

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
Electroplast S.A.

Servando Gómez 2450, 12100 Montevideo, Uruguay

Certified location:

Servando Gómez 2450, 12100 Montevideo, Uruguay

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50279-Z6-00, the decision dated 2019-01-22 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-02-25 to 2024-02-24

Registration No.: 50279-16-06

A handwritten signature in black ink, appearing to read "Ruth Delbeck-Bayer".

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-01-22
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50279-16-06

Valid from 2019-02-25 to 2024-02-24

Revision status of the annex: 0 dated 2019-02-25

Devices/device categories included in the certificate:

Class I s:

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

- MD 0101 + MDS 7006
 - Urology devices
 - Cistometry catheter
 - Stone extractor
 - Anesthesia devices
 - Accessories for Bronchial Double lumen tube like different connectors

Class II a:

- MD 0101 + MDS 7006
 - Urology devices
 - Ureter catheter
 - Foleyplast catheter
 - Endo-Urology devices
 - Nephrostomy Set/Catheter
 - Anesthesia devices
 - Tracheal tubes
 - Bronchial Double lumen tube
 - Digestive devices
 - Stomach and oesophageal tubes
 - Rectal tube
 - Surgical devices
 - Embolectomy catheter

Class II b:

- MD 0101 + MDS 7006
 - Anesthesia devices
 - Tracheostomy tube
- MD 0203 + MDS 7006
 - Urology devices
 - Ureter stent



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