



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

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

2020-04-21 Stockholm

Name, position and signature

Olof Nord
CEO

Document No. D8264-08	Document Name Declaration of Conformity 71 High Cut Off Brain Microdialysis Catheters
--------------------------	--