

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 group: Rinsing fluid

Basic UDI-DI: 7332699_330_006_X3

Intended purpose: The Rinsing Fluid is intended to be used to rinse the liquid system of the ISCUS/ISCUS^{flex} Microdialysis Analyzers between each assay

Risk class: IVDR, Class A

Notified Body: N/A

Conformity assessment: Self Declaration

Type designation/model:

Catalogue number (REF)	Product name
8002171	Rinsing Fluid for M Dialysis Microdialysis Analysers

We hereby declare that the above mentioned device(s) comply with applicable requirements in EU *in vitro* diagnostic Medical Device Regulation (IVDR) 2017/746.

This EU Declaration of conformity is issued under the sole responsibility of the manufacturer.

Date and place of issue

2023-09-21
Stockholm

Name, position and signature


Olof Nord, CEO

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 group: Rinsing fluid

Basic UDI-DI: 7332699_330_006_X3

Intended purpose: The Rinsing Fluid is intended to be used to rinse the liquid system of the ISCUS/ISCUS^{flex} Microdialysis Analyzers between each assay

Risk class: IVDR, Class A

Notified Body: N/A

Conformity assessment: Self Declaration

Type designation/model:

Catalogue number (REF)	Product name
8002171	Rinsing Fluid for M Dialysis Microdialysis Analysers

We hereby declare that the above mentioned device(s) comply with applicable requirements in EU *in vitro* diagnostic Medical Device Regulation (IVDR) 2017/746.

This EU Declaration of conformity is issued under the sole responsibility of the manufacturer.

Date and place of issue

Name, position and signature

Olof Nord, CEO

Document No. D10323-01	Document Name IVDR Declaration of conformity Rinsing fluid
---------------------------	---