μ dialysis

DECLARATION OF CONFORMITY

Manufacturer's Name:	M Dialysis AB
Manufacturer's Address:	Hammarby Fabriksväg 43 SE-120 30 Stockholm SWEDEN
Product type:	Microdialysis Pump Kit
Product class:	Class IIa
Brand name and trade mark:	M Dialysis AB

Type designation/model:

Ref. no	Name
8003790	MD Pump Kit, Peripheral Tissue
	(contains 1 x 106 Syringe, 1 x Battery and 1 x Perfusion Fluid T1)
8003791	MD Pump Kit, Brain Tissue
	(contains 1 x 106 Syringe, 1 x Battery and 1 x Perfusion Fluid CNS)

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

Name, position and signature

2023-06-05 Stockholm

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Charlotte Woschnagg QA / RA Manager

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Document No.	Document Name
D8307-08	Declaration of conformity MD Pump Kit