intertek
Total Quality. Assured.

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

CERTIFICATE HISTORY

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

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

Issued to: M Dialysis AB

Certificate number: 28620178542-01

Certificate valid from: 2024-08-30

Product List Issue Date:
30 July 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Infusion and injection devices			
Basic UDI-DI: 7332699_320_003_W9			
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
Basic UDI-DI: 7332699_320_004_WC			
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
Basic UDI-DI: 7332699_320_005_WF			
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

[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
8050191 - 61 High Cut-Off Microdialysis Catheter 310/30 (including Splitable Introducer SI-2)	Class IIa F05		2024-06-10
Basic UDI-DI: 7332699_330_005_WY			
8050151 - 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
Basic UDI-DI: 7332699_330_012_WU			
8010343 - Splitable Introducer SI-2	Class IIa A018003		2024-06-10
Syringe Pumps			
Basic UDI-DI: 7332699_300_002_V4			
P000003 - 106 Microdialysis Pump	Class IIa Z12030302		2024-06-10
P000127 - 107 Microdialysis Pump	Class IIa Z12030302		2024-06-10

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

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

Certificate number: 28620178542-01
Product list issue date: 30 July 2025