Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Dongguan Kaiser Technology Co., Ltd.
No.6, 2nd Road, Sanjiang Industrial Block, Hengli Town, Dongguan City,
523462 Guangdong,
P.R. China

Contact

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

Date November 29, 2023

Notified Body Confirmation Letter
Reference. : 10923445

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:

Dongguan Kaiser Technology Co., Ltd.
No.6, 2nd Road, Sanjiang Industrial Block, Hengli Town, Dongguan City,
523462 Guangdong,
P.R. China
SRN Number (if available): CN-MF-000006968

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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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**
Surgical Lavage Units Model No.2500 Basic UDI-DI: **697318164KCE-0101HX** **697318164KCE-0102HZ**	Class IIa	N/A	Certificate # DD 2110503-1 NB #0197
Bone Drill(machine only) **Model No.SP-002-1** Basic UDI-DI: **697318164KCE-0401JE**	Class IIa	N/A	Certificate # DD 2110503-1 NB #0197
Orthopedic Reamers(mahine only) **Model No.SP-002-2** Basic UDI-DI: **697318164KCE-0501JK**	Class IIa	N/A	Certificate # DD 2110503-1 NB #0197
Electrical Surgical Bone Saws(mahine only) **Model No.SP-002-3**	Class IIa	N/A	Certificate # DD 2110503-1 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**
Basic UDI-DI: **697318164KCE-0601JQ**			
Warming and Cooling Therapy **Model No.TP1000** Basic UDI-DI: **697318164KCE-0901K7**	Class IIa	N/A	Certificate # DD 2110503-1 NB #0197
Blanket Warming Units **Model No.85000** Basic UDI-DI: **697318164KCE-1201JB**	Class IIa	N/A	Certificate # DD 2110503-1 NB #0197
Surigical Illuminators **Model No.LS2000** Basic UDI-DI: **697318164KCE-0801K2**	Class IIa	Surgical Light Stick Model No.LS2000	Certificate # DD 2110503-1 NB #0197
Bone Cement Mixer Syringe **Model No.5000-12** Basic UDI-DI: **697318164KCE-1001HZ**	Class IIa	N/A	Certificate # DD 2110503-1 NB #0197
Bone Cement Mixer **Model No.5000** Basic UDI-DI: **697318164KCE-0701JV**	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 2110503-1 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
2023-11-29	10923445	Initial issue