EC CERTIFICATE

PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE

(Annex V of the directive 93/42/EEC on medical devices)

No. 266401

issued to

Fogless International AB
Storgatan 24
SE-567 32 VAGGERYD
Sweden

We hereby certify that the Quality System of

Fogless International AB

for production, final inspection and marketing of

Respiratory devices for tracheostomy and anaesthesia care such as speaking valves, humidifiers, cannulae and endotracheal tubes, including accessories,

medical devices in class IIa, has been assessed with respect to the conformity assessment procedure described in Article 11.2 (c) and Annex V of Council Directive 93/42/EEC on Medical Devices, as latest amended by Council Directive 2007/47/EC, and found to comply with the requirements.

The Council Directive 93/42/EEC is implemented in Swedish Law by the national regulation LVFS 2003:11, as latest amended by LVFS 2013:11.

This certificate applies to activities performed at
Storgatan 24, SE-567 32 Vaggeryd, Sweden

This certificate was originally issued on 6th October 2000 and remains valid until 6th of July 2020 provided that the conditions connected to this certificate are fulfilled

SP Technical Research Institute of Sweden
Certification - Notified Body No. 0402

Lennart Aronsson
I have approved this document
07 July 2015

Lennart Aronsson
Product Certification Manager

Signed by: Karin Andresen
Reason: I am the author of this document
Date & Time: 2015-07-07 09:29:46 +02:00

Karin Andresen
Certification Officer

SP Technical Research Institute of Sweden
Box 857, SE-501 15 Borås,
SwedenPhone: +46 10-516 50 00
E-mail/internet: info@sp.se/www.sp.se

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Conditions

Validity

The certificate will remain valid until the expiry date, and allows the holder to use SPs notified body identification number 0402 in conjunction with the CE-mark, on products covered by this certificate, provided that the conditions stated below are fulfilled:

- that surveillance audits are performed, with approved result;
- that the company notifies SP on all modifications on the products, and that the company does not apply the CE-mark to any new or modified products without confirmation from SP;
- that the company notifies SP on all significant changes in the quality system, in its activities and/or organization
- that the certificate is not used in a misleading manner, e.g. in marketing activities.
- that the company notifies SP about vigilance actions, if any

Basis for certificate

- The documentation presented has been examined and assessed by SP in accordance with LVFS 2003:11, as amended by LVFS 2013:11, annex 5, item 3.2.
- An initial audit and follow-up audits of the quality system at the company's premises has been performed by SP.
- SP file 5P05375.

Surveillance

SP will perform surveillance inspections to ensure that the company maintains and applies the quality system that is subject of the certificate.
In accordance with the EU Commission recommendations of 2013-09-24, there will also be unannounced audits during the three year period. These audits can be performed at the manufacturers as well as at selected crucial supplier's premises.

Miscellaneous

Additional conditions appear in "Terms and conditions for audit and assessment of management systems as notified body" and in Agreement concerning continuous inspection between Fogless International AB and SP.

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Certificate history

Issue	Date	Activity
1	6th October 2000	Certificate issued
2	5th January 2001	Certificate revised, from annex VI to annex V
3	12th October 2004	Certificate revised, address changed
4	30th June 2010	Certificate revised and extended: product group octagon® with OctaTrach and Professor Carl-Eric Lindholm's LAO-Tube added
5	12th March 2012	Certificate revised and extended: Basic set 760 and Basic set 770 added
6	12th December 2012	Certificate revised: Octagon products removed from certificate
7	31st October 2013	Certificate revised and extended: product SPIRO Speaking Valve 710R (red) added
8	30 April 2015	Certificate revised and extended: product LAO 7 and 8 mm added
9	7th of July 2015	Certificate re-issued

Register of products covered by the certificate

Product Description	Article No.	GMDN code	Classification
SPIRO Speaking Valve	701	36071	IIa
SPIRO Humidifier/ Night Valve	702	41189	
SPIRO Speaking Valve	710	36071	
SPIRO Speaking Valve	710R	36071	
SPIRO Filter 740	740	37597	
Basic set Speaking Valve	760		
Basic set HME	770		
octagon® LAO 7 mm Endotracheal Tube. Lindholm Anatomical Oval Endotracheal Tube 7 mm	1071	14085	
octagon® LAO 8 mm Endotracheal Tube. Lindholm Anatomical Oval Endotracheal Tube 8 mm	1081	14085	

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