EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation restricted to the aspects of manufacture concerned with the conformity of the devices with sterility and metrological requirements - has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620123041

Revision:
01

Initial Certification Date:
29 March 2022

Date of Certification Decision:
22 June 2023

Certificate Issue Date:
22 June 2023

Certificate Expiry Date:
28 March 2027

Observe Medical AB

Krokslätts Parkgata 4, SE-431 68 Mölndal, Sweden

Manufacturer SRN: SE-MF-000017468

Scope:

Sterility and, where appropriate, metrology aspects of devices as detailed in attached product list

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Audit Report Reference	**CN00172-08**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620123041	29 March 2022	Initial certificate

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PRODUCT LIST FOR CERTIFICATE

Issued to: Observe Medical AB

Certificate number: 28620123041-01

Certificate valid from: 2023-06-22

Product list issue date:
07 July 2026

Product	Classification and EMDN	Intended use[1]	Date Added
Class I sterile devices			
Basic UDI-DI: 0735005767050U4			
1206 - Sippi Disposable Unit	Class I(s) A060303		2022-03-29
Basic UDI-DI: 0735005767500UE			
84062182 - UnoMeter™ Original Exchange bag 3.0L	Class I(s) A06030301		2023-06-15
84077181 - UnoMeter™ Original Exchange bag 2.0L	Class I(s) A06030301		2023-06-15
84162172 - UnoMeter™ Omni Exchange bag 3.0L	Class I(s) A06030301		2026-03-16
84177171 - UnoMeter™ Omni Exchange bag 2.0L	Class I(s) A06030301		2026-03-16
Class I sterile devices with measuring function			
Basic UDI-DI: 0735005767400U9			
1710085 - UnoMeter™ Safeti™ Plus, 2.0L, 150 cm, SH	Class I(s,m) A06030302		2024-09-12
1710086 - UnoMeter™ Safeti™ Plus, 2.0L, 110 cm, SH	Class I(s,m) A06030302		2024-09-12
1710087 - UnoMeter™ Safeti™ Plus, 2.0L, 150 cm, SC	Class I(s,m) A06030302		2024-09-12
1710088 - UnoMeter™ Safeti™ Plus, 2.0L, 110 cm, SC	Class I(s,m) A06030302		2024-09-12
1710089 - UnoMeter™ Safeti™ Plus, 2.0L, 120 cm, SH	Class I(s,m) A06030302		2024-09-12
1710090 - UnoMeter™ Safeti™ Plus, 2.0L, 200 cm, SH	Class I(s,m) A06030302		2024-09-12

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
1720075 - UnoMeter™ Safeti™ Max, 2.0L, 150 cm, SH	Class I(s,m) A06030302		2026-03-16
1720076 - UnoMeter™ Safeti™ Max, 2.0L, 110 cm, SH	Class I(s,m) A06030302		2026-03-16
1720077 - UnoMeter™ Safeti™ Max, 2.0L, 150 cm, SC	Class I(s,m) A06030302		2026-03-16
1720078 - UnoMeter™ Safeti™ Max, 2.0L, 110 cm, SC	Class I(s,m) A06030302		2026-03-16
1720079 - UnoMeter™ Safeti™ Max, 2.0L, 120 cm, SH	Class I(s,m) A06030302		2026-03-16
1720080 - UnoMeter™ Safeti™ Max, 2.0L, 200 cm, SH	Class I(s,m) A06030302		2026-03-16
25001183 - UnoMeter™ 500, 2.0L, 110 cm, NRV, SC	Class I(s,m) A06030302		2023-06-15
25001184 - UnoMeter™ 500, 2.0L, 110 cm, 2xNRV, SC	Class I(s,m) A06030302		2023-06-15
25012183 - UnoMeter™ 500, 2.0L, 150 cm, NRV, SC	Class I(s,m) A06030302		2023-06-15
25012184 - UnoMeter™ 500, 2.0L, 150 cm, 2xNRV, SC	Class I(s,m) A06030302		2023-06-15
25039742 - UnoMeter™ 500, 2.0L, 110 cm, NRV, SH	Class I(s,m) A06030302		2023-06-15
25039743 - UnoMeter™ 500, 2.0L, 110 cm, 2xNRV, SH	Class I(s,m) A06030302		2023-06-15
25104742 - UnoMeter™ 500, 2.0L, 150 cm, NRV, SH	Class I(s,m) A06030302		2023-06-15
25104743 - UnoMeter™ 500, 2.0L, 150 cm, 2xNRV, SH	Class I(s,m) A06030302		2023-06-15

David Ben Williams
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