

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 Bolt 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_002_W6

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 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

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.

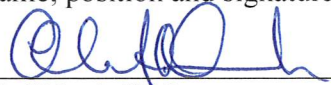
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Signed for and on behalf of the manufacturer M Dialysis AB

Date and place of issue

Stockholm 2024-06-27

Name, position and signature



Olof Nord, CEO

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