Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Apex (Guangzhou) Tools & Orthopedics Co.
No. 25, Yonghua Road,
Yonghe, GETDD,
511356, Guangzhou,
P.R. China

Contact

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

Date February 22, 2024

Notified Body Confirmation Letter
Reference. : 10924145

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:

Apex (Guangzhou) Tools & Orthopedics Co.
No. 25, Yonghua Road,
Yonghe, GETDD,
511356, Guangzhou,
P.R. China
SRN Number (if available): CN-MF-000018403

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

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Board of Management

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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**
DISPOSABLE PULSE LAVAGE Model: 201-02-00 Basic UDI-DI: 695727722010200TD	Class IIa	PULSE LAVAGE Model: 201-02-00	Certificate # DD 601476240001 NB #0197
DISPOSABLE PULSE LAVAGE Model:201-03-00 Basic UDI-DI: 695727722010300TJ	Class IIa	PULSE LAVAGE Model: 201-03-00	Certificate # DD 601476240001 NB #0197
DISPOSABLE PULSE LAVAGE Model: 201-04-00 Basic UDI-DI: 695727722010400TP	Class IIa	PULSE LAVAGE Model: 201-04-00	Certificate # DD 601476240001 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
DISPOSABLE PULSE LAVAGE Model: 201-05-00 Basic UDI-DI: 695727722010500TU	Class IIa	PULSE LAVAGE Model: 201-05-00	Certificate # DD 60147624 0001 NB #0197
DISPOSABLE PULSE IRRIGATION KIT Model: 209-01 Basic UDI-DI: 6957277220901CN	Class IIa	N/A	Certificate # DD 60147624 0001 NB #0197
DISPOSABLE PULSE IRRIGATION KIT Model: 209-02 Basic UDI-DI: 6957277220902CQ	Class IIa	N/A	Certificate # DD 60147624 0001 NB #0197
SHOWER SPRAY TIP WITH SPLASH SHIELD Model: 201-00-37 Basic UDI-DI: 695727722010037TS	Class IIa	N/A	Certificate # DD 60147624 0001 NB #0197
FAN SPRAY TIP WITH SPLASH SHIELD Model: 201-00-44 Basic UDI-DI: 695727722010044TP	Class IIa	N/A	Certificate # DD 60147624 0001 NB #0197
FEMORAL SPRAY TIP Model: 201-00-46 Basic UDI-DI: 695727722010046TT	Class IIa	N/A	Certificate # DD 60147624 0001 NB #0197
SHOWER SPRAY TIP Model: 201-00-50 Basic UDI-DI: 695727722010050TJ	Class IIa	N/A	Certificate # DD 60147624 0001 NB #0197
FAN SPRAY TIP Model: 201-00-51 Basic UDI-DI: 695727722010051TL	Class IIa	N/A	Certificate # DD 60147624 0001 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
FEMORAL BRUSH TIP Model: 201-00-52 Basic UDI-DI: 695727722010052TN	Class IIa	N/A	Certificate # DD 60147624 0001 NB #0197
SPLASH SHIELD. 6INCH Model:201-00-80 Basic UDI-DI: 695727722010080TT	Class IIa	6" SPLASH SHIELD Model:201-00-80	Certificate # DD 60147624 0001 NB #0197
Kirschner Wire and Steinmann Pin Basic UDI-DI: 6957277211003B9	Class IIa	Surgical Guide Wires	Certificate # DD 60147624 0001 NB #0197
Surgical Drill Bit Basic UDI-DI: 6957277209003CN	Class IIa	N/A	Certificate # DD 60147624 0001 NB #0197
Surgical Saw Blade Basic UDI-DI: 6957277209001CJ	Class IIa	N/A	Certificate # DD 60147624 0001 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
2024/02/22	10924145	Initial issue

TÜVRheinland®

EC Certificate

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

Registration No.: DD 60147624 0001

Report No.: 17062402 009

Manufacturer:

Apex (Guangzhou)
Tools & Orthopedics Co.
No. 25 Yonghua Road,
Yonghe, GETDD
511356 Guangzhou
P.R. China

Products:

Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60113790 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2020-08-24

Date: 2020-08-24

Notified Body

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60147624 0001
Report No.: 17062402 009

Manufacturer:
Apex (Guangzhou)
Tools & Orthopedics Co.
No. 25 Yonghua Road,
Yonghe, GETDD
511356 Guangzhou
P.R. China

Products:

- Disposable Pulse Lavages
- Disposable Skin Staplers
- Surgical Saw Blades
- Surgical Drill Bits
- Kirschner Wires and Steinmann Pins
- Disposable Pulse Irrigation Kits
- Disposable Lavage Tips

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Disposable Skin Staple Removers
- Disposable Irrigation Bags

Notified Body

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-08-24

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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 Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- 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	Apex (Guangzhou) Tools & Orthopedics Co.
Manufacturer address and contact details	No. 25 Yonghua Road, Yonghe, GETDD 511356 Guangzhou P.R. China
Single Registration Number (SRN) (if available)	CN-MF-000018403
Authorised Representative name (if applicable)	Wellkang Ltd
Authorised Representative address and contact details	Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland AuthRep@CE-marking.eu +44(33)33031126
Single Registration Number (SRN) (if available)	XI-AR-000001836

Authorised Representative name (if applicable)	Wellkang Ltd
Authorised Representative address and contact details	Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland AuthRep@CE-marking.eu +44(33)33031126
Single Registration Number (SRN) (if available)	XI-AR-000001836

Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH
Notified body number (if applicable)	CE0197
Directive Certificate number(s) to which this confirmation is made (if applicable)	DD 60147624 0001
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26
End date of extended validity/transition period	2028-12-31

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate,** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** 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** as listed above

  Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

  Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment will be submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreement will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Quality Management System (QMS)**

  A QMS in accordance with Article 10(9) MDR is in place.

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

  - The device(s) continue to comply with the 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: Apex (Guangzhou) Tools & Orthopedics Co.

Location & Date: Guangzhou, 2023-11-17

Signature, Print Name, Title: Leo Yi, Director of Quality

Contact Details (at least email): leeoyi@apexitool.net

Schedule of Devices

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

Identification of the devices	**Directive Certificate number to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**
Disposable Pulse Lavages	DD 60147624 0001	2024-05-26	TÜV Rheinland LGA Products GmbH, CE0197	TÜV Rheinland LGA Products GmbH, CE0197	2028-12-31
Disposable Pulse Irrigation Kits	DD 60147624 0001	2024-05-26	TÜV Rheinland LGA Products GmbH, CE0197	TÜV Rheinland LGA Products GmbH, CE0197	2028-12-31
Disposable Lavage Tips	DD 60147624 0001	2024-05-26	TÜV Rheinland LGA Products GmbH, CE0197	TÜV Rheinland LGA Products GmbH, CE0197	2028-12-31
Surgical Saw Blades	DD 60147624 0001	2024-05-26	TÜV Rheinland LGA Products GmbH, CE0197	TÜV Rheinland LGA Products GmbH, CE0197	2028-12-31
Surgical Drill Bits	DD 60147624 0001	2024-05-26	TÜV Rheinland LGA Products GmbH, CE0197	TÜV Rheinland LGA Products GmbH, CE0197	2028-12-31
Kirschner Wires and Steinmann Pins	DD 60147624 0001	2024-05-26	TÜV Rheinland LGA Products GmbH, CE0197	TÜV Rheinland LGA Products GmbH, CE0197	2028-12-31