Business Stream Products
Certification Department

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LGA
Precisely Right.

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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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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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:** **69710776100 2J2**	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:** **6971077610 03J4**	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:** **69710761011J3**	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 <u>NOT</u> 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