



DECLARATION OF CONFORMITY

Manufacturer's Name: M Dialysis AB

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

Product type: High Cut-Off 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
EC certificate #41319031-02
ISO 13485 certificate #0106135-01

Type designation/model:

Ref. no	Name
8010320	71 High Cut-Off Brain Microdialysis Catheter 60/10
8010331	71 High Cut-Off Brain Microdialysis Catheter 60/20
8010337	71 High Cut-Off Brain Microdialysis Catheter 60/30
8010954	71 High Cut-Off 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

2023-01-10 Stockholm

Name, position and signature

Olof Nord
CEO

Document No. D8264-09	Document Name Declaration of Conformity 71 High Cut Off Brain Microdialysis Catheters
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