

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: 106 / 107 Microdialysis Pumps

Intended purpose: The microdialysis pump is a portable syringe pump intended to pump perfusion fluid and dialysate through a M Dialysis catheter, enabling microdialysis.

Risk class: Class IIa (Rule 12)

Basic UDI-DI: 7332699_300_002_V4

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 |
|------------------------|--|------------|
| 106 Microdialysis pump | P000003 7332699_300_002_V4 | IIa |
| 107 Microdialysis pump | P000127 7332699_300_002_V4 | 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.

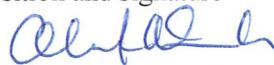
This EU Declaration of conformity is issued under the sole responsibility of the manufacturer.

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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| Document No. D10650-01 | Document Name MDR Declaration of Conformity 106 / 107 Microdialysis Pump |
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