

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60142554 0001

Report No.: 28300430 005

Manufacturer: SUMINISTROS HOSPITALARIOS, S.A.
C/ Tortosa, 199-201
08918 Badalona - Barcelona
Spain

Products: (see attachment for products included)

Replaces EC Certificate, Registration No.: DD 60114271 0001

Expiry Date: 2022-01-25

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-02-28

Date: 2020-02-28

Notified Body



Rafal Byczkowski

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60142554 0001
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Products included:

- Non sterile surgical sewn dressings with X-Ray and without X-Ray
- Non Sterile Surgical Folder 8 ply Dressings with x-Ray and without XRay

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- Sterile instruments covers
- Sterile non-woven gowns for operating rooms and patient examination
- Sterile non-woven sheets for operating rooms
- Sterile, abrasive cleaners for electrosurgical electrodes

Date: 2020-02-28

Notified Body

Rafal Byczkowski

