TÜVRheinland®

EC Certificate

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

Registration No.: DD 60144747 0001

Report No.: 16803928 007

Manufacturer:

RENOLIT Plastic Tech. (BJ) Ltd.
No. 3, Yanqi River West Road
Beijing Yanqi Economic Development Zone, Huairou District
101407 Beijing
China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions of Disposable Drainage Bags for Peritoneal Dialysis and Disposable Drainage Bags for Peritoneal Dialysis with Tubing

Replaces Approval, Registration No.: DD 60109583 0001

Expiry Date: 2024-05-27

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: 2019-12-11

Date: 2019-12-11

Notified Body
TÜV Rheinland LGA Products GmbH
Zertifizierungsstelle
Jing Zhang

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.