

DECLARATION OF CONFORMITY

Manufacturer's Name:

M Dialysis AB

Manufacturer's Address:

Hammarby Fabriksväg 43

SE-120 30 Stockholm

SWEDEN

Product type:

Forceps to be used as accessory for 70 and 71

Brain Microdialysis Catheters

Product class:

Class I

Brand name and trade mark:

M Dialysis AB

Conformity assessment:

MDD 93/42/EEC, Annex II excluding (4)

Notified Body:

Self Declaration

Type designation/model:

| Ref. no | Name | |
|---------|---------|--|
| P000056 | Forceps | |

We hereby declare that the above mentioned device(s) comply with applicable requirements in the swedish law 1993:584 and the Swedish Medical Products Agency regulation LVFS 2003:11 regarding medical devices.

The product(s) fulfils hereby the requirements in the European Medical Device Directive 93/42/EEC.

Date and place of issue

Name, position and signature

2023-01-11 Stockholm

Charlotte Woschnagg

QA / RA Manager

| Document No. | Document Name |
|--------------|-----------------------------------|
| D8302-07 | Declaration of conformity Forceps |