

# $\mu$ 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:** 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:** MDR 2017/745, Annex IX excluding chapter II (only those aspects related 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
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.**

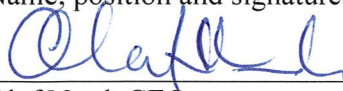
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**Signed for and on behalf of the manufacturer M Dialysis AB**

Date and place of issue

Stockholm 2024-06-10

Name, position and signature

  
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Olof Nord, CEO

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