Annex to the EC Certificate No. 51121-16-04

Valid from 2020-01-25 to 2024-05-26

Revision status of the annex: 0 dated 2019-11-29

Devices/device categories included in the certificate:

Class II b:

Non-active cardiovascular implants
Stent delivery system, self-expandable
Product family mc-peripheral

- mc-p 5F
  Standard, long and transradial/transbrachial
- mc-p II 6F
- multi-LOC 6F
- mc-pII 2-LOC 3-LOC 6F

Class III:

Non-active endoluminal cardiovascular implants
Stent delivery system, self-expandable
mc-aortic-stent

- mc-a 12F
- mc-a 14F
- mc-a 16F

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

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Notified Body ID-number: 0124