



## 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:**

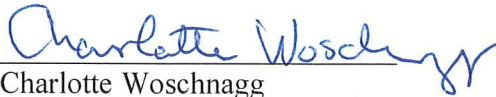
Ref. no	Name
8010343	Splitable Introducer SI-2

**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

2023-01-11 Stockholm

Name, position and signature

  
Charlotte Woschnagg  
QA / RA Manager

Document No.	Document Name
D8291-07	Declaration of Conformity for Splitable introducer SI-2