TÜVRheinland®

EC Certificate

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

Registration No.: DD 60138932 0001

Report No.: 21211591 010

Manufacturer:

Udo Heisig GmbH
The Disposables Company
Hermann-Oberth-Str. 17
85640 Putzbrunn
Deutschland

Products:

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:
- sterile OP-Patient Covers
- sterile OP-Device Covers

Replaces Certificate, Registration No.: DD 60129903 0001

Expiry Date: 2024-05-22

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: 2019-05-23

Date: 2019-05-15

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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.