

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: 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
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.

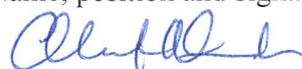
This EU Declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of the manufacturer M Dialysis AB

Date and place of issue

Name, position and signature

Stockholm 2026-03-06



Olof Nord, CEO

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