μ dialysis

CE	**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: ISCUS^{flex} Microdialyis Analyzer

Intended purpose: ISCUS^{flex} is a Microdialysis Analyzer intended for supporting clinical decisions based on tissue chemistry. ISCUS^{flex} is only intended for the analyses of microdialysis samples.

The device shall not be used as the sole basis for decisions as to diagnosis or therapy.

ISCUS^{flex} is also intended to be used for general research purposes

Risk class: IVDR, Class A

Basic UDI-DI: 7332699_F0701_300_RA

Notified Body: N/A

Conformity assessment: Self Declaration

Type designation/model:

Catalogue number (REF)	Product name
8003295	ISCUS^{flex} Microdialysis Analyzer

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

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