



<b>DECLARATION OF CONFORMITY</b>
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**Manufacturer's Name:** M Dialysis AB

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

**Product type:** 61 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
8010226	61 Microdialysis Catheter
8050191	61 High Cut off Microdialysis Catheter

**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

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