

Certificate of registration / Registreringsbevis

Manufacturer or Authorised Representative / Tillverkare eller Auktoriserad Representant

Organisation:	M Dialysis AB
Organisation no/Organisationsnr:	556868-2586
Postal address/Postadress:	Hammarby Fabriksväg 43, 120 30 Stockholm Sweden

This certificate is valid until / Detta registreringsbevis gäller till: 2020-05-25

Medical Products Agency hereby confirms that the above mentioned manufacturer/authorised representative has registered the listed medical devices in accordance with the regulations issued by Medical Products Agency

- LVFS 2003:11 on medical devices
- LVFS 2001:7 on medical devices for in vitro diagnostics
- LVFS 2001:5 on active implantable medical devices

The manufacturer or his authorised representative is responsible for the products listed in this certificate and must ensure that they are in accordance with the legislation in force (the Act (1993:584) on medical devices and the regulations issued by Medical Products Agency, LVFS 2003:11, LVFS 2001:7, LVFS 2001:5)

Läkemedelsverket bekräftar härmed att ovan angivna tillverkare/auktoriserade representant fullgjort sin skyldighet att registrera angivna medicintekniska produkter i enlighet med kraven i Läkemedelsverkets föreskrifter

- LVFS 2003:11, om medicintekniska produkter
- LVFS 2001:7, om medicintekniska produkter för in vitro diagnostik
- LVFS 2001:5 om aktiva medicintekniska produkter för implantation

Tillverkaren eller dennes auktoriserade representant, svarar för att de produkter som ingår i detta bevis uppfyller kraven i gällande författningar (lag (1993:584) om medicintekniska produkter samt Läkemedelsverkets föreskrifter LVFS 2003:11, LVFS 2001:7; LVFS 2001:5).

Products / Produkter

PID	Product/Produkt	Article No/Artikelnr	Riskclass	GMDN
105165	ISCUS flex Microdialysis Analyzer, incl: Documentation and accessories, 8001030 ICU Pilot software CD, 8002921 transport case	8003295	IVD, Generella	45468
105167	Reagent Set A	8002163	IVD, Generella	45467
105168	Reagent Set B	8002164	IVD, Generella	45467
105169	Reagent Set C	8002165	IVD, Generella	45467
105170	ICUpilot Software, swe	8001801	MD, Klass I	17223
105172	ISCUS Microdialysis Analyser exkl. pumps	8002720	IVD, Generella	45468
105173	Microvials/Mikroprovör	P000001	IVD, Generella	45467
105174	Tunneling Needle/Stålkanyl för tunnelering	P000055	MD, Klass I	45467
105175	Forceps / Pincett	P000056	MD, Klass I	45467
105176	Microvials in rack, sterile	P000154	IVD, Generella	45467
105177	ICUpilot Software, eng	8001027	MD, Klass I	17223
105178	600 Microdialysis Analyser Bedside system	8001600	IVD, Generella	45468
105179	Glucose Reagent	P000023	IVD, Generella	45467
105180	Glutamate Reagent	P000064	IVD, Generella	45467
105181	Glycerol Reagent	P000025	IVD, Generella	45467
105182	Calibrator A	P000057	IVD, Generella	45467
105183	Control Samples	8010201	IVD, Generella	45467
105184	Lactate Reagent	P000024	IVD, Generella	45467
105185	Pyruvate Reagent	P000063	IVD, Generella	45467
105186	L-P-G Reagent Kit	8010361	IVD, Generella	45467
105187	Reagent Kit	P000011	IVD, Generella	45467
105189	Urea Reagent	P000026	IVD, Generella	45467
105190	Rinsing Fluid 8x0,5 L	8002171	IVD, Generella	45467