

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: 106 Syringe

Intended purpose: Sterile, single use syringe intended to contain and supply the perfusion fluid to M Dialysis catheters

Risk class: Class Is (Rule 1 and 2)

Basic UDI-DI: 7332699_330_004_WV

Notified Body: Intertek Medical Notified Body AB (NB 2862)

Conformity assessment: In accordance with Regulation (EU) 2017/745, Annex IX, Chapters I & III, with technical documentation assessment limited to sterility aspects of the device

Issued certificates: EC certificate QMS #28620170242
ISO 13485 certificate #0106135

Type designation/model:

Product Name	Catalogue number (REF) Basic UDI-DI	Risk Class
106 Syringe	8010191 7332699_330_004_WV	Is

We hereby declare that the above mentioned device(s) comply with applicable requirements in EU Medical Device Regulation (MDR) 2017/745.

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

Stockholm 2026-03-06

Name, position and signature


Olof Nord, CEO

Document No. D10651-01	Document Name MDR Declaration of Conformity 106 Syringe
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