

ZIBO EASTMED HELTHCARE PRODUCTS CO., LTD.

EC Declaration of Conformity

INVOICE NO.:DM202304-VDS

Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd.

Address: NO.118,HUAGUANG ROAD, ZHANGDIAN DISTRICT 2550000, ZIBO CITY,SHANDONG PROVINCE CHINA.

Products as well as made for company: SCVETRO DESIGN SRL

**DISPOSABLE SYRINGE, HYPODERMIC NEEDLE,DENTAL NEELDES, FOLEY CATHETER
PRIMA BRAND for Single Use:**

DISPOSABLE SYRINGE: Lot No.: ZEH6476 Mfg Date: 2023/08/31 Exp. Date:2028/08/31

HYPODERMIC NEEDLE: Lot No.:ZEH6476 Mfg Date: 2023/08/31 Exp. Date:2028/08/31

DENTAL NEELDES : ZEH6476 Mfg Date: 2023/08/31 Exp. Date:2028/08/31

NEBULIZER MASK: ZEH6476 Mfg Date: 2023/08/31 Exp. Date:2028/08/31

Classification: (MDD Annex IX) 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:

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

Standards:

All applicable harmonized standards published in the Official Journal of the European Communities: ISO 13485:2012, ISO 10993

EC Representative: Humiss Beratung GmbH

Gneisenaustraße 8 40477 Düsseldorf, Germany

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

Certificate: DD 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

