EC CERTIFICATION

TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapter II

We hereby declare that a conformity assessment of the technical documentation according to Annex II and III has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the technical documentation for the below listed products 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

*For the class III devices covered by this certificate an EU Quality Management System certificate according to Annex IX is also required.

Certificate Number:
28620178541

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
28620178541	10 June 2024	Initial Issue

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PRODUCT LIST FOR CERTIFICATE

Issued to: M Dialysis AB

Certificate number: 28620178541-01

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 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 Micrdialysis 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
Basic UDI-DI: 7332699_320_002_W6			
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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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.