

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.

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 2024-06-10 Name, position and signature



Olof Nord, CEO

Document No. D10323-02	Document Name IVDR Declaration of conformity Rinsing fluid
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