



## 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

2023-06-05 Stockholm

Name, position and signature

Charlotte Woschnagg  
QA / RA Manager

Document No.	Document Name
D8264-10	Declaration of Conformity 71 High Cut Off Brain Microdialysis Catheters



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