

Leboo Healthcare Products Limited

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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

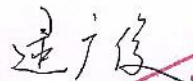
This is to certify that,

ECOCHIMIE Ltd.
5/1, Cuza Voda str.
2060MD, Chisinau,
Republic of Moldova
Tel/fax +373(22)-52-34-32, 52-34-22
infoecochimie@gmail.com
info@ecochimie.md
www.ecochimie.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

北京安信信乐希医药有限公司
LEBOO HEALTHCARE PRODUCTS LIMITED

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

Registration No.: DD 60096669 0001

Report No.: 16803824 001

Manufacturer: **LEBOO HEALTHCARE PRODUCTS LIMITED**
Room 1312, Ziran-Xintiandi 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 sites 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

Notified Body


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.



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60096669 0001
Report No.: 16803824 001

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

Sites included:

Facility 1:
Linwan Industrial Park, Xiantao City, 433000,
Hubei Province, China

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

Notified Body



Date: 2014-10-21



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Registration No.:**
Report No.:

SX 60096670 0001
16803824 001

Organization: LEBOO HEALTHCARE
PRODUCTS LIMITED
Room 1312,Ziran-Xintiandi 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, 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:

Facility 1:
Linwan Industrial Park, Xiantao City, 433000,
Hubei Province, China

Facility 2:
Penchang Rd, Xiantao 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.: 16803824 005
This Certificate is valid until: 2020-10-20

Certification Body



Date 2017-10-31

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



Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate

Registration No.: SX 60124315 0001
Report No.: 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 PE Products: Shoe Covers, Tray Covers, Pouches, Caps, Gloves, Aprons, Gowns, Sleeve Covers, Bags
- Disposable Patient Examination Gloves

Certification Body



Date: 2017-10-31





EC DECLARATION OF CONFORMITY



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

LEBOO HEALTHCARE PRODUCTS LIMITED

Beijing, 19.10.2012
Place , date

Lu Guangjun, Management Representative

Legally binding signature, Function

EC Declaration of Conformity

Page 1/1



EC DECLARATION OF CONFORMITY



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

of class

**-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)

Class Is

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

It bears the mark

CE 0197

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
Tillystraße 2, 90431, Nürnberg, Germany
Registration No.: DD 60096669 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

LEBOO HEALTHCARE PRODUCTS LIMITED

Beijing, 19.10.2012
Place , date

Lu Guangjun, Management Representative

Legally binding signature, Function

EC Declaration of Conformity

Page 1/1

