EC Certificate

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

TÜVRheinland®

Registration No.: DD 60127334 0001

Report No.: 16801929 008

Manufacturer:

Lights Medical Manufacture Co.,Ltd.
No. 19, Quanda Road,
Wuqing Development Area
Tianjin, 301700
China

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Date: 2022.01.27 10:20:33 EET
Reason: MoldSign Signature
Location: Moldova

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions of Wet Pack Products for Cleaning of Medical Devices(Gamma-irradiation Sterilization)

Replaces Approval, Registration No.: DD 60111411 0001

Expiry Date: 2023-04-17

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: 2018-04-18

Date: 2018-04-17

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

X. Ren

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.