

## FULL QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE

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

**SC 1415-11**

issued to

**Wing Plast AB**

Nitgatan 11,  
SE-333 33 SMÅLANDSSTENAR  
Sweden

We hereby certify that the Quality System of

**Wing Plast AB**

for design, production, final inspection and marketing of  
**medical devices**

in class IS, IIA, IIB 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, and found to comply with the requirements.

For devices in class I Sterile, the assessment has been restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

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

This certificate applies to activities performed at  
**Nitgatan 11, SE-333 33 SMÅLANDSSTENAR**  
Sweden

This certificate was originally issued on 25<sup>th</sup> September 2012 and remains valid until 25<sup>st</sup> of September 2022 provided that the conditions connected to this certificate are fulfilled.

**RISE Research Institutes of Sweden AB**  
Certification - Notified Body No. 0402

Lennart Aronsson

Karin Andresen

Certificate No. SC1415-11 | issue 8 | 2017-11-10

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

2017-08-24



## 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 2.
- An initial audit and follow-up audits of the quality system at the company's premises in Smålandsstenar has been performed by RISE.
- RISE file 7P05778

### 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 Wing Plast AB and RISE.

## Certificate history

Issue	Date	Activity
1	25th September 2012	The certificate was issued
2	8th March 2013	Certificate revised, Proctoscope and Rectoscope added
3	7 <sup>th</sup> August 2014	Certificate revised, New Proctoscope added
4	30 <sup>th</sup> October 2015	Certificate revised, Hand Blower added
5	29 <sup>th</sup> June 2016	Certificate revised, devices added as below
6	25 <sup>th</sup> September 2016	Certificate revised, devices added as below
7	25 <sup>th</sup> September 2017	Certificate prolonged
8	10 <sup>th</sup> November 2017	Certificate revised, devices added as below

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## Register of products covered by the certificate

Product	Article No:	Class:
Olivkoppling ADA	A420	<b>I Sterile</b>
Proctoscope Tube Wolf	4844120	
Rectoscope Tube Wolf	4844255	
Diamond-Gerjy Proctoscope	A1511	
Hand Blower Sterile	412700	
TraumaSpec	A1380	
Forceps White	A410	
Holder for Scalpel	9603	
Cord Ring	9607	
Cord Ring Latexfree	9607S	
Cord Clamp	303100	
<b>White Balance cup</b>	<b>A430</b>	
CetroHook	9601	
Scalpel	9602	
<b>SafeTrach</b>	<b>ST1020</b>	<b>IIb</b>
Prolapse Ring	9613	
Prolapse Ring with Membrane	9614	
Prolapse Ring Donut	9615	
Prolapse Ring Incontinence	9616	
Prolapse Ring Flexible	9617	

Note: New products in **bold**

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