Business Stream Products
Certification Department

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TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Shenzhen Hawk Medical Instrument Co., Ltd.
1st-4th Floor, Building C, Jianyetai Industrial
Zone, No.11 Minhuan Road, Fukang Community,
Longhua Street, Longhua District,
Shenzhen, 518109, Guangdong,
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date March 14, 2024

Notified Body Confirmation Letter
Reference. : 10924195

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:

Shenzhen Hawk Medical Instrument Co., Ltd.
1st-4th Floor, Building C, Jianyetai Industrial
Zone, No.11 Minhuan Road, Fukang Community,
Longhua Street, Longhua District,
Shenzhen, 518109, Guangdong,
P.R. China
SRN Number (if available): CN-MF-000013071

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

Samuel Qin

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**
Infusion Pump Model: HK-100, HK-100I, HK-100II **Basic UDI-DI:** 692050654000-402163	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2183512-1 NB#0197
Infusion Pump Model: hawk-i1 **Basic UDI-DI:** 692050654022-40298F	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2183512-1 NB#0197
Syringe Pump Model: HK-400, HK-400I, HK-400II **Basic UDI-DI:** 692050654038-4047BG	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2183512-1 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
Syringe Pump Model: HK-400III **Basic UDI-DI:** 692050654048-4055BY	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2183512-1 NB#0197
Syringe Pump Model: hawk-s1 **Basic UDI-DI:** 692050654056-4057BT	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2183512-1 NB#0197
Infusion Pump Management Units Model: HAWK-WS1, HAWK-WS2 **Basic UDI-DI:** 692050654126-4137AS	Class IIb excluding Class IIb implantable non-WET	Infusion Workstation Model: HAWK-WS1, HAWK-WS2	Certificate # HD 2183512-1 NB#0197
Enteral Feeding Pump Model: HK-300 **Basic UDI-DI:** 692050654058-4061CC	Class IIa	N/A	Certificate # HD 2183512-1 NB#0197
Fluid Warmer Model: Hawk-fw1 **Basic UDI-DI:** 692050654226-4227BF	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 2183512-1 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	10924195	Initial issue