EC Declaration of Conformity

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

whose single Authorized Representative
Name: Humiss Beratung GmbH
Add: Gneisenaustraße 8
40477 Düsseldorf, Germany

We, the manufacturer, herewith declare that the products

Butterfly Needles with Luer Adaptor G21 and G23

meet the provisions of MDD 93/42/EEC Amended by 2007/47/EC which apply to them
The medical device has been assigned to class is according to (MDD Annex V. rule X): IIa. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to MDD 93/42/EEC Amended by 2007/47/EC.

Compliance of the designated product with the MDD 93/42/EEC Amended by 2007/47/EC has been assessed and certified by the Notified Body

TüV Rheinland LGA Products Gmbh,
TillystrabE 2 – 90431 Nürnberg
Certificate No: DD 2173581-1
Issue date: 2021-04-28
Expiry date: 2024-05-26

following the procedure relating to the EC Declaration of Conformity set out in MDD 93/42/EEC Amended by 2007/47/EC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Zibo Eastmed Healthcare Products Co., Ltd
Address: No.118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong China

Zibo, 2022/2/14
Place, date

For and on behalf of ZIBO EASTMED HEALTHCARE PRODUCTS CO., LIMITED
Legally binding signature, Functio
Authorized Signature(s)

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

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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®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2173581-1

Organization: Zibo Eastmed Healthcare Products Co., Ltd.
No.118 Huaguang Road, Zhangdian District, Zibo, 255000 Shandong, P.R. 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
Design and Development, Manufacture and Distribution of Foley Catheters for Single Use

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	190139346 110
Effective date:	2022-08-17
Expiry date:	2025-08-16
Issue date:	2022-08-11

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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

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

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