

# Annex to the EC Certificate No. 50923-16-06

Valid from 2020-01-08 to 2024-05-26

Revision status of the annex: 1 dated 2020-03-30

Devices/device categories included in the certificate:

## Class Is:

For the products listed below, the review of the Quality System refers exclusively to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

- 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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