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 Trach Accessories

REF	Name	Class	GMDN code
7756	HME DigiTop O2	IIa	58705
7769	Freevent O2 Adaptor 10pcs	IIa	58705
8007	Freevent O2 Adaptor Mini 10 pcs	IIa	58705
8034	Freevent Dressing Softfoam L	Is	15624
8035	Freevent Dressing Softfoam S	Is	15624
8036	Freevent Dressing Softfoam Slim L	Is	15624

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. 41310296-04

Competent Authority: *Medical Products Agency, Sweden*

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