

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: Brain Microdialysis Catheter

Intended purpose: The Brain Microdialysis Catheter is intended to enable microdialysis of the extracellular (interstitial) fluid of the brain tissue.

Risk class: Class III (Rule 7)

Basic UDI-DI: 7332699_320_001_W3

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 #28620178540
EC design examination certificate #28620178541
ISO 13485 certificate #0106135-01

Type designation/model:

| Product Name | Catalogue number (REF) Basic UDI-DI | Risk Class |
|---|--|------------|
| 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 |

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| Document No. D10653-01 | Document Name MDR Declaration of Conformity Brain Microdialysis Catheter |
|---------------------------|---|

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.

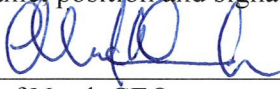
This EU Declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of the manufacturer M Dialysis AB

Date and place of issue

Stockholm 2024-06-27

Name, position and signature



Olof Nord, CEO

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