



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

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

2020-06-16 Stockholm

Name, position and signature

Olof Nord
CEO

Document No.
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Document Name
Declaration of Conformity MDD - MD System 1.0