

EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapter I

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:

- Microdialysis catheters

Certificate Number:
28620178540

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 | TD00314-01 M Dialysis AB 71 High Cut-Off Brain Microdialysis Catheter 60/10 |
| | |
| | |
| 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 |
|------------------------------|---------------|---------------------------|
| 28620178540 | 10 June 2024 | Initial certificate |
| | | |

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PRODUCT LIST FOR CERTIFICATE

Issued to: M Dialysis AB
Certificate number: 28620178540-01
Certificate valid from: 2024-06-10

Product List Issue Date:
05 September 2024

| Product | Classification and EMDN | Intended use ¹ | Date Added |
|--|-------------------------|---|------------|
| Microdialysis catheters | | | |
| <i>Basic UDI-DI: 7332699_320_001_W3</i> | | | |
| 8010320 - 71 High Cut-Off Brain Microdialysis Catheter 60/10 | Class III F05 | The 71 High Cut-Off Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue | 2024-06-10 |
| 8010331 - 71 High Cut-Off Brain Microdialysis Catheter 60/20 | Class III F05 | The 71 High Cut-Off Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue | 2024-06-10 |
| 8010337 - 71 High Cut-Off Brain Microdialysis Catheter 60/30 | Class III F05 | The 71 High Cut-Off Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue | 2024-06-10 |
| P000049 - 70 Brain Microdialysis Catheter 60/10 | Class III F05 | The 70 Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue | 2024-06-10 |
| P000050 - 70 Brain Microdialysis Catheter 100/10 | Class III F05 | The 70 Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue | 2024-06-10 |
| P000080 - 70 Brain Microdialysis Catheter 60/20 | Class III F05 | The 70 Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue | 2024-06-10 |
| <i>Basic UDI-DI: 7332699_320_002_W6</i> | | | |
| 8010954 - 71 High Cut-Off Microdialysis Bolt Catheter 130/10 | Class III F05 | The 71 High Cut-Off Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue | 2024-06-10 |
| P000131 - 70 Microdialysis Bolt Catheter 130/10 | Class III F05 | The 70 Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue | 2024-06-10 |



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

