ShowerAid	I	62047
8233	Provox XtraBase (3pcs)	I	62175
8234	Provox FlexiDerm Round (3pcs)	I	62175
8235	Provox FlexiDerm Oval (3pcs)	I	62175

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8236	Provox OptiDerm Round	(3pcs)	I	62175
8237	Provox OptiDerm Oval	(3pcs)	I	62175
8238	Provox FlexiDerm Plus	(3pcs)	I	62175
8239	Provox OptiDerm Plus	(3pcs)	I	62175
8240	Provox Regular Plus	(3pcs)	I	62175
8241	Provox Regular Round	(3pcs)	I	62175
8242	Provox Regular Oval	(3pcs)	I	62175
8243	Provox Wipes		I	58978
8308	Provox Life Shower		I	62047
8309	Provox Day Adhesive		I	62175

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Valid Certificates are controlled and filed by QA/RA Department. For standards applied see Applicable Standards & Essential Requirements for each product.

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The Provox HME Cassettes

REF	Name	Class	GMDN code
7240	Provox HME Cassette Normal (20 pcs)	I	58705
7241	Provox HME Cassette HiFlow (20 pcs)	I	58705
7242	Provox HME Cassette Normal (30 pcs)	I	58705
7243	Provox HME Cassette HiFlow (30 pcs)	I	58705
7240C	Provox HME Cassette Normal (20 pcs)	I	58705
7241C	Provox HME Cassette HiFlow (20 pcs)	I	58705
7242C	Provox HME Cassette Normal (30 pcs)	I	58705
7243C	Provox HME Cassette HiFlow (30 pcs)	I	58705
7236	HME Compact, Normal	I	58705
7237	HME Compact, HiFlow	I	58705
7238	HME Compact, Starterkit	I	58705
7247	Provox Micron HME (5 pcs)	I	58705
7248	Provox Micron HME (30 pcs)	I	58705
7250	Provox HME StarterKit	I	58705
7257	Provox HME Let's Start Sample Bag	I	58705
7240X	Provox XtraMoist HME (20 pcs)	I	58705
7241X	Provox XtraFlow HME (20 pcs)	I	58705
7272	Provox XtraFlow HME (20 pcs)	I	58705
7273	Provox XtraMoist HME (20 pcs)	I	58705
7290	Provox XtraMoist HME (30 pcs)	I	58705
7291	Provox XtraFlow HME (30 pcs)	I	58705
7290ES	Provox XtraMoist HME (20 pcs)	I	58705
7291ES	Provox XtraFlow HME (20 pcs)	I	58705
7297	Provox XtraMoist HME (5 pcs)	I	58705
7298	Provox XtraFlow HME (5 pcs)	I	58705
8229	Provox XtraFlow & XtraMoist HME (5+5pcs)	I	58705
8013	Provox Luna HME	I	58705
8025	Provox Luna Set	I	58705
8310	Provox Life Away HME Light	I	58705
8311	Provox Life Home HME	I	58705
8312	Provox Life Energy HME	I	58705
8313	Provox Life Protect HME	I	58705

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8224AU	Provox Coming Home Australia	I	58705
8224BEFR	Provox Coming Home Belgium/French	I	58705
8224BENL	Provox Coming Home Belgium/Dutch	I	58705
8224CA	Provox Coming Home Canada	I	58705
8224CHDE	Provox Coming Home Switzerland/German	I	58705
8224CHFR	Provox Coming Home Switzerland/French	I	58705
8224DE	Provox Coming Home Germany	I	58705
8224DK	Provox Coming Home Denmark	I	58705
8224EM	Provox Coming Home Generic	I	58705
8224ES	Provox Coming Home Spain	I	58705
8224FI	Provox Coming Home Finland	I	58705
8224FR	Provox Coming Home France	I	58705
8224GB	Provox Coming Home GB	I	58705
8224IT	Provox Coming Home Italy	I	58705
8224JP	Provox Coming Home Japan	I	58705
8224NL	Provox Coming Home Netherlands	I	58705
8224NO	Provox Coming Home Norway	I	58705
8224PL	Provox Coming Home Poland	I	58705
8224PT	Provox Coming Home Portugal	I	58705
8224SE	Provox Coming Home Sweden	I	58705
8224US	Provox Coming Home USA	I	58705
8228JP	Provox Coming Home Daytime Japan	I	58705
8227AU	Provox Living Well Australia	I	58705
8227CA	Provox Living Well Canada	I	58705
8227CHDE	Provox Living Well Switzerland/German	I	58705
8227CHFR	Provox Living Well Switzerland/French	I	58705
8227DE	Provox Living Well Germany	I	58705
8227DK	Provox Living Well Denmark	I	58705
8227EM	Provox Living Well Generic	I	58705
8227ES	Provox Living Well Spain	I	58705
8227FI	Provox Living Well Finland	I	58705
8227FR	Provox Living Well France	I	58705
8227GB	Provox Living Well Great Britain	I	58705
8227IT	Provox Living Well Italy	I	58705
8227JP	Provox Living Well Japan	I	58705
8227NL	Provox Living Well Netherlands	I	58705
8227NO	Provox Living Well Norway	I	58705
8227PT	Provox Living Well Portugal	I	58705
8227SE	Provox Living Well Sweden	I	58705
8227US	Provox Living Well United States	I	58705

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The Provox Lary Products

REF	Name	Class	GMDN code
7601	Provox LaryTube 8/27	IIb	38792
7602	Provox LaryTube 8/36	IIb	38792
7603	Provox LaryTube 8/55	IIb	38792
7605	Provox LaryTube 9/27	IIb	38792
7606	Provox LaryTube 9/36	IIb	38792
7607	Provox LaryTube 9/55	IIb	38792
7609	Provox LaryTube 10/27	IIb	38792
7610	Provox LaryTube 10/36	IIb	38792
7611	Provox LaryTube 10/55	IIb	38792
7613	Provox LaryTube 12/27	IIb	38792
7614	Provox LaryTube 12/36	IIb	38792
7615	Provox LaryTube 12/55	IIb	38792
7624	Provox LaryTube 8/36 with Ring	IIb	38792
7625	Provox LaryTube 8/55 with Ring	IIb	38792
7626	Provox LaryTube 9/36 with Ring	IIb	38792
7627	Provox LaryTube 9/55 with Ring	IIb	38792
7628	Provox LaryTube 10/36 with Ring	IIb	38792
7629	Provox LaryTube 10/55 with Ring	IIb	38792
7630	Provox LaryTube 12/36 with Ring	IIb	38792
7631	Provox LaryTube 12/55 with Ring	IIb	38792
7637	Provox LaryTube 8/36, Fenestrated	IIb	38792
7638	Provox LaryTube 8/55, Fenestrated	IIb	38792
7640	Provox LaryTube 9/36, Fenestrated	IIb	38792
7641	Provox LaryTube 9/55, Fenestrated	IIb	38792
7643	Provox LaryTube 10/36, Fenestrated	IIb	38792
7644	Provox LaryTube 10/55, Fenestrated	IIb	38792
7646	Provox LaryTube 12/36, Fenestrated	IIb	38792
7647	Provox LaryTube 12/55, Fenestrated	IIb	38792
7601FR	Provox LaryTube 8/27	IIb	38792
7602FR	Provox LaryTube 8/36	IIb	38792
7603FR	Provox LaryTube 8/55	IIb	38792
7605FR	Provox LaryTube 9/27	IIb	38792

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7606FR	Provox LaryTube 9/36	IIb	38792
7607FR	Provox LaryTube 9/55	IIb	38792
7609FR	Provox LaryTube 10/27	IIb	38792
7610FR	Provox LaryTube 10/36	IIb	38792
7611FR	Provox LaryTube 10/55	IIb	38792
7613FR	Provox LaryTube 12/27	IIb	38792
7614FR	Provox LaryTube 12/36	IIb	38792
7615FR	Provox LaryTube 12/55	IIb	38792
7624FR	Provox LaryTube 8/36 with Ring	IIb	38792
7625FR	Provox LaryTube 8/55 with Ring	IIb	38792
7626FR	Provox LaryTube 9/36 with Ring	IIb	38792
7627FR	Provox LaryTube 9/55 with Ring	IIb	38792
7628FR	Provox LaryTube 10/36 with Ring	IIb	38792
7629FR	Provox LaryTube 10/55 with Ring	IIb	38792
7630FR	Provox LaryTube 12/36 with Ring	IIb	38792
7631FR	Provox LaryTube 12/55 with Ring	IIb	38792
7637FR	Provox LaryTube 8/36, Fenestrated	IIb	38792
7638FR	Provox LaryTube 8/55, Fenestrated	IIb	38792
7640FR	Provox LaryTube 9/36, Fenestrated	IIb	38792
7641FR	Provox LaryTube 9/55, Fenestrated	IIb	38792
7643FR	Provox LaryTube 10/36, Fenestrated	IIb	38792
7644FR	Provox LaryTube 10/55, Fenestrated	IIb	38792
7646FR	Provox LaryTube 12/36, Fenestrated	IIb	38792
7647FR	Provox LaryTube 12/55, Fenestrated	IIb	38792
7648	Provox LaryTube Sizer Kit	IIa	38792
7654	Provox FenestrationPunch	I	38792
7660	Provox TubeBrush 8 mm	I	34883
7661	Provox TubeBrush 12 mm	I	34883
7668	Provox TubeHolder	I	35752
7669	Provox LaryClip	I	35752
7671	Provox LaryButton 12/8	IIb	14093
7672	Provox LaryButton 14/8	IIb	14093
7673	Provox LaryButton 16/8	IIb	14093
7674	Provox LaryButton 18/8	IIb	14093
7685	Provox LaryButton 12/18	IIb	14093
7686	Provox LaryButton 14/18	IIb	14093
7687	Provox LaryButton 16/18	IIb	14093
7688	Provox LaryButton 18/18	IIb	14093
7690	Provox LaryButton Sizer Kit	IIa	14093
8250	Provox Swab Small	I	58717
8251	Provox Swab Medium	I	58717
8252	Provox Swab Large	I	58717
8258	Provox Swab XtraLarge	I	58717

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The Provox NID Voice Prosthesis System

REF	Name	Class	GMDN code
7101	Provox NID 17, 6mm	IIb	44412
7102	Provox NID 17, 8mm	IIb	44412
7103	Provox NID 17, 10mm	IIb	44412
7104	Provox NID 17, 12mm	IIb	44412
7105	Provox NID 17, 14mm	IIb	44412
7106	Provox NID 17, 18mm	IIb	44412
7111	Provox NID 20, 6mm	IIb	44412
7112	Provox NID 20, 8mm	IIb	44412
7113	Provox NID 20, 10mm	IIb	44412
7114	Provox NID 20, 12mm	IIb	44412
7115	Provox NID 20, 14mm	IIb	44412
7116	Provox NID 20, 18mm	IIb	44412

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The Provox Vega System

REF	Name	Class	GMDN code
7770	Provox Vega XtraSeal 17Fr, 4mm	IIb	42533
7771	Provox Vega XtraSeal 17Fr, 6mm	IIb	42533
7772	Provox Vega XtraSeal 17Fr, 8mm	IIb	42533
7773	Provox Vega XtraSeal 17Fr, 10mm	IIb	42533
7774	Provox Vega XtraSeal 17Fr, 12.5mm	IIb	42533
7775	Provox Vega XtraSeal 17Fr, 15mm	IIb	42533
7776	Provox Vega XtraSeal 20Fr, 4mm	IIb	42533
7777	Provox Vega XtraSeal 20Fr, 6mm	IIb	42533
7778	Provox Vega XtraSeal 20Fr, 8mm	IIb	42533
7779	Provox Vega XtraSeal 20Fr, 10mm	IIb	42533
7780	Provox Vega XtraSeal 20Fr, 12.5mm	IIb	42533
7781	Provox Vega XtraSeal 20Fr, 15mm	IIb	42533
7782	Provox Vega XtraSeal 22.5Fr, 4mm	IIb	42533
7783	Provox Vega XtraSeal 22.5Fr, 6mm	IIb	42533
7784	Provox Vega XtraSeal 22.5Fr, 8mm	IIb	42533
7785	Provox Vega XtraSeal 22.5Fr, 10mm	IIb	42533
7786	Provox Vega XtraSeal 22.5Fr, 12.5mm	IIb	42533
7787	Provox Vega XtraSeal 22.5Fr, 15mm	IIb	42533
8110	Provox Vega 17Fr, 4 mm	IIb	42533
8111	Provox Vega 17Fr, 6 mm	IIb	42533
8112	Provox Vega 17Fr, 8 mm	IIb	42533
8113	Provox Vega 17Fr, 10 mm	IIb	42533
8114	Provox Vega 17Fr, 12.5 mm	IIb	42533
8115	Provox Vega 17Fr, 15 mm	IIb	42533
8120	Provox Vega 20Fr, 4 mm	IIb	42533
8121	Provox Vega 20Fr, 6 mm	IIb	42533
8122	Provox Vega 20Fr, 8 mm	IIb	42533
8123	Provox Vega 20Fr, 10 mm	IIb	42533
8124	Provox Vega 20Fr, 12.5 mm	IIb	42533
8125	Provox Vega 20Fr, 15 mm	IIb	42533
8130	Provox Vega 22.5Fr, 4 mm	IIb	42533
8131	Provox Vega 22.5Fr, 6 mm	IIb	42533

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8132	Provox Vega 22.5Fr, 8 mm	IIb	42533
8133	Provox Vega 22.5Fr, 10 mm	IIb	42533
8134	Provox Vega 22.5Fr, 12.5 mm	IIb	42533
8135	Provox Vega 22.5Fr, 15 mm	IIb	42533
8140	Provox Vega Puncture Set 17Fr 8mm	IIb	42533
8141	Provox Vega Puncture Set 17Fr 10mm	IIb	42533
8142	Provox Vega Puncture Set 17Fr 12,5mm	IIb	42533
8143	Provox Vega Puncture Set 17Fr 15mm	IIb	42533
8144	Provox Vega Puncture Set 20Fr 8mm	IIb	42533
8145	Provox Vega Puncture Set 20Fr 10mm	IIb	42533
8146	Provox Vega Puncture Set 20Fr 12,5mm	IIb	42533
8147	Provox Vega Puncture Set 22,5Fr 8mm	IIb	42533
8148	Provox Vega Puncture Set 22,5Fr 10mm	IIb	42533
8149	Provox Vega Puncture Set 22,5Fr 12,5mm	IIb	42533
8140US	Provox Vega Puncture Set 17Fr 8mm	IIb	42533
8141US	Provox Vega Puncture Set 17Fr 10mm	IIb	42533
8142US	Provox Vega Puncture Set 17Fr 12,5mm	IIb	42533
8143US	Provox Vega Puncture Set 17Fr 15mm	IIb	42533
8144US	Provox Vega Puncture Set 20Fr 8mm	IIb	42533
8145US	Provox Vega Puncture Set 20Fr 10mm	IIb	42533
8146US	Provox Vega Puncture Set 20Fr 12,5mm	IIb	42533
8147US	Provox Vega Puncture Set 22,5Fr 8mm	IIb	42533
8148US	Provox Vega Puncture Set 22,5Fr 10mm	IIb	42533
8149US	Provox Vega Puncture Set 22,5Fr 12,5mm	IIb	42533
4270	Provox Vega 17Fr 4mm	IIb	42533
4271	Provox Vega 17Fr 6mm	IIb	42533
4272	Provox Vega 17Fr 8mm	IIb	42533
4273	Provox Vega 17Fr 10mm	IIb	42533
4274	Provox Vega 17Fr 12,5mm	IIb	42533
4275	Provox Vega 17Fr 15mm	IIb	42533
4276	Provox Vega 20Fr 4mm	IIb	42533
4277	Provox Vega 20Fr 6mm	IIb	42533
4278	Provox Vega 20Fr 8mm	IIb	42533
4279	Provox Vega 20Fr 10mm	IIb	42533
4280	Provox Vega 20Fr 12,5mm	IIb	42533
4281	Provox Vega 20Fr 15mm	IIb	42533
4282	Provox Vega 22,5Fr 4mm	IIb	42533
4283	Provox Vega 22,5Fr 6mm	IIb	42533
4284	Provox Vega 22,5Fr 8mm	IIb	42533
4285	Provox Vega 22,5Fr 10mm	IIb	42533
4286	Provox Vega 22,5Fr 12,5mm	IIb	42533
4287	Provox Vega 22,5Fr 15mm	IIb	42533
8270	Provox Vega 17Fr 4mm	IIb	42533
8271	Provox Vega 17Fr 6mm	IIb	42533
8272	Provox Vega 17Fr 8mm	IIb	42533
8273	Provox Vega 17Fr 10mm	IIb	42533

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8274	Provox Vega 17Fr 12,5mm	IIb	42533
8275	Provox Vega 17Fr 15mm	IIb	42533
8276	Provox Vega 20Fr 4mm	IIb	42533
8277	Provox Vega 20Fr 6mm	IIb	42533
8278	Provox Vega 20Fr 8mm	IIb	42533
8279	Provox Vega 20Fr 10mm	IIb	42533
8280	Provox Vega 20Fr 12,5mm	IIb	42533
8281	Provox Vega 20Fr 15mm	IIb	42533
8282	Provox Vega 22,5Fr 4mm	IIb	42533
8283	Provox Vega 22,5Fr 6mm	IIb	42533
8284	Provox Vega 22,5Fr 8mm	IIb	42533
8285	Provox Vega 22,5Fr 10mm	IIb	42533
8286	Provox Vega 22,5Fr 12,5mm	IIb	42533
8287	Provox Vega 22,5Fr 15mm	IIb	42533
4288	Provox Vega XtraSeal 17Fr 4mm	IIb	42533
4289	Provox Vega XtraSeal 17Fr 6mm	IIb	42533
4290	Provox Vega XtraSeal 17Fr 8mm	IIb	42533
4291	Provox Vega XtraSeal 17Fr 10mm	IIb	42533
4292	Provox Vega XtraSeal 17Fr 12,5mm	IIb	42533
4293	Provox Vega XtraSeal 17Fr 15mm	IIb	42533
4294	Provox Vega XtraSeal 20Fr 4mm	IIb	42533
4295	Provox Vega XtraSeal 20Fr 6mm	IIb	42533
4296	Provox Vega XtraSeal 20Fr 8mm	IIb	42533
4297	Provox Vega XtraSeal 20Fr 10mm	IIb	42533
4298	Provox Vega XtraSeal 20Fr 12,5mm	IIb	42533
4299	Provox Vega XtraSeal 20Fr 15mm	IIb	42533
4300	Provox Vega XtraSeal 22,5Fr 4mm	IIb	42533
4301	Provox Vega XtraSeal 22,5Fr 6mm	IIb	42533
4302	Provox Vega XtraSeal 22,5Fr 8mm	IIb	42533
4303	Provox Vega XtraSeal 22,5Fr 10mm	IIb	42533
4304	Provox Vega XtraSeal 22,5Fr 12,5mm	IIb	42533
4305	Provox Vega XtraSeal 22,5Fr 15mm	IIb	42533
8288	Provox Vega XtraSeal 17Fr 4mm	IIb	42533
8289	Provox Vega XtraSeal 17Fr 6mm	IIb	42533
8290	Provox Vega XtraSeal 17Fr 8mm	IIb	42533
8291	Provox Vega XtraSeal 17Fr 10mm	IIb	42533
8292	Provox Vega XtraSeal 17Fr 12,5mm	IIb	42533
8293	Provox Vega XtraSeal 17Fr 15mm	IIb	42533
8294	Provox Vega XtraSeal 20Fr 4mm	IIb	42533
8295	Provox Vega XtraSeal 20Fr 6mm	IIb	42533
8296	Provox Vega XtraSeal 20Fr 8mm	IIb	42533
8297	Provox Vega XtraSeal 20Fr 10mm	IIb	42533
8298	Provox Vega XtraSeal 20Fr 12,5mm	IIb	42533
8299	Provox Vega XtraSeal 20Fr 15mm	IIb	42533
8300	Provox Vega XtraSeal 22,5Fr 4mm	IIb	42533
8301	Provox Vega XtraSeal 22,5Fr 6mm	IIb	42533

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8302	Provox Vega XtraSeal 22.5Fr 8mm	IIb	42533
8303	Provox Vega XtraSeal 22.5Fr 10mm	IIb	42533
8304	Provox Vega XtraSeal 22.5Fr 12.5mm	IIb	42533
8305	Provox Vega XtraSeal 22.5Fr 15mm	IIb	42533

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Declaration of Conformity

We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11 transposing European Medical Devices Directive 93/42/EEC.

The Provox Voice Prosthesis System

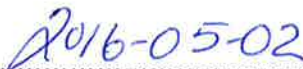
REF	Name	Class	Rule
7208	Provox 4,5 mm	IIb	2.4 Rule 8
7200	Provox 6 mm	IIb	2.4 Rule 8
7201	Provox 8 mm	IIb	2.4 Rule 8
7202	Provox 10 mm	IIb	2.4 Rule 8

Atos Medical AB

Reviewed by:




Marie Lange
Vice President QA & RA


Date

Approved by:


Rolf Karlberg
Atos Medical Site Manager


Date

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Released:	QA	Ulrika Svensson - SEHRBHNU	2019-04-18 - 15:50

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The Provox2 Voice Prosthesis System

REF	Name	Class	GMDN code
7216	Provox2 4,5 mm	IIb	42533
7217	Provox2 6 mm	IIb	42533
7218	Provox2 8 mm	IIb	42533
7219	Provox2 10 mm	IIb	42533
7221	Provox2 12,5 mm	IIb	42533
7224	Provox2 15 mm	IIb	42533

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The Rhinology Products

REF	Name	Class	Rule
7370	Nasal Vent Splint	Ila	2.3 Rule 7
7350	Nasal Splint Small 0.25	Ila	2.3 Rule 7
7355	Nasal Splint Small 0.50	Ila	2.3 Rule 7
7360	Nasal Splint Large 0.25	Ila	2.3 Rule 7
7365	Nasal Splint Large 0.50	Ila	2.3 Rule 7
7352	Nasal Splint Sheeting 0.25	Ila	2.3 Rule 7
7366	Nasal Splint Sheeting 0.50	Ila	2.3 Rule 7
7367	Nasofix Thermo, Small	I	1.4 Rule 4
7368	Nasofix Thermo, Large	I	1.4 Rule 4
7369	Nasofix Thermo, Custom-cut	I	1.4 Rule 4
7380	Septal Button	Ila	2.1 Rule 5

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The SinoJect System

REF	Name	Class	Rule
7303	SinoJect Instrument	I	2.2 Rule 6
7302	SinoJect Staytube, Catheter for Puncture	Ila	2.1 Rule 5
7300	SinoJect Lavage Tube, Female Cone Connection	Ila	2.1 Rule 5
7304	SinoJect Lavage Tube, Luer Cone Connection	Ila	2.1 Rule 5
7305	SinoJect Rods Set	I	2.2 Rule 6

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The TheraBite Jaw Motion Rehabilitation System

REF	Name	Class	GMDN code
TH001	TheraBite Jaw Motion Rehabilitation System, Adult	I	17802
TH002	TheraBite Jaw Motion Rehabilitation System, Pediatric	I	17802
PA001	TheraBite Bite Pad, Regular	I	17802
PA002	TheraBite Bite Pad, Edentulous	I	17802
PA003	TheraBite Bite Pad, Pediatric	I	17802
SC001	TheraBite Range of Motion Scale	I	17802
8260	TheraBite ActiveBand Kit	I	17802

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The Trach-HME Products

REF	Name	Class	GMDN code
7704	TrachPhone (50 pcs)	IIa	58705
7705	MEDIFLUX HCH F6 (Medival)	IIa	58705
7707	TrachPhone (30 pcs)	IIa	58705

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The TympoVent Otologic Ventilation Tubes

REF	Name	Class	GMDN code
7000	T-Tube 6,0 mm	IIb	33794
7001	T-Tube 7,5 mm	IIb	33794
7002	T-Tube 12,0 mm	IIb	33794
7003	Straight Tube (OD=2,2 mm)	IIb	33794
7010	Straight Tube (OD=2,7 mm)	IIb	33794
7012	Straight Tube (OD=2,4 mm)	IIb	33794
7013	Bevel Bobbin	IIb	33794
7014-W	Reuter Bobbin white	IIb	33794
7016	Collar Button	IIb	33794
7017	Tübingen Type Titanium	IIb	33794
7018	Star Tube 1,0 mm	IIb	33794
7020	Shepard with tail (fluoroplastic)	IIb	33794
7021	Shepard with tail (silicone)	IIb	33794
7024	Reuter Bobbin	IIb	33794
7029	Armstrong Bevel Grommet (silicone)	IIb	33794
7030	Shepard w/o tail (fluoroplastic)	IIb	33794
7031	Donaldson (silicone)	IIb	33794
7034	Armstrong Plain End (silicone)	IIb	33794
7037	Donaldson (fluoroplastic)	IIb	33794
7038	Armstrong Bevel Grommet (fluoroplastic)	IIb	33794
7039	Paparella with tab (ID=1,1 mm)	IIb	33794
7043	Tübingen Type Gold ID=1,25 with wire	IIb	33794
7044	Tübingen Type Gold ID=1,25 without wire	IIb	33794
7045	Tübingen Type Gold ID=1,50 with wire	IIb	33794
7046	Tübingen Type Gold ID=1,50 without wire	IIb	33794

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