EC Certificate

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

Registration No.: DD 60147410 0001

Report No.: 15091168 009

Manufacturer:

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: DD 60107079 0001

Expiry Date: 2020-12-22

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: 2020-04-13

Date: 2020-04-13

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH 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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60147410 0001
Report No.: 15091168 009

Manufacturer:

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Disposable Surgical Gowns, Disposable Face Masks, Disposable Shoe Covers, Disposable Caps, Surgical Drapes, Surgical Packs

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Herbert Zhong

Date: 2020-04-13