μ dialysis

DECLARATION OF CONFORMITY

Manufacturer´s Name:	M Dialysis AB
Manufacturer´s Address:	Hammarby Fabriksväg 43 SE-120 30 Stockholm SWEDEN
Product type:	Sterile Perfusion fluid CNS Dextran for microdialysis
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
8050151	Perfusion fluid CNS Dextran

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

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