

# $\mu$ 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:** MDR 2017/745, Annex IX excluding chapter II (only those aspects related 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
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.**

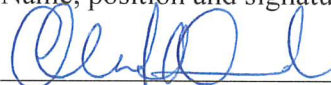
Document No. D10644-00	Document Name MDR Declaration of Conformity Forceps
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**Signed for and on behalf of the manufacturer M Dialysis AB**

Date and place of issue

Stockholm 2024-05-14

Name, position and signature



Olof Nord, CEO

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