

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

**Attachment to
Certificate**

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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