TÜVRheinland®

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.

Digitally signed by Iarovoi Petru
Date: 2020.01.18 20:15:02 EET
Reason: MoldSign Signature
Location: Moldova

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-08-29

TÜVRheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®

Date: 2019-08-29

Wenxiang Zhang

TÜVRheinland®

Doc. 2/2, Rev. 0

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

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH

Date: 2019-08-29

Wenxiang Zhang

TÜVRheinland®

EC Certificate

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 2173581-1

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

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.

Report No.: 190131456 110

Effective date: 2021-04-28

Expiry date: 2024-05-26

Issue date: 2021-04-28

TÜV Rheinland LGA Products GmbH

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

EC Certificate

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 2173581-1

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

- 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

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

Replaces Approval, Registration No.: DD 60138881 0001

Report No.: 190131456 110

Effective date: 2021-04-28

Expiry date: 2024-05-26

Issue date: 2021-04-28

TÜV Rheinland LGA Products GmbH

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