



## DECLARATION OF CONFORMITY

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

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

**Product type:** Tunnelating Needle to be used as accessory for  
70 and 71 Brain Microdialysis Catheters

**Product class:** Class I

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

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

**Notified Body:** Self Declaration

**Type designation/model:**

Ref. no	Name
P000055	Tunnelating Needle

**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
D8301-08	Declaration of conformity Tunnelating Needle



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