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EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2173581-1

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

Products: Foley Catheters for Single Use

Replaces Approval, Registration No.: HD 60138879 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 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

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

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TÜV Rheinland LGA Products GmbH

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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

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