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 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.

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