

# $\mu$ 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:** Linear Microdialysis Catheter

**Intended purpose:** The Linear Microdialysis Catheter (66) is intended to enable microdialysis in skin, adipose and resting skeletal muscle tissues.

**Risk class:** Class IIa (Rule 7)

**Basic UDI-DI:** 7332699\_320\_003\_W9

**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
66 Linear Microdialysis Catheter 30mm	8010650 7332699_320_003_W9	IIa
66 Linear Microdialysis Catheter 10mm	8010670 7332699_320_003_W9	IIa
66 High Cut-Off Linear Microdialysis Catheter 30mm	8010651 7332699_320_003_W9	IIa
66 High Cut-Off Linear Microdialysis Catheter 10mm	8010671 7332699_320_003_W9	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.**

Document No. D10657-00	Document Name MDR Declaration of Conformity Linear Microdialysis Catheter
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**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 2024-06-10

Name, position and signature

  
Olof Nord, CEO

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