

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

Brett

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

BOX 1105, 3E-104 22 Rista, 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		
None		

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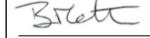
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CERTIFICATE HISTORY

PRECEDING CERTIFICATE	DATE OF ISSUE	IDENTIFICATION OF CHANGES
NUMBER		
28620178540	10 June 2024	Initial certificate





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			
Basic UDI-DI: 7332699_320_001_W3			
8010320 - 71 High Cut-Off Brain	Class III	The 71 High Cut-Off Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue	2024-06-10
Microdialysis Catheter 60/10	F05		
8010331 - 71 High Cut-Off Brain	Class III	The 71 High Cut-Off Microdialysis Catheters are intended to enable microdialysis of the extracellular fluid of the brain tissue	2024-06-10
Microdialysis Catheter 60/20	F05	microdialysis of the extracellular fluid of the brain tissue	
8010337 - 71 High Cut-Off Brain	Class III	The 71 High Cut-Off Microdialysis Catheters are intended to enable	2024-06-10
Microdialysis Catheter 60/30	F05	microdialysis of the extracellular fluid of the brain tissue	
P000049 - 70 Brain Microdialysis	Class III	The 70 Microdialysis Catheters are intended to enable microdialysis	2024-06-10
Catheter 60/10	F05	of the extracellular fluid of the brain tissue	
P000050 - 70 Brain Microdialysis	Class III	The 70 Microdialysis Catheters are intended to enable microdialysis	2024-06-10
Catheter 100/10	F05	of the extracellular fluid of the brain tissue	
P000080 - 70 Brain Micrdialysis	Class III	The 70 Microdialysis Catheters are intended to enable microdialysis	2024-06-10
Catheter 60/20	F05	of the extracellular fluid of the brain tissue	
Basic UDI-DI: 7332699_320_002_W6			
8010954 - 71 High Cut-Off	Class III	The 71 High Cut-Off Microdialysis Catheters are intended to enable	2024-06-10
Microdialysis Bolt Catheter 130/10	F05	microdialysis of the extracellular fluid of the brain tissue	
P000131 - 70 Microdialysis Bolt	Class III	The 70 Microdialysis Catheters are intended to enable microdialysis	2024-06-10
Catheter 130/10	F05	of the extracellular fluid of the brain tissue	



Certification Authority, MDR

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