



DECLARATION OF CONFORMITY

Manufacturer's Name: M Dialysis AB

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

Product type: Microdialysis Pumps and Syringe, Syringe and batteries for use with Microdialysis Pumps

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
P000003	106 Microdialysis Pump
P000127	107 Microdialysis Pump
8010191	106 Syringe
8001788	Batteries 6 V for 106 & 107 MD Pump

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

2023-01-10 Stockholm

Name, position and signature

Olof Nord
CEO

Document No. D8290-09	Document Name Declaration of conformity Pump_Syringe_Battery
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