



EG CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM CERTIFICATE

Cert no. SC0538-18

issued to

AB Ulax

Merkuriusgatan 8
591 32 Motala

We hereby certify that the Quality System of AB Ulax for design, production, final inspection and marketing of

products for Heat and Moisture Exchangers (HME), Bacterial/Viral Filters and tubing for connection of the HME,

medical devices in class IIA, has been assessed with respect to the conformity assessment procedure according to Annex II (with the exemption of section 4) 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
Merkuriusgatan 8, SE-591 32 MOTALA Sweden

Originally issued	2018-09-26
Expiry date	2023-09-25

Issued by Notified body 0402

Helén Dahl

Karin Andresen

RISE Research Institutes of Sweden AB | Certification
Box 857, SE-501 15 Borås, Sweden
Phone: +46 10-516 50 00
certifiering@ri.se | www.ri.se



Certificate no. SC0538-18 | issue 1 | 2018-09-26

This certificate may not be reproduced other than in full, except with the prior written approval by RISE Certification.

Page 1(2)

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 II.
- An initial audit and follow-up audits of the quality system at the company's premises in Motala has been performed by RISE.
- RISE file 8P05947

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 "Terms and conditions for audit and assessment of management systems as notified body" and in Agreement concerning continuous inspection between AB ULAX and RISE.

Certificate history

Issue	Date	Activity
1	26 September 2018	Original certificate

Register of products covered by the certificate

Product	Art.no.	Class
Bacterial/ Viral filters	4030, 5030	IIa
Tubings for connection of HME devices	2200	IIa
HME Trach	6000, 6060	IIa

Note: New products in **bold**