

μ dialysis

DECLARATION OF CONFORMITY

Manufacturer's Name: M Dialysis AB

Manufacturer's Address: Hammarby Fabriksväg 43
SE-120 30 Stockholm
SWEDEN

SRN: SE-MF-000017466

Product: Microdialysis Sampling System, Non-Brain

Intended purpose: The Microdialysis sampling system is intended to enable human microdialysis of the interstitial fluid of tissues, and blood.

Risk class: Class IIa

Basic UDI-DI: 7332699_360_001_Y7

Notified Body: Intertek Medical Notified Body AB (NB 2862)

Conformity assessment: MDR 2017/745, Annex IX excluding chapter II (only those aspects related to the reuse of the device, including cleaning, disinfections, sterilization and related instructions)

Issued certificates: EC certificate QMS #28620170242
EC design examination certificate #TBD
ISO 13485 certificate #0106135-01

Type designation/model:

Product Name	Catalogue number (REF) Basic UDI-DI	Risk Class
Microdialysis Sampling System (Non-Brain)	8079000 7332699_360_001_Y7	IIa
106 Microdialysis pump	P000003 7332699_300_002_V4	IIa
107 Microdialysis pump	P000127 7332699_300_002_V4	IIa
106 Syringe	8010191 7332699_330_004_WV	Is
Perfusion fluid T1	P000034 7332699_330_005_WY	IIa
61 Microdialysis Catheter 310/30	8010226 7332699_320_005_WF	IIa
61 High Cut-Off Microdialysis Catheter 310/30	8050191 7332699_320_005_WF	IIa

Document No. D10413-01	Document Name MDR Declaration of Conformity Microdialysis Sampling System, Non-Brain
---------------------------	---

63 Microdialysis Catheter 60/10	8010509 7332699_320_005_WF	Ila
63 Microdialysis Catheter 40/30	8010514 7332699_320_005_WF	Ila
66 Linear Microdialysis Catheter 30mm	8010650 7332699_320_003_W9	Ila
66 Linear Microdialysis Catheter 10mm	8010670 7332699_320_003_W9	Ila
66 High Cut-Off Linear Microdialysis Catheter 30mm	8010651 7332699_320_003_W9	Ila
66 High Cut-Off Linear Microdialysis Catheter 10mm	8010671 7332699_320_003_W9	Ila
67 IV Microdialysis Catheter 46/10	8050090 7332699_320_004_WC	Ila
67 IV Microdialysis Catheter 46/20	8050091 7332699_320_004_WC	Ila
67 IV Microdialysis Catheter 46/30	8050092 7332699_320_004_WC	Ila
67 IV Microdialysis Catheter 130/10	8050093 7332699_320_004_WC	Ila
Splitable introducer SI-2	8010343 7332699_330_012_WU	Ila
Tunnelating needle	P000055 7332699_330_011_WR	Ir

We hereby declare that the above mentioned device(s) comply with applicable requirements in EU Medical Device Regulation (MDR) 2017/745.

A translation of this Declaration of Conformity into another EU official language is made available upon request.

This EU Declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of the manufacturer M Dialysis AB

Date and place of issue

Stockholm 2024-06-10

Name, position and signature


Olof Nord, CEO

Document No. D10413-01	Document Name MDR Declaration of Conformity Microdialysis Sampling System, Non-Brain
---------------------------	---