

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

Registration No.: DD 60114668 0001

Report No.: 16803824 004

Manufacturer:

**LEBOO HEALTHCARE**  
**PRODUCTS LIMITED**  
A-1001, Lar Valley International  
No. 168 Guang'anmen Wai St.,  
Xicheng District  
100055 Beijing  
China

Products:

Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: DD 60096669 0001

Expiry Date:

2019-10-20

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.

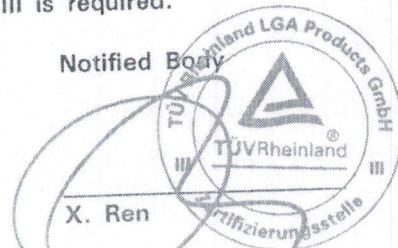
Effective Date:

2017-04-01

Date:

2017-04-01

Notified Body



**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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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Attachment to  
Certificate

Registration No.: DD 60114668 0001  
Report No.: 16803824 004

Manufacturer:

**LEBOO HEALTHCARE**  
**PRODUCTS LIMITED**  
A-1001, Lar Valley International  
No. 168 Guang'anmen Wai St.,  
Xicheng District  
100055 Beijing  
China

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

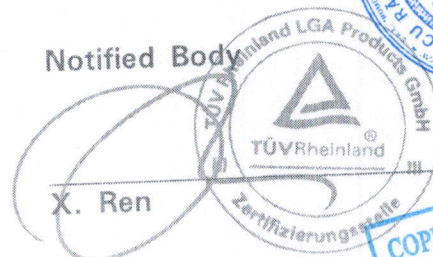
Sterile Surgical Gowns, Sterile Surgical Drapes,  
Sterile Surgical Packs, Sterile Pouches

Sites included:

Linwan Industrial Park, Xiantao City, 433000,  
Hubei Province, China

Penchang Rd, Xiantao City, 433000, Hubei Province, China

Notified Body



Date: 2017-04-01



**COPIA CORESPUNDE  
ORIGINALULUI**

# EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:

LEBOO HEALTHCARE PRODUCTS LIMITED  
A-1001, Lar Valley International, No.168 Guang'anmen Wai  
St., Xicheng District, Beijing 100055, China

We declare under our sole responsibility that  
the medical device:

Sterile Surgical Gowns; Sterile Surgical Drapes;  
Sterile Surgical Packs; Sterile Pouches

of class:

Is

according to annex IX of Directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure:

Directive 93/42/EEC Annex V

Registration No.:

DD 60114668 0001

Notified Body:

TÜV Rheinland LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg, Deutschland  
CE 0197

Report No.: 16803824 004  
Issue date: 2014-10-21  
Expiry date: 2019-10-20

The above mentioned declaration of  
Conformity is exclusively under the  
responsibility of

LEBOO HEALTHCARE PRODUCTS LIMITED  
Leboo Healthcare Products Limited  
北京安信乐布医疗用品有限公司



Beijing, April 1<sup>st</sup>, 2017

/ Place, date /

Guangjun Lu Management Representative

/ Name and function /





# EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:

LEBOO HEALTHCARE PRODUCTS LIMITED  
A-1001, Lar Valley International, No.168 Guang'anmen Wai St.,  
Xicheng District, Beijing 100055, China

We declare under our sole responsibility that

the medical device:

-Non-woven Products: Surgical Gowns, Surgical Drapes,  
Surgical Packs, Pouches, Caps, Coveralls, Face masks, Suits,  
Underpads, Gloves, Towels, Wipes, Sheets, Packs, Shoe  
Covers, Aprons, Gowns, Trousers, Sleeve Covers, Slippers,  
Pillow Covers, Beard Covers, Bags, Bibs, Rolls, Briefs, hair  
bands;

-Disposable PE products: Shoe Covers, Tray Covers, Pouches,  
Caps, Gloves, Aprons, Gowns, Sleeve Covers, Bags

-Disposable Vinyl Examination Gloves

-Disposable Nitrile Examination Gloves

- Disposable PVC products (Covers, Aprons, Rolls, Sheets, Bags)

- Disposable Paper products (Mask, Caps, Rolls, Sheets, Bags)

of class:

Class I

according to annex IX of Directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure:

Directive 93/42/EEC Annex VII

The above mentioned declaration of  
Conformity is exclusively under the  
responsibility of

LEBOO HEALTHCARE PRODUCTS LIMITED  
Leboo Healthcare Products Limited  
北京安信乐布医疗用品有限公司



Beijing, April 1<sup>st</sup>, 2017

/ Place, date /

Guangjun Lu Management Representative

/ Name and function /



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**LEBOO HEALTHCARE  
PRODUCTS LIMITED**

A-1001, Lar Valley International  
No. 168 Guang'anmen Wai St.,  
Xicheng District  
100055 Beijing  
China

has established and applies a quality management system for medical devices  
for the following scope:

**Manufacture and Distribution of Medical Devices**

(see attachment for products and additional sites included)

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012  
EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

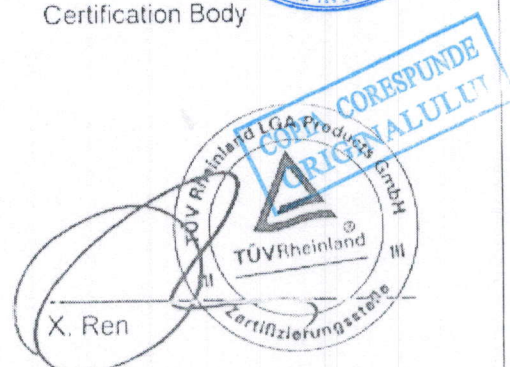
Effective Date: 2020-04-01  
Certificate Registration No.: SX 60114670 0001  
An audit was performed. Report No.: 16803824 004  
This Certificate is valid until: 2020-10-20

Certification Body



Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02

Date 2020-04-01



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

Attachment to  
Certificate

Registration No.: **SX 60114670 0001**  
Report No.: **16803824 004**

Organization: **LEBOO HEALTHCARE  
PRODUCTS LIMITED**  
A-1001, Lar Valley International  
No. 168 Guang'anmen Wai St.,  
Xicheng District  
100055 Beijing  
China

**Scope:**

**Products:**

- Non-woven Products: Surgical Gowns, Surgical Drapes, Surgical Packs, Pouches, Caps, Coveralls, Face Masks, Suits, Underpads, Gloves, Towels, Wipes, Sheets, Packs, Shoe Covers, Aprons, Gowns, Trousers, Sleeve Covers, Pillow Covers, Beard Covers, Bags, Bibs, Rolls
- Disposable PE Products: Shoe Covers, Tray Covers, Pouches, Caps, Gloves, Aprons, Gowns, Sleeve Covers, Bags
- Disposable Patient Examination Gloves

**Sites included:**

Linwan Industrial Park, Xiantao City, 433000  
Hubei Province, China  
Manufacture of the a.m. products

Penchang Rd, Xiantao City, 433000, Hubei Province, China  
ETO Sterilization of Surgical Gowns, Surgical Drapes,  
Surgical Packs, Pouches

**Certification Body**



Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02

Date: 2020-04-01

