



# EC CERTIFICATE

## PRODUCTION QUALITY ASSURANCE SYSTEM CERTIFICATE

Cert no. 6155 LVFS

issued to

### Tobin Sweden AB

Arntorpsgatan 26, 44245 KUNGÄLV, SWEDEN

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

### Irrigation kit, Eye

medical devices in class Is 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

*The assessment has been restricted to the aspects of manufacture concerned with the conformity of the devices with securing and maintaining sterile conditions.*

This certificate applies to activities performed at  
**Arntorpsgatan 26, 442 45 Kungälv, Sweden**

Originally issued	2001-12-11
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 13:08:69 +01:00

Helén Dahl

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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 Kungälv has been performed by RISE.
- RISE file Ecert ID 69724

**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
	11 december 2001	Original certificate issued by another NB
1	29 November 2019	Certificate issued and cover products according to register of products
2	3 July 2020	Certificate revised, validity extended and product added

Register of products covered by the certificate

Produkt	Artikelnummer	Klass
TOBIN Eyewash Saline solution, 200ml	79	I s
TOBIN Eyewash Saline solution, 500ml	125	I s
TOBIN Eyewash Saline solution, 1000ml	78	I s
TOBIN Eyewash Phosphate buffered solution, 200ml	94	I s
TOBIN Eyewash Phosphate buffered solution, 500 ml	227	I s
TOBIN Eyewash Phosphate buffered solution, 1000 ml	77	I s
TOBIN Eyewash Acetic acid 0,5%, 200 ml	92	I s
TOBIN Eyewash Borate buffered solution, 200 ml	109	I s
TOBIN Eyewash Borate buffered solution, 500 ml	427	I s
TOBIN Eyewash Borate buffered solution, 1000 ml	101	I s
<b>TOBIN Eyewash Saline solution, 20 ml</b>	<b>120</b>	<b>I s</b>

Note: New products in **bold**