



# CERTIFIKAT

## EC CERTIFICATE

PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE  
(Annex V of the directive 93/42/EEC on medical devices)

**No. 26 64 01**

issued to

**Fogless International AB**  
**Box 84**  
**SE-551 12 Jönköping**  
**SWEDEN**

We hereby certify that the Quality Management System of

**Fogless International AB**

for production, final inspection and marketing of  
speaking valves and humidifiers for tracheostomy cannulae, including accessories, and  
intratracheal tubes, medical devices in class IIa,

has been assessed with respect to the conformity assessment procedure  
described in Article 11.2 (b) 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 2009:18.

This certificate applies to activities performed at

**Storgatan 24, SE-567 32 Vaggeryd, Sweden**

This certificate was originally issued on 6<sup>th</sup> October 2000 and remains valid until 30<sup>th</sup> June 2015  
provided that the conditions set out in the relevant appendix are fulfilled.

This is issue no. 4 of the certificate.

Borås 30<sup>th</sup> June 2010

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

  
Lennart Månsson  
Certification Manager

  
Lennart Aronsson  
Certification Officer

Certificate no 26 64 01, issue no 4, dated 30<sup>th</sup> June 2010, page 1(3)

**SP Technical Research Institute of Sweden**

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