μ dialysis

DECLARATION OF CONFORMITY

Manufacturer's Name: M Dialysis AB

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

SRN: SE-MF-000017466

Product: Perfusion Fluids (T1, CNS, CNS Dextran)

Intended purpose: The Perfusion Fluid (T1/CNS/CNS Dextran) is intended to act as a carrier inside the M Dialysis microdialysis catheters.

Risk class: Class IIa (Rule 2)

Basic UDI-DI: 7332699_330_005_WY

Notified Body: Intertek Medical Notified Body AB (NB 2862)

Conformity assessment: MDR 2017/745, Annex IX excluding chapter II (only those aspects related to to the reuse of the device, including cleaning, disinfections, sterilization and related instructions)

Issued certificates: EC certificate QMS #28620170242
EC design examination certificate #TBD
ISO 13485 certificate #0106135-01

Type designation/model:

Product Name	**Catalogue number (REF)** **Basic UDI-DI**	**Risk Class**
Perfusion fluid T1	P000034 7332699_330_005_WY	IIa
Perfusion fluid CNS	P000151 7332699_330_005_WY	IIa
Perfusion fluid CNS Dextran	8050151 7332699_330_005_WY	IIa

We hereby declare that the above mentioned device(s) comply with applicable requirements in EU Medical Device Regulation (MDR) 2017/745.

A translation of this Declaration of Conformity into another EU official language is made available upon request.

This EU Declaration of conformity is issued under the sole responsibility of the manufacturer.

Document No.	Document Name
D10652-00	MDR Declaration of Conformity Perfusion Fluids

Signed for and on behalf of the manufacturer M Dialysis AB

Date and place of issue

Stockholm 2024-06-10

Name, position and signature

Olof Nord, CEO