



DECLARATION OF CONFORMITY

Manufacturer's Name: M Dialysis AB

Manufacturer's Address: Hammarby Fabriksväg 43
SE-120 30 Stockholm
SWEDEN

Product type: Splitable introducer for microdialysis catheter

Product class: Class IIa

Brand name and trade mark: M Dialysis AB

Notified Body: Intertek Semko AB,
identification number 0413

Conformity assessment: MDD 93/42/EEC, Annex II excluding (4)

Issued certificates: EC certificate #41319041-03
ISO 13485 certificate #0106135-01

Type designation/model:

Ref. no	Name
8010343	Splitable Introducer SI-2

We hereby declare that the above mentioned device(s) comply with applicable requirements in the swedish law 1993:584 and the Swedish Medical Products Agency regulation LVFS 2003:11 regarding medical devices.

The product(s) fulfils hereby the requirements in the European Medical Device Directive 93/42/EEC.

Date and place of issue

2023-06-05 Stockholm

Name, position and signature

Charlotte Woschnagg
QA / RA Manager

Document No.	Document Name
D8291-08	Declaration of Conformity for Splitable introducer SI-2



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