EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 2008073-1

Manufacturer: Shandong Hapool Medical Technology Co., Ltd.
West of Kunming Road, West Zone, Economic Development District,
Heze City, 40076 Shandong, P.R. China

Products: Scalp Vein Sets, Three-way Stopcocks, Disposable Syringe with Needles, Infusion Sets, Insulin Syringes, IV. Flow Regulators, Needle Free Connectors, Intravenous Infusion Sets with Burette, Blood Transfusion Sets and Sterile Latex Surgical Gloves
For the Following Medical Devices the Scope covers the Aspects of Manufacture concerned with Securing and Maintaining Sterile Conditions: Sterile Urine Drainage Bags and Sterile Surgical Gowns

Replaces Approval, Registration No.: DD 60146789 0001

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.: 190129226 110

Effective date: 2021-04-26

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TÜV Rheinland LGA Products GmbH

Jing Zhang
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Shandong Hapool Medical Technology Co., Ltd.
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Date January 29, 2024

Notified Body Confirmation Letter
Reference. : 190152424

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:

Shandong Hapool Medical Technology Co., Ltd.
No. 111, Changguo Road, Zhangdian District,
Zibo, 255021 Shandong
P.R. China
SRN Number: CN-MF-000033408

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: Three-way Stopcocks (Size Code includes: 37.2x11.0mm, with or without extension tube) **Please refer to the attachment (File no. HAPOOL-CE04, Date 2018.05.08) for specifications and models of Three-way Stopcocks for single use, which all included when applying for MDR.** **Basic UDI-DI: 697657476A0703F2**	Class IIa	Three-way Stopcocks (Model: 37.2x11.0mm, with or without extension tube) Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2008073-1 NB #: 0197
Device name: Infusion Sets	Class IIa	Infusion Sets (Model: W-IS-GA, W-IS-GB, W-IS-GC, W-IS-GD)	Certificate #: DD 2008073-1 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**
(Size Code includes W-IS-GA, W-IS-GB, W-IS-GC, W-IS-GD) **Please refer to the attachment (File no. HAPOOL-CE03, Date 2018.09.08) for specifications and models of Infusion Sets for single use, which all included when applying for MDR** **Basic UDI-DI:** **Model: W-IS-GA** **697657476A030101AAW** **Model: W-IS-GB** **697657476A030101BAY** **Model: W-IS-GC** **697657476A030101CB2** **Model: W-IS-GD** **697657476A030101DB4**		Note: The device will be replaced made by the IMF from OEM supplier.	
Device name: I.V. Flow Regulators **(Size Code includes S, M)** **Please refer to the attachment (File no. HAPOOL-CE03-09, Date 2020.03.18) for specifications and models of I.V. Flow Regulators for single use, which all included when applying for MDR** **Basic UDI-DI:** **697657476A0301048F**	Class IIa	IV. Flow Regulators (Model: L,M,S) Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2008073-1 NB #: 0197
Device name: Blood Transfusion Sets **(Size Code includes BT-S, BT-B)** **Please refer to the attachment (File no. HAPOOL-CE06, Date 2019.07.08) for specifications and models of Blood Transfusion Sets for**	Class IIa	Blood Transfusion Sets (Model:-BT-S, BT-B) Note: The device will be replaced made by the IMF from OEM supplier.	Certificate #: DD 2008073-1 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
single use, which all included when applying for MDR **Basic UDI-DI:** **Model: BT-S** **697657476Z121799Q4** **Model: BT-B** **697657476Z121799AVP**			

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
2024/01/29	190152424	Initial issue