

 atosmedical.com	Document title Declaration of Conformity
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This document has been electronically signed by the persons above.

We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing Annex II, with the exemption of section 4 (for class IIa and class IIb devices) and Annex VII (for class I devices) of the European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

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

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.

Notified Body: Intertek Semko AB, Sweden. Identification no. 0413
EC-certificate no. 41310296-03

Competent Authority: Medical Products Agency, Sweden

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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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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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