# 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 relating to the conformity of the devices with reusability requirements - has been carried out following the requirements of Regulation (EU) 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:**
28620170242

**Revision:**
01

**Initial Certification Date:**
19 March 2024

**Date of Certification Decision:**
30 August 2024

**Certificate Issue Date:**
30 August 2024

**Certificate Expiry Date:**
18 December 2028

## M Dialysis AB

Hammarby Fabriksväg 43 120 30 Stockholm Sweden

Manufacturer SRN: SE-MF-000017466

**Scope:**

Reusability aspects of devices as detailed in attached product list

Sterility 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.

## PRODUCT LIST FOR CERTIFICATE

*See attached Product List*

## EXAMINATION AND TESTS PERFORMED

| | |
|---|---|
| **Last Audit report reference** | **Stage 1 audit ACTY-2022-607917** |
| | **Stage 2 audit ACTY-2022-607919** |
| | |

## CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

| |
|---|
| None |

## CERTIFICATE HISTORY

| PRECEDING CERTIFICATE NUMBER | DATE OF ISSUE | IDENTIFICATION OF CHANGES |
|---|---|---|
| 28620170242 | 19 March 2024 | Initial certificate |
| | | |
| | | |

**Certificate Number:**
28620170242

**Revision:**
01

**Initial Certification Date:**
19 March 2024

**Date of Certification Decision:**
30 August 2024

**Certificate Issue Date:**
30 August 2024

**Certificate Expiry Date:**
18 December 2028

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

**Issued to:** M Dialysis AB

**Certificate number:** 28620170242

**Certificate valid from:** 2024-08-30

**Product List Issue Date:**
30 August 2024

| Product | Classification and EMDN | Intended use[1] | Date Added |
|---|---|---|---|
| **Class I reusable surgical instruments** | | | |
| ***Basic UDI-DI: 7332699_330_010_WN*** | | | |
| P000056 - Forceps | Class I(r)<br>L23 | | 2024-03-19 |
| ***Basic UDI-DI: 7332699_330_011_WR*** | | | |
| P000055 - Tunnelating needle | Class I(r)<br>A010199 | | 2024-03-19 |
| **Class I sterile devices** | | | |
| ***Basic UDI-DI: 7332699_330_004_WV*** | | | |
| 8010191 - 106 Syringe | Class I(s)<br>A020199 | | 2024-03-19 |

**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.

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