

Annex to the EC Certificate No. 50923-16-08

Valid from 2021-02-18 to 2024-05-26

Revision status of the annex: 0 dated 2021-02-18

Devices/device categories included in the certificate:

Class Is:

For the products listed below, review of the Quality System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Trachealator (Airway Dilation Catheter)

Class IIa:

- Lamprey – Suction Dissector

Class III:

- Escape Aspiration Catheter
- Cape Cross PTCA Balloon Catheter
- Cape Cross NC PTCA Balloon Catheter

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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