



DECLARATION OF CONFORMITY

Manufacturer's Name: M Dialysis AB

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

Product type: 66 Linear microdialysis catheter

Product class: Class IIa

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 certificate #41319041-03
ISO 13485 certificate #0106135-01

Type designation/model:

Ref. no	Name
8010650	66 Linear Catheter 30mm 20kD
8010651	66 High Cut Off Linear Catheter 30mm 100 kD
8010670	66 Linear Catheter 10mm 20 kD
8010671	66 High Cut Off Linear Catheter 10mm 100 kD

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. D8306-08	Document Name Declaration of Conformity 66 Linear Catheter
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