μ 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: Peripheral Tissue Microdialysis Catheter

Intended purpose: The Peripheral Tissue Microdialysis catheter is intended to enable microdialysis in subcutaneous adipose tissue (63), resting skeletal muscle (63), hepatic tissue (61, 63) or in the intraperitoneal cavity (61).

Risk class: Class IIa (Rule 7)

Basic UDI-DI: 7332699_320_005_WF

Notified Body: Intertek Medical Notified Body AB (NB 2862)

Conformity assessment: MDR 2017/745, Annex IX excluding chapter II (only those aspects related to 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**
61 Microdialysis Catheter 310/30	8010226 7332699_320_005_WF	IIa
61 High Cut-Off Microdialysis Catheter 310/30	8050191 7332699_320_005_WF	IIa
63 Microdialysis Catheter 60/10	8010509 7332699_320_005_WF	IIa
63 Microdialysis Catheter 40/30	8010514 7332699_320_005_WF	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 2024-06-10

Name, position and signature

Olof Nord, CEO