



**Leboo Healthcare Products Limited**

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Fax: +86 10 82608720

Email: [lvw@leboo.com.cn](mailto:lvw@leboo.com.cn)

Website: [www.leboo.com.cn](http://www.leboo.com.cn)

Add: A1-1502 Long-Rang World Building, Suzhou Road, Haidian District, Beijing 100080, China

Date of issue: Feb. 19, 2014

**CERTIFICATE OF AUTHORISATION**

Distributorship for Leboo Healthcare Products Ltd products.

**To whom it may concern**

This is to certify that,

**ECOCHEMIE Ltd.**

5/1, Cuza Voda str.

2060MD, Chisinau,

Republic of Moldova

Tel/fax +373(22)-52-34-32, 52-34-22

[info@ecochemie.com](mailto:info@ecochemie.com)

[info@ecochemie.md](mailto:info@ecochemie.md)

[www.ecochemie.md](http://www.ecochemie.md)

is our authorized distributor for the complete Leboo Healthcare Products Ltd product line.

This company is able to provide competitive and professional sales information, to take parts in tenders and after-sales service of **Leboo Healthcare Products Ltd** products to their customers in his area and to participate in tenders on behalf of **Leboo Healthcare Products Ltd**

President

Leboo Healthcare Products Ltd



**EC Certificate**

Directive 93/42/EEC Annex V

Production Quality Assurance

Medical Devices



Registration No.: DD 60096669 0001

Report No.: 168038224 001

**Manufacturer:**

LEBOO HEALTHCARE  
PRODUCTS LIMITED

Room 1312, Zhen-Xintian Building

106 Majiapu East Rd, Fengtai

100068 Beijing

China

**Products:**

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Surgical Gowns, Sterile Surgical Drapes,

Sterile Surgical Packs, Sterile Pouches

(see attachment for additional items included)

Replaces Approval, Registration No.: DD 60026724 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:**

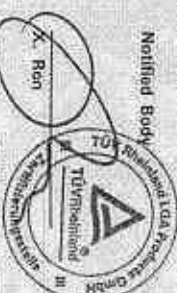
2014-10-21

**Date:**

2014-10-21

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.





Doc. 1/1, Rev. 0

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

Attachment to  
Certificate  
Registration No.: DD 60096669 0001  
Report No.: 16803824 001

Manufacturer:  
**LEBOO HEALTHCARE  
PRODUCTS LIMITED**  
Room 1312, Ziran-Xinland Building  
106 Majiapu East Rd, Fengtai  
100068 Beijing  
China

**Sites included:**

Facility 1:  
Linmen Industrial Park, Xiancao City, 433000,  
Hubei Province, China

Facility 2:  
Penchang Rd, Xiancao City, 433000, Hubei Province, China



Date: 2014-10-21

Notified Body



Doc. 1/1, Rev. 0

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

Attachment to  
Registration No.: SX 60096670 0001  
Report No.: 16803824 001

Organization:  
**LEBOO HEALTHCARE  
PRODUCTS LIMITED**  
Room 1312, Ziran-Xinland Building  
106 Majiapu East Rd, Fengtai  
100068 Beijing  
China

**Scope:**

**Products:**

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

**Sites included:**

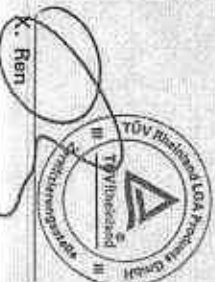
Facility 1:  
Linmen Industrial Park, Xiancao City, 433000,  
Hubei Province, China

Facility 2:  
Penchang Rd, Xiancao City, 433000, Hubei Province, China

Certification Body



Date: 2014-10-21



# Certificate



The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**LEBOO HEALTHCARE  
PRODUCTS LIMITED**  
A-1506, 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 Disposable Medical Devices**  
(see attachment for products included)

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

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

Effective Date: 2017-10-31

Certificate Registration No.: SX 60124315 0001

An audit was performed. Report No.: 16503824 005

This Certificate is valid until:

2020-10-20

Certification Body



Deutsche  
Akreditierungsstelle  
D-ZM 14169-01-02

Date 2017-10-31

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 201 800-1001 Fax: +49 201 800-3025 e-mail: cert@tuev-rheinland.com

Doc. 1/1, Rev. 0



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

Attachment to

Certificate

Registration No.:

Report No.:

SX 60124315 0001  
16803824 005

Organization:

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

Scope:

Products:

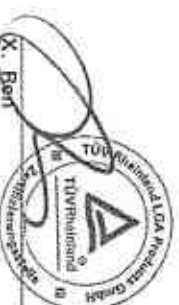
- Non-woven Products: Surgical Gowns, Surgical Drapes, Surgical Packs, Pouches, Caps, Coveralls, Face Masks, Suits, Underpads, Gloves, Towels, Wipes, Sheets, Packs, Shoe Covers, Aprons, Gowns, Trousers, Sleeve Covers, Pillow Covers, Beard covers, Bags, Bibs, Rolls
- Disposable P3 Products: Shoe covers, Tray Covers, Pouches, Caps, gloves, Aprons, Gowns, Sleeve Covers, Bags
- Disposable Patient Examination Gloves

Certification Body



Deutsche  
Akreditierungsstelle  
D-ZM 14169-01-02

Date: 2017-10-31





## EC DECLARATION OF CONFORMITY



Manufacturer:

LEBOO HEALTHCARE PRODUCTS LIMITED  
Room 1312, Ziran-Xinland Building, 106 Majiapu East Rd,  
Fengtai, Beijing, 100069, China

whose single Authorized Representative:

SUNGO Certification Company Limited  
RM101, MAPLE HOUSE, 118 HIGH STREET, PURLEY, LONDON,  
ENGLAND.

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, 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, Sheets, Pillow case, Pallet  
covers, Bibs;  
- Disposable Vinyl Examination Gloves  
- Disposable Nitrile Examination Gloves  
- Disposable Razors  
- Urine Cup for Single Use  
- Urine Bag for Single Use  
(Name, type or model, batch or serial number, possibly sources and number of items)

of class

Class I  
according to annex IX of direct. 93/42/EEC

meets all the provisions of the directive 93/42/EEC (or 90/385/EEC) which apply to it.

Conformity assessment procedure

93/42/EEC, Annex V

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

Beijing, 19.10.2012  
Place, date

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

Lu Guangjun, Management Representative

Legally binding signature, Function

EC Declaration of Conformity

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## EC DECLARATION OF CONFORMITY



Manufacturer:

LEBOO HEALTHCARE PRODUCTS LIMITED  
Room 1312, Ziran-Xinland Building, 106 Majiapu East Rd,  
Fengtai, Beijing, 100069, China

whose single Authorized Representative:

SUNGO Certification Company Limited  
RM101, MAPLE HOUSE, 118 HIGH STREET, PURLEY, LONDON,  
ENGLAND.

We declare under our sole responsibility  
that:

the medical device

-Sterile non-woven products: Surgical Gowns, Surgical Drapes, Surgical  
Packs, Pouches, Face masks, Isolation gowns, Coveralls)  
(Name, type or model, batch or serial number, possibly sources and number of items)

of class

Class Is  
according to annex IX of direct. 93/42/EEC

It bears the mark



Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality  
management system by the Notified Body

TÜV Rheinland LGA Products GmbH  
Trilysstraße 2, 90431, Nürnberg, Germany  
Registration No.: DD 6009669 0001  
Report No.: 16803824 001  
Issue date: 2014-10-21  
Expiry date: 2019-10-20

The product concerned has been manufactured under a quality management system according to Annex V of  
Directive 93/42/EEC.

Conformity assessment procedure

93/42/EEC, Annex V

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

Beijing, 19.10.2012  
Place, date

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

Lu Guangjun, Management Representative

Legally binding signature, Function

EC Declaration of Conformity

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