TÜVRheinland®

EC Certificate

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

Registration No.: DD 60148254 0001

Report No.: 31993533 002

Manufacturer:
Invotec International, Inc.
6833 Phillips Industrial Blvd.
Jacksonville FL 32256
USA

Products:
Specialty Surgical Products for Otorhinolaryngology and Facial Plastic Surgery

Products: see attachment

Replaces Approval, Registration No.: DD 60110664 0001

Expiry Date: 2024-05-26

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: 2021-04-28

Date: 2021-04-28

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Dipl.-Ing. S. Pane

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60148254 0001
Report No.: 31993533 002

Manufacturer: Invotec International, Inc.
6833 Phillips Industrial Blvd.
Jacksonville FL 32256
USA

Products Class IIa:
- Nasal Septal button
- Tracheal T-Tube
- Burs
- Laryngeal Surface Electrode

For the aspects of manufacture concerned with securing and maintaining sterile conditions (Class I Sterile):
- Internal Nasal Splints
- Ear Dressings
- Silicone Sheeting
- Nasal Balloon Catheters
- Clearview Flexible Scope Covers
- PVA Sponges
- PVA Wipes

Notified Body
TÜVRheinland

Date: 2021-04-28

Dipl.-Ing. S. Pane