



# EC CERTIFICATE

## PRODUCTION QUALITY ASSURANCE SYSTEM CERTIFICATE

Cert no. 391601

issued to

**J.H Orsing AB**

Box 16077  
250 16 RÅÅ

We hereby certify that the Quality System of J.H Orsing AB for production, final inspection and marketing of

**single use dental devices,**

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  
**Torbornavägen 26 SE- 253 68 Helsingborg, Sweden**

Originally issued  
Expiry date

01 July 2004  
01 February 2021

Issued by Notified body 0402

Hélen Dahl

Karin Andresen

**RISE Research Institutes of Sweden AB** | Certification  
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This certificate may not be reproduced other than in full, except with the prior written approval by RISE Certification.

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**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 Helsingborg has been performed by RISE.
- RISE file 21333

**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 J.H Orsing AB and RISE.

**Certificate history**

Issue	Date	Activity
1	1st July 2004	Original certificate issued
2	1st February 2011	Issue 2, certificate revised
3	February 1, 2016	Issue 3, certificate revised and products added
4	February 7, 2018	Issue 4, certificate revised and products added
5	April 10, 2019	Issue 5, certificate updated with correct address and some products removed and some added

Register of products covered by the certificate

Device Description	Product Name	REF	Class
Saliva ejectors	Hygoformic® U	U1000 U2000 U100, U2100 U100LB, U1100LB U100LG, U1100LG U100PK, U1100PK	IIa
Saliva ejectors	Hygoformic® L	L1000 <b>L1000LB</b> <b>L1000PK</b>	IIa
Aspirator tubes	Hygovac® Hygovac® Vent Hygovac® Green Hygovac® Vent Green	V100, V1000, V2800 V100V, V1000V, V2800V V100G, V1000G V25VG	IIa
Aspirator tubes	Hygovac® Bio	B100, B1000 BS100, BS1000 B100LG, B1000LG BS100LG, BS1000LG	IIa
Aspirator tubes	Scantube®	AT100, AT1000, AT2000 LB100, LB1000 LC100, LC1000 LG100, LG1000 MG100, MG1000 OR100, OR1000 PK100, PK1000 PU100, PU1000 BK100, BK1000 BL100, BL1000 YW100, YW1000	IIa
Aspirator tubes	Scantube® Vent	AV100, AV1000 AV100BL, AV1000BL AV100LB, AV1000LB AV100MG, AV1000MG AV100OR, AV1000OR AV100PU, AV1000PU	IIa
Aspirator tubes	Vacuform	V100B, V2000B	IIa
Aspirator tubes	Orbis	DP100, DP2000	IIa
Aspirator tubes	Top Dent T-Vac Top Dent T-Vac Vent	T100WH, T100LB, T1000WH, T1000LB TV100BL, TV1000BL	IIa
Angles for aspirator tubes	Angle	A100 A100LB A100MG A100OR A100PU	IIa
Aspirator tip	Hygotip® Hygosurge® Hygosurge® XL Hygojet® Microtip®	TP25 HS25 HS25XL HJ25 MT25	IIa

Note: New products in **bold**