



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

2023-01-11 Stockholm

Name, position and signature

Charlotte Woschnagg
QA / RA Manager

Document No. D8301-07	Document Name Declaration of conformity Tunnelating Needle
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