EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60121146 0001

Report No.: 16801042 007

Manufacturer:
Changzhou Operson Imp And Exp
Co., Ltd.
#7008, #12083~12085 Modern City
217 Huangshan Road, Changzhou
213022 Jiangsu
China

Products:
- Non Absorbable Suture with or without Needles
- Tracheostomy Tubes
- Urethral Catheters
- All Silicone Foley Catheters

Replaces Approval, Registration No.: HD 60077582 0001

Expiry Date: 2022-08-22

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

X. Ren

Effective Date: 2017-08-29

Date: 2017-08-29

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.

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