EC Certificate

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

Registration No.: DD 60148503 0001

Report No.: 50307116 002

Manufacturer:
Shanghai Xing Yu Medical Equipment
Co., Ltd.
3 Floor, Building 21, No.3825 Xin Zhuan Road
Dong Jing Town, Song Jiang District
201601 Shanghai
P.R. China

Products:
- Gutta Percha Points
- Sterile Absorbent Paper Points
- Dental Root Canal Instruments

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: 2020-06-23

Date: 2020-06-23

Notified Body

Jing Zhang

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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Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shanghai Xing Yu Medical Equipment
Co., Ltd.
3 Floor, Building 21, No.3825 Xin Z
201601 SHANGHAI
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date June 23, 2020

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60148503 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. DD 60148503 0001.

Kind regards

Certification body

Jing Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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Contact

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Date May 17, 2024

Shanghai Xing Yu Medical Equipment Co., Ltd.
101 Room, 1st Floor, Building 6, No.868 Xin Ge Road, Song Jiang District
201612 Shanghai,
P.R. China

Notified Body Confirmation Letter
Reference. : 190155200

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:

Shanghai Xing Yu Medical Equipment Co., Ltd.
101 Room, 1st Floor, Building 6, No.868 Xin Ge Road, Song Jiang District
201612 Shanghai,
P.R. China
SRN Number: CN-MF-000032268

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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Germany

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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

Jing 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: Gutta Percha Points **Basic UDI-DI:** 697492240GP3U	Class IIa	N/A	Certificate #: DD 60148503 0001 NB#: 0197
Device name: Sterile Absorbent Paper Points **Basic UDI-DI:** 697492240PP4P	Class IIa	N/A	Certificate #: DD 60148503 0001 NB#: 0197
Device name: Dental Root Canal Instruments **Basic UDI-DI:** 697492240FILESMT	Class IIa	N/A	Certificate #: DD 60148503 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
2024/05/16	190155200	Initial issue
2024/05/17	190155200	Revised manufacturer address