

**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



**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**



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**LGAD**

**Precisely Right.**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

LEBOO HEALTHCARE  
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Contact

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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

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LGA Products GmbH

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