

# EC CERTIFICATION

## QUALITY MANAGEMENT SYSTEM CERTIFICATE Regulation (EU) 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 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.

### M Dialysis AB

Hammarby Fabriksväg 43 120 30 Stockholm Sweden

Manufacturer SRN: SE-MF-000017466

#### Scope:

- Infusion and injection devices
- Syringe Pumps

**Certificate Number:**

28620178542

**Revision:**

01

**Initial Certification Date:**

10 June 2024

**Certificate Decision Date:**

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**

*See attached product list*

**EXAMINATION AND TESTS PERFORMED**

Technical Assessment Report Reference	TD00314-02 M Dialysis AB 107 Microdialysis Pump
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
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**CERTIFICATE HISTORY**

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620178542-00	10 June 2024	Initial certificate



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## PRODUCT LIST FOR CERTIFICATE

**Issued to:** M Dialysis AB  
**Certificate number:** 28620178542-01  
**Certificate valid from:** 2024-08-30

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

Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
<b>Infusion and injection devices</b>			
<i>Basic UDI-DI: 7332699_320_003_W9</i>			
8010650 - 66 Linear Microdialysis Catheter 30mm/20kD (including Needle Introducer)	Class IIa F05		2024-06-10
8010651 - 66 Linear Microdialysis Catheter 30mm/100kD (including Needle Introducer)	Class IIa F05		2024-06-10
8010670 - 66 Linear Microdialysis Catheter 10mm/20kD (including Needle Introducer)	Class IIa F05		2024-06-10
8010671 - 66 Linear Microdialysis Catheter 10mm/100kD (including Needle Introducer)	Class IIa F05		2024-06-10
<i>Basic UDI-DI: 7332699_320_004_WC</i>			
8050090 - 67 IV Microdialysis Catheter 46/10 (including PVC)	Class IIa F05		2024-06-10
8050091 - 67 IV Microdialysis Catheter 46/20 (including PVC)	Class IIa F05		2024-06-10
8050092 - 67 IV Microdialysis Catheter 46/30 (including PVC)	Class IIa F05		2024-06-10
8050093 - 67 IV Microdialysis Catheter 130/10 (including PVC)	Class IIa F05		2024-06-10
<i>Basic UDI-DI: 7332699_320_005_WF</i>			
8010226 - 61 Microdialysis Catheter 310/30 (including Splitable Introducer SI-2)	Class IIa F05		2024-06-10
8010509 - 63 Microdialysis Catheter 60/10 (including Splitable Introducer SI-2)	Class IIa F05		2024-06-10
8010514 - 63 Microdialysis Catheter 40/30 (including Splitable Introducer SI-2)	Class IIa F05		2024-06-10

<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
8050191 - 61 High Cut-Off Microdialysis Catheter 310/30 (including Splitable Introducer SI-2)	Class IIa F05		2024-06-10
<b>Basic UDI-DI: 7332699_330_005_WY</b>			
8050154 - Perfusion fluid CNS Dextran	Class IIa V0999		2024-06-10
P000034 - Perfusion fluid T1	Class IIa V0999		2024-06-10
P000151 - Perfusion fluid CNS	Class IIa V0999		2024-06-10
<b>Basic UDI-DI: 7332699_330_012_WU</b>			
8010343 - Splitable Introducer SI-2	Class IIa A018003		2024-06-10
<b>Syringe Pumps</b>			
<b>Basic UDI-DI: 7332699_300_002_V4</b>			
P000003 - 106 Microdialysis Pump	Class IIa Z12030302		2024-06-10
P000127 - 107 Microdialysis Pump	Class IIa Z12030302		2024-06-10

*Brian Mather*

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Certificate number: 28620178542-01  
Product list issue date: 30 August 2024

