EC CERTIFICATE

PRODUCTION QUALITY ASSURANCE SYSTEM CERTIFICATE

Cert no. 266401

issued to

Fogless International AB

Storgatan 24, 56732 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 according to Annex V of Council Directive 93/42/EEC on Medical Devices, as latest amended by Council Directive 2007/47/EC is implemented in Swedish Law by the national regulation LVFS 2003:11, and found to comply with the requirements

This certificate applies to activities performed at

Storgatan 24, 567 32 Vaggeryd, Sweden

Originally issued	2000-10-06
Decision date	2020-07-03
Expiry date	2024-05-26

Issued by Notified body 0402

Signed by: Helén Dahl
I am the author of this document
2020-07-03 08:46:09 +01:00

Helén Dahl

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SP

SWEDAC ACKREDITERING
Ackred. no 1002
Certification of Management Systems
ISO/IEC 17021-1

Conditions

Validity

The certificate will remain valid until the expiry date, and allows the holder to use RISE 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 RISE 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 RISE;
- that the company notifies RISE 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 RISE about vigilance actions, if any.

Basis for certificate

- The documentation presented has been examined and assessed by RISE in accordance with LVFS 2003:11, Annex V.
- An initial audit and follow-up audits of the quality system at the company's premises in Vaggeryd has been performed by RISE.
- RISE file Ecert ID 66066

Surveillance

RISE 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 once per every three years. These audits can be performed at the manufacturers as well as at selected crucial supplier's premises.

Miscellaneous

Additional conditions appear in "RISE General Terms – Assignment" and "Rules and process assessment of medical devices as notified body LVFS 2003:11".

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 July 2015	Certificate re-issued
10	3rd July 2020	Certificate revised, validity extended

Register of products covered by the certificate

Product	Art.no.	Class
SPIRO Speaking Valve	701	IIa
SPIRO Humidifier/ Night Valve	702	IIa
SPIRO Speaking Valve	710	IIa
SPIRO Speaking Valve	710R	IIa
SPIRO Filter 740	740	IIa
Basic set Speaking Valve	760	IIa
Basic set HME	770	IIa
octagon® LAO 7 mm Endotracheal Tube. Lindholm Anatomical Oval Endotracheal Tube 7 mm	1071	IIa
octagon® LAO 8 mm Endotracheal Tube. Lindholm Anatomical Oval Endotracheal Tube 8 mm	1081	IIa

Note: New products in **bold**