

# 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.

## 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

### 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



### 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.



**PRODUCT LIST FOR CERTIFICATE**  
*See attached Product List*

**EXAMINATION AND TESTS PERFORMED**

<b>Audit Report Reference</b>	CN00172-08

**CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE**

None

**CERTIFICATE HISTORY**

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

**Certificate Number:**  
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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:**  
 12 September 2024

Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
<b>Class I sterile devices</b>			
<i>Basic UDI-DI: 0735005767050U4</i>			
1206 - Sippi Disposable Unit	Class I(s) A060303		2022-03-29
<i>Basic UDI-DI: 0735005767500UE</i>			
84062182 - UnoMeter™ 500 Exchange bag 3.0L, NRV, Free Flow	Class I(s) A06030301		2023-06-15
84077181 - UnoMeter™ 500 Exchange bag 2.0L, NRV, Free Flow	Class I(s) A06030301		2023-06-15
<b>Class I sterile devices with measuring function</b>			
<i>Basic UDI-DI: 0735005767400U9</i>			
1710085 - UnoMeter™ Safeti Plus, 2.0L bag, straps and round hook, 150cm tube, Free flow bottom outlet	Class I(s,m) A06030302		2024-09-12
1710086 - UnoMeter™ Safeti Plus, 2.0L bag, straps and round hook, 110cm tube, Free flow bottom outlet	Class I(s,m) A06030302		2024-09-12
1710087 - UnoMeter™ Safeti Plus, 2.0L bag, straps and cord, 150cm tube, Free flow bottom outlet	Class I(s,m) A06030302		2024-09-12
1710088 - UnoMeter™ Safeti Plus, 2.0L bag, straps and cord, 110cm tube, Free flow bottom outlet	Class I(s,m) A06030302		2024-09-12
1710089 - UnoMeter™ Safeti Plus, 2.0L bag, straps and round hook, 120cm tube, Free flow bottom outlet	Class I(s,m) A06030302		2024-09-12
1710090 - UnoMeter™ Safeti Plus, 2.0L bag, straps and round hook, 200cm tube, Free flow bottom outlet	Class I(s,m) A06030302		2024-09-12
25001183 - UnoMeter™ 500 2.0L Exchange bag, NRV, Straps, 110 cm, Free flow	Class I(s,m) A06030302		2023-06-15

<sup>1</sup>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 <sup>1</sup>	Date Added
25001184 - UnoMeter™ 500 2.0L Exchange bag, Double NRV, Straps, 110 cm, Free flow	Class I(s,m) A06030302		2023-06-15
25012183 - UnoMeter™ 500 2.0L Exchange bag, NRV, Straps, 150 cm, Free flow	Class I(s,m) A06030302		2023-06-15
25012184 - UnoMeter™ 500 2.0L Exchange bag, Double NRV, Straps, 150 cm, Free flow	Class I(s,m) A06030302		2023-06-15
25039742 - UnoMeter™ 500 2.0L Exchange bag, NRV, Straps and round hook, 110 cm, Free flow	Class I(s,m) A06030302		2023-06-15
25039743 - UnoMeter™ 500 2.0L Exchange bag, Double NRV, Straps and round hook, 110 cm, Free flow	Class I(s,m) A06030302		2023-06-15
25104742 - UnoMeter™ 500 2.0L Exchange bag, NRV, Straps and round hook, 150 cm, Free flow	Class I(s,m) A06030302		2023-06-15
25104743 - UnoMeter™ 500 2.0L Exchange bag, Double NRV, Straps and round hook, 150 cm, Free flow	Class I(s,m) A06030302		2023-06-15



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Certificate number: 28620123041-01

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