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:	Forceps
Intended purpose:	The Forceps is intended to facilitate handling of the 70 and 71 Brain Microdialysis Catheters during insertion. It is not intended to come in contact with tissue.
Risk class:	Class Ir (Rule 6)
Basic UDI-DI:	7332699_330_010_WN
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
Forceps	P000056 7332699_330_010_WN	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