



## DECLARATION OF CONFORMITY

**Manufacturer's Name:** M Dialysis AB

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

**Product type:** 70 Brain Microdialysis Catheter

**Product class:** Class III

**Brand name and trade mark:** M Dialysis AB

**Notified Body:** Intertek Semko AB,  
identification number 0413

**Conformity assessment:** MDD 93/42/EEC, Annex II excluding (4)

**Issued certificates:** EC QMS certificate #41319021-02 (exp date 2024-05-26)  
EC certificate #41319031-02 (exp date 2024-05-26)  
ISO 13485 certificate #0106135-01 (exp date 2023-12-18)

**Type designation/model:**

Ref. no	Name
P000049	70 Brain Microdialysis Catheter 60/10
P000050	70 Brain Microdialysis Catheter 100/10
P000051	70 Brain Microdialysis Catheter 90/20
P000052	70 Brain Microdialysis Catheter 80/30
P000080	70 Brain Microdialysis Catheter 60/20
P000081	70 Brain Microdialysis Catheter 60/30
P000131	70 Microdialysis Bolt Catheter 130/10

**We hereby declare that the above mentioned device(s) comply with applicable requirements in the swedish law 1993:584 and the Swedish Medical Products Agency regulation LVFS 2003:11 regarding medical devices.**

**The product(s) fulfils hereby the requirements in the European Medical Device Directive 93/42/EEC.**

Date and place of issue

2023-06-05 Stockholm

Name, position and signature

Charlotte Woschnagg  
QA / RA Manager

Document No. D8271-08	Document Name Declaration of Conformity 70 Brain Microdialysis Catheter
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