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: Tunnelating needle

Intended purpose: The tunnelating needle is used to introduce the catheter through the scalp when using the Brain Microdialysis Catheters, or through the abdominal wall during Gastro Intestinal and Transplant Surgery.

Risk class: Class Ir (Rule 6)

Basic UDI-DI: 7332699_330_011_WR

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 #28620170242
ISO 13485 certificate #0106135-01

Type designation/model:

Product Name	Catalogue number (REF) Basic UDI-DI	Risk Class
Tunnelating needle	P000055 7332699_330_011_WR	Ir

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 2024-05-14

Name, position and signature

Olof Nord, CEO