TÜVRheinland®

EC Certificate

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

Registration No.: DD 60141952 0001

Report No.: 16803824 008

Manufacturer:

LEBOO HEALTHCARE
PRODUCTS LIMITED
A-1506, Lar Valley International
No. 168 Guang'anmen Wai St.,
Xicheng District
100055 Beijing
China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Surgical Gowns, Sterile Surgical Drapes, Sterile Surgical Packs, Sterile Pouches

Replaces Approval, Registration No.: DD 60124314 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: 2019-08-28

Date: 2019-08-28

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Wenxiang 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.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

LEBOO HEALTHCARE
PRODUCTS LIMITED
A-1506, Lar Valley International
No. 168 Guang'anmen Wai St.,
Xicheng District
100055 BEIJING
CHINA

Contact

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Mail service@de.tuv.com

Date August 28, 2019

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60141952 Sheet 0001
Device : Medical Device
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60141952 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Wenxiang Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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