

## 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:** In accordance with Regulation (EU) 2017/745, Annex IX, Chapters I and III.

**Issued certificates:** EC certificate QMS #28620178542  
ISO 13485 certificate #0106135

### 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.**

**Signed for and on behalf of the manufacturer M Dialysis AB**

Date and place of issue

Stockholm 2026-03-06

Name, position and signature

  
Olof Nord, CEO

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