

**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**

Doc. 1/2, Rev. 0

**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**



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

Doc. 2/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60138881 0001  
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**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**