

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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Doc. 1/2, 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:

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



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



Date: 2019-08-29

