Declaration of Conformity

We,

Tobin Sweden AB
Arntorpsgatan 26
SE-442 45 Kungälv
Sweden

Art.Nr	*DEVICE*	*Medical Device Class*
78	TOBIN Eyewash Saline Solution 1000 ml (Wero REF 280029)	Is
77	TOBIN Eyewash Phosphate Buffered Solution 1000 ml (Wero REF 280048)	Is
101	TOBIN Eyewash Borate Buffered Solution 1000 ml	Is
79	TOBIN Pocket Eyewash Saline Solution 200 ml (Wero REF 280028)	Is
94	TOBIN Pocket Eyewash Phosphate Buffered Solution 200 ml (Wero REF 280044)	Is
102	TOBIN Pocket Eyewash Borate Buffered Solution 200 ml	Is
92	TOBIN Pocket Eyewash Acetic Acid Solution 200 ml	Is
125	TOBIN Eyewash Saline Solution 500 ml (Wero REF 280069)	Is
427	TOBIN Eyewash Borate Buffered solution 500 ml	Is
227	TOBIN Eyewash Phosphate Buffered Solution 500 ml (Wero REF 280063)	Is
120	TOBIN Eyewash Saline Solution 20 ml (Wero REF 280050)	Is

hereby declare that the above devices in Tobin Eyewash Systems, Class I(s), comply with applicable requirements in the Swedish Act **2021:600** concerning medical devices as well as Swedish Medical Products Agency regulations **LVFS 2003:11** on medical devices. The products also meet the requirements in European Directive **93/42/EEC.**

We comply with the applicable requirements in the **European Standard EN 15154-4:2009 Emergency safety showers - Part 4: Non plumbed-in eyewash units.**

Medical devices verified by our Notified Body RISE # **0402**

EC-certificate and ISO 13485 certificate are available upon request.

Kungälv, 2021-08-18

Tobin Sweden AB

Stig Andersson
Managing director

TOBIN SWEDEN AB

Self-Declaration of Compliance Article 120 of Regulation (EU) 2017/745 (MDR) and Article 1, paragraph 3c) of REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745

We, Tobin Sweden AB hereby declare that we are in compliance with the transitional provisions outlined under Article 120 of Regulation (EU) 2017/745 (Medical Device Regulation - MDR) and Article 1, paragraph 3c) of REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745.

As per the requirements of Article 120, we confirm that the medical devices manufactured and placed on the market by Tobin Sweden AB are in accordance with the provisions of the Medical Devices Directive 93/42/EEC (MDD) and are being transitioned to compliance with the MDR.

Tobin Sweden AB maintains a thorough system for tracking and documenting compliance, ensuring that all devices remain safe, effective, and conform to the applicable regulatory requirements during the transition period.

Tobin Sweden AB also declares that we are in compliance in terms of Article 1, paragraph 3c) of REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745:

3c) Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:
(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
(b) there are no significant changes in the design and intended purpose;
(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);
(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

Kungälv the 11th of November 2024
Sincerely,

Stig Andersson
CEO
Tobin Sweden AB

RISE Medical Notified Body Confirmation Letter

Tobin Sweden AB
Arntorpsgatan 26, 442 45
Kungälv, Sweden
2024-09-13

RISE Medical Notified Body AB– Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, RISE Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 3033 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Tobin Sweden AB
Arntorpsgatan 26, 442 45
Kungälv, Sweden

SRN Number (if available): SE-MF-000003781

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Sara Bergh
Enhetschef Certifiering

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TOBIN Eyewash Saline solution, 200ml	Class IIa	N/A	Cert no. 6155 LVFS
TOBIN Eyewash Saline solution, 500ml	Class IIa	N/A	Cert no. 6155 LVFS
TOBIN Eyewash Saline solution, 1000ml	Class IIa	N/A	Cert no. 6155 LVFS
TOBIN Eyewash Phosphate buffered solution, 200ml	Class IIa	N/A	Cert no. 6155 LVFS
TOBIN Eyewash Phosphate buffered solution, 500 ml	Class IIa	N/A	Cert no. 6155 LVFS
TOBIN Eyewash Phosphate buffered solution, 1000 ml	Class IIa	N/A	Cert no. 6155 LVFS
TOBIN Eyewash Borate buffered solution, 200 ml	Class IIa	N/A	Cert no. 6155 LVFS
TOBIN Eyewash Borate buffered solution, 500 ml	Class IIa	N/A	Cert no. 6155 LVFS
TOBIN Eyewash Borate buffered solution, 1000 ml	Class IIa	N/A	Cert no. 6155 LVFS
TOBIN Eyewash Saline solution, 20 ml	Class I devices placed on the market in sterile condition	N/A	Cert no. 6155 LVFS

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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-09-13	1	Initial issue

Verifikat

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Dokument

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Signerare

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