



## 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

**Intended purpose:** The Rinsing Fluid is intended to be used to rinse the liquid system of the ISCUS/ISCUS<sup>flex</sup> Microdialysis Analyzers between each assay

**Risk class:** IVDR, Class A

**Basic UDI-DI:** 7332699\_F0999\_330\_33

**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

2022-06-13, Stockholm

Name, position and signature

  
\_\_\_\_\_  
Olof Nord, CEO

<b>CE</b>	<b>DECLARATION OF CONFORMITY</b>
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Document No. D10323-00	Document Name IVDR Declaration of conformity Rinsing fluid
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