Dongguan Kaiser Technology Co., Ltd

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Dongguan Kaiser Technology Co., Ltd.
Manufacturer address and contact details	No.6, 2nd Road , Sanjiang Industrial Block , Hengli Town , Dongguan City , 523462 Guangdong , P.R. China
Single Registration Number (SRN) (if available)	CN-MF-000006968

Authorised Representative name (if applicable)	MedNet EC-REP GmbH
Authorised Representative address and contact details	Borkstraße, 10 48163 Münster
Single Registration Number (SRN) (if available)	DE-AR-000000002

Notified body name (if applicable)	TUV rheinland □ See attached schedule
Notified body number (if applicable)	CE 0197 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	DD 2110503-1 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024.05.26 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

End date of extended validity/transition period	2028..12.31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

■ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

■ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Up classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

■ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

■ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☐ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name : Dongguan Kaiser Technology Co., Ltd.

Location & Date : Dongguan, 2024.03.08

Signature, Print Name, Title : Aaron Chang Aaron Chang/Project Manager

Contact Details : aaron@kaiser-tech.com.tw

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Surgical lavage Units	**DD 2110503-1**	**204.05.26**	TUV rheinland/0197	TUV rheinland/0197	2028.12.31	No applicable
Bone Drill(machine only)	**DD 2110503-1**	**204.05.26**	TUV rheinland/0197	TUV rheinland/0197	2028.12.31	No applicable
Orthopedic Reamers(machine only)	**DD 2110503-1**	**204.05.26**	TUV rheinland/0197	TUV rheinland/0197	2028.12.31	No applicable
Electrical Surgical Bone Saws(machine only)	**DD 2110503-1**	**204.05.26**	TUV rheinland/0197	TUV rheinland/0197	2028.12.31	No applicable
Warming and Cooling Therapy	**DD 2110503-1**	**204.05.26**	TUV rheinland/0197	TUV rheinland/0197	2028.12.31	No applicable
Blanket Warming Units	**DD 2110503-1**	**204.05.26**	TUV rheinland/0197	TUV rheinland/0197	2028.12.31	No applicable
Surgical illuminators	**DD 2110503-1**	**204.05.26**	TUV rheinland/0197	TUV rheinland/0197	2028.12.31	No applicable
Bone Cement Mixer Syringe	**DD 2110503-1**	**204.05.26**	TUV rheinland/0197	TUV rheinland/0197	2028.12.31	No applicable

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Bone Cement Mixer	**DD 2110503-1**	**204.05.26**	TUV rheinland/0197	TUV rheinland/0197	2028.12.31	No applicable

Business Stream Products
Certification Department

TÜVRheinland®
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

9/610 E 10.10 ® TÜV, TUEV, TUV are registered trademarks. Utilisation and application requires prior approval.

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 (machine 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 (machine 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

EC Certificate

TÜVRheinland®

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

Registration No.:	DD 2110503-1
Manufacturer:	Dongguan Kaiser Technology Co., Ltd. No.6, 2nd Road, Sanjiang Industrial Block, Hengli Town, Dongguan City, 523462 Guangdong P.R. China
Products:	Bone Drills (machine only), Orthopedic Reamers (machine only), Electrical Surgical Bone Saws (machine only), Surgical Lavage Units, Surgical Illuminators, Bone Cement Mixer Syringe, Warming and Cooling Therapy, Blanket Warming Units; Aspects of manufacture concerned with securing and maintaining sterile conditions: Bone Cement Mixer, Torque Instruments Manual

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.:	10918671-100
Effective date:	2021-04-13
Expiry date:	2024-05-26
Issue date:	2021-04-13

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Dipl.-Ing. W. Hsu
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.

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.