TÜVRheinland®

EC Certificate

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

Registration No.: DD 60135422 0001

Report No.: 15083140 006

Manufacturer:

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions:
Face Masks, Surgical Gowns, Coveralls, Caps

Replaces Approval, Registration No.: DD 60102531 0001

Expiry Date: 2024-01-16

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: 2019-07-16

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Notified Body

M.Sc. M. Aihara

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.

Anhänge:

CE-Zertifikat Medizinische Einmalmasken englisch.jpg 649 KB