

ZIBO EASTMED HEALTHCARE PRODUCTS CO., LTD.

EC Declaration of Conformity

Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd.

Address: No.118 Huaguang Road,Zhangdian District, Zibo 255000 Shandong,P.R. China.

Products: Sterile Infusion Sets for Single Use;Sterile Syringe For Single Use;Sterile Insulin Syringe for Single Use; Sterile Hypodermic Needles for Single Use;Sterile Intravenous Needles for Single Use; Insulin Needle for Single Use; Blood Transfusion Sets;Sterile Safety Auto Disable Syringe for Single Use;LV.Flow Regulator for Single Use; Three-way Stopcock and Extension Tube ; Infusion set with Burette; LV.Cannula for Single Use;Sterile Dental Needles for Single Use; Sterile Heparin Cap for Single Use; Sterile Three-way Stopcock for Single Use; Disposable Surgical Blades(with and without handle); Sterile Blood Lancets; Sterile and non-sterile Nasal Oxygen Cannula; Sterile and Non-sterile Oxygen Masks;Sterile and non-sterile Nebulizer masks; 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 bag for Single Use; Sterile Vaginal Dilators for Single Use; Sterile Latex Examination Gloves,Wound Plaster; Foley Catheters for Single Use

Classification: (MDD Annex V) IIa

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documents are retained under the premise of the manufacturer and the notify body.

DIRECTIVES

General Applicable Directives:

Medical Device Directive: COUNCIL DIRECTIVE MDD 93/42/EEC OF 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards:

All applicable harmonized standards published in the Official Journal of the European Communities:
ISO 13485:2016, ISO 10993

EC Representative: Humiss Beratung GmbH

Add: Gneisenaustraße 8, 40477 Düsseldorf, Germany

SRN: DE-AR-000023447

Notified Body: TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431Nürnberg notified under #0197 to the EC Commission

Certificate: DD 2173581-1 HD 2173581-1

Expiry Date of CE Certificate: 2024-05-26

Effective Date of CE Certificate: 2021-04-28

Zibo Eastmed Healthcare Products Co., Ltd.

General Manager 东迈医疗技术有限公司

Date: Apr.26,2021 3703213088140

