μ dialysis

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_300_001_UZ
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

2023-08-21

Stockholm

Name, position and signature

Olof Nord, CEO

μ dialysis

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_300_001_UZ

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

Name, position and signature

_____
Olof Nord, CEO