

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Zibo Eastmed Healthcare
Products Co., Ltd.**
No.118 Huaguang Road, Zhangdian District
Zibo
255000 Shandong
China

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

(see attachment for scope 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: 2019-08-29
Certificate Registration No.: SX 60138882 0001
An audit was performed. Report No.: 16805598 006
This Certificate is valid until: 2022-08-16

Certification Body



Date 2019-08-29



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60138882 0001
Report No.: 16805598 006

Organization: Zibo Eastmed Healthcare
Products Co., Ltd.
No.118 Huaguang Road, Zhangdian District
Zibo
255000 Shandong
China

Scope:

Manufacture and Distribution of Sterile and non-sterile Nasal Oxygen Cannula, Sterile and non-sterile Oxygen Masks, Sterile and non-sterile Nebulizer Masks, Sterile Blood Lancets, Disposable Surgical Blades (with and without handle), Insulin Needles for Single Use, Sterile Insulin Syringes for Single Use, Sterile Three-way Stopcocks for Single Use, Sterile Heparin Cap for Single Use, Sterile Dental Needles for Single Use, I.V.Cannula for Single Use, Infusion Set with Burette, Three-way Stopcock and Extension Tube, I.V.Flow Regulator for Single Use, Sterile Syringes for Single Use, Sterile Infusion Sets for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Intravenous Needles for Single Use, Sterile Safety Auto Disable Syringes for Single Use, Blood Transfusion Sets, Latex Surgical Gloves, Blood Collection Sets for Single Use, Disposable Suction Catheter for use in Respiratory Tract, Disposable Stomach Catheter, Endotracheal Tube for Single Use, Sterile Urine Bags for Single use, Sterile Vaginal Dilators for Single Use, Sterile Latex Examination Gloves, Wound Plaster;

Certification Body



Date: 2019-08-29

Wenxiang Zhang

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60138882 0001
Report No.: 16805598 006

Organization: Zibo Eastmed Healthcare
Products Co., Ltd.
No.118 Huaguang Road, Zhangdian District
Zibo
255000 Shandong
China

Scope: Design and Development, Manufacture and Distribution of
Foley Catheters for Single Use

Certification Body



Date: 2019-08-29



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

Registration No.: DD 60138881 0001

Report No.: 16805598 006

Manufacturer: Zibo Eastmed Healthcare
Products Co., Ltd.
No.118 Huaguang Road, Zhangdian District
Zibo
255000 Shandong
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60111852 0001

Expiry Date: 2021-08-16

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: 2019-08-29

Date: 2019-08-29

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60138881 0001
Report No.: 16805598 006

Manufacturer: Zibo Eastmed Healthcare
Products Co., Ltd.
No.118 Huaguang Road, Zhangdian District
Zibo
255000 Shandong
China

Products:

- Sterile and non-sterile Nasal Oxygen Cannula
- Sterile and non-sterile Oxygen Masks
- Sterile and non-sterile Nebulizer Masks
- Sterile Blood Lancets
- Disposable Surgical Blades (with and without handle)
- Insulin Needles for Single Use
- Sterile Insulin Syringes for Single Use
- Sterile Three-way Stopcocks for Single Use
- Sterile Heparin Cap for Single Use
- Sterile Dental Needles for Single Use
- I.V.Cannula for Single Use
- Infusion Set with Burette
- Three-way Stopcock and Extension Tube
- I.V.Flow Regulator for Single Use
- Sterile Syringes for Single Use
- Sterile Infusion Sets for Single Use
- Sterile Hypodermic Needles for Single Use
- Sterile Intravenous Needles for Single Use
- Sterile Safety Auto Disable Syringes for Single Use
- Blood Transfusion Sets

Date: 2019-08-29

Notified Body



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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60138881 0001
Report No.: 16805598 006

Manufacturer: Zibo Eastmed Healthcare
Products Co., Ltd.
No.118 Huaguang Road, Zhangdian District
Zibo
255000 Shandong
China

Products:

- Latex Surgical Gloves
- Blood Collection Sets for Single Use
- Disposable Suction Catheter for use in Respiratory Tract
- Disposable Stomach Catheter
- Endotracheal Tube for Single Use

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Sterile Urine Bags for Single use
- Sterile Vaginal Dilators for Single Use
- Sterile Latex Examination Gloves
- Wound Plaster

Date: 2019-08-29

Notified Body



Wenxiang Zhang