

EC Declaration of Conformity

Manufacturer: whose single Authorized Representative
Name: Zibo Eastmed Healthcare Name: HUMISS TRADING S. L.
Products Co., Ltd
Add: No.118 Huaguang Road, Zhangdian Add: Calle Luis Buñuel 12, MADRID,
District, Zibo 255000, Shandong 28018, Spain
China SRN: ES-AR-000040177
We, the manufacturer, herewith declare that the products

Disposable infusion set with metal spike

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



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

End date of extended validity:2028-12-31

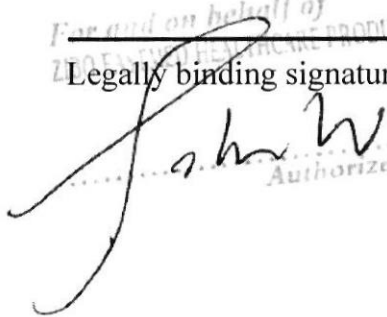
following the procedure relating to the EC Declaration of Conformity set out in MDD
93/42/EEC Amended by 2007/47/EC.

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, 2024/5/26

Place, date

For and on behalf of
ZIBO EASTMED HEALTHCARE PRODUCTS CO., LIMITED
Legally binding signature, Function

Authorized Signature(s)



TÜV Rheinland LGA Products GmbH • 51105 Köln

Contact

Tel. +49 911 655-5225

Mail: medical-products@de.tuv.com

Date March 14, 2024

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

Notified Body Confirmation Letter

Reference. : 190153021

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Zibo Eastmed Healthcare Products Co., Ltd.
No.118 Huaguang Road, Zhangdian District, Zibo,
255000 Shandong,
P.R. China
SRN Number: CN-MF-000032259

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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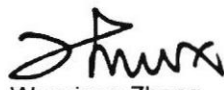
Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübli

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body



Wenxiang Zhang
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: I.V. Flow Regulator for Single Use Basic UDI-DI: 697107761001HY	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197
Device name: Sterile Syringes for Single Use Basic UDI-DI: 697107761002J2	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197
Device name: Sterile Infusion Sets for Single Use Basic UDI-DI: 697107761003J4	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: Sterile Hypodermic Needles for Single Use Basic UDI-DI: 697107761004J6	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197
Device name: Sterile Intravenous Needles for Single Use Basic UDI-DI: 697107761005J8	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197
Device name: Infusion Set with Burette Basic UDI-DI: 697107761006JA	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197
Device name: Blood Transfusion Sets Basic UDI-DI: 697107761007JC	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197
Device name: Sterile Urine Bags for Single Use Basic UDI-DI: 697107761008JE	Class I devices placed on the market in sterile condition	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197
Device name: Three-way Stopcock and Extension Tube Basic UDI-DI: 697107761009JG	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197
Device name: Sterile Heparin Cap for Single Use Basic UDI-DI: 697107761010HZ	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197
Device name: Sterile Three-way Stopcocks for Single Use Basic UDI-DI: 697107761011J3	Class IIa	Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2173581-1 NB#: 0197

Table 2: Devices covered by this letter and for which the NB is **NOT** responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/14	190153021	Initial issue

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



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.

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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