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:	In accordance with Regulation (EU) 2017/745, Annex IX, Chapters I & III, with technical documentation assessment limited to reusability aspects of the device
Issued certificates:	EC certificate #28620170242 ISO 13485 certificate #0106135

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 2026-03-06

Name, position and signature

Olof Nord, CEO