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 System
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:

Name: MD System 1.0		
8070228		MD System Complete
	incl:	*8070014 MD unit, 8070088 MD Unit Holder*
		8070151 MD Cartridge, 8070198 MD Amplifier, Users Manual, MD Monitor
8072019		MD Monitor Arm Standard runner
8072020		MD Monitor Arm Pole
8072029		MD Monitor Deskstand
8072038		MD Monitor Arm Pole/Standard runner
8050187		MD System Sensor LPG kit
	incl:	*8070203 MD Sensor LPG, 8072001 Catheter Extension*
8070081		Syringe Orange
8072009		MD Calibrator
8070198		MD Amplifier

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

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