

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, Brain

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

Risk class: Class III

Basic UDI-DI: 7332699_360_002_YA

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 (Brain)	8080000 7332699_360_002_YA	III
106 Microdialysis pump	P000003 7332699_300_002_V4	Ila
107 Microdialysis pump	P000127 7332699_300_002_V4	Ila
106 Syringe	8010191 7332699_330_004_WV	Is
Perfusion fluid CNS	P000151 7332699_330_005_WY	Ila
Perfusion fluid CNS Dextran	8050151 7332699_330_005_WY	Ila

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70 Brain Microdialysis Catheter 60/10	P000049 7332699_320_001_W3	III
70 Brain Microdialysis Catheter 60/20	P000080 7332699_320_001_W3	III
70 Brain Microdialysis Catheter 100/10	P000050 7332699_320_001_W3	III
71 High Cut-Off Brain Microdialysis Catheter 60/10	8010320 7332699_320_001_W3	III
71 High Cut-Off Brain Microdialysis Catheter 60/20	8010331 7332699_320_001_W3	III
71 High Cut-Off Brain Microdialysis Catheter 60/30	8010337 7332699_320_001_W3	III
70 Microdialysis Bolt catheter 130/10	P000131 7332699_320_002_W6	III
71 High Cut-Off Microdialysis Bolt Catheter 130/10	8010954 7332699_320_002_W6	III
Forceps	P000056 7332699_330_010_WN	Ir
Tunneling 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

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