

EC Certificate



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

Registration No.: DD 2031977-1

Manufacturer: Shenzhen Yurucheng Dental
Materials Co., Ltd.
101-201, Building 4, No.1 Branch
of Zhongcheng Life Science Park,
No.14 Zhongxing
Road, Xiuxin Community, Kengzi street
office,
Pingshan District, Shenzhen,
518122 Guangdong
P.R. China

Products: Zirconia Dental Ceramics



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.: 17054652 004

Effective date: 2021-04-14

Expiry date: 2024-05-26

Issue date: 2021-04-14

A blue ink signature is written over a circular stamp. The stamp contains the TÜVRheinland logo and the text 'TÜV Rheinland LGA Products GmbH' and 'Tillystraße 2 · 90431 Nürnberg · Germany'. Below the signature, the name 'Jing Zhang' is printed.

Jing Zhang
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.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Shenzhen Yurucheng Dental Materials Co., Ltd.
101, 201, 301, Building A,
No. 35, Zhuqing Rd., Shijing Community, Shijing Street,
Pingshan District, Shenzhen,
518118 Guangdong
P.R. China

Contact

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

Date July 04, 2023

Application for: QMS

Certificate No. : DD 2031977-1
Requirement : MDD 93/42/EEC Annex V
Confirmation letter ID : DOC_2023-07-04_DD 2031977-1
Report no. : 10922420-100

Dear Madame or Sir,

Update of information to Certificate no. DD 2031977-1, issued on 14.04.2021

The change notification received on 03.01.2023 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address: 101-201, Building 4, No.1 Branch of Zhongcheng Life Science Park, No.14 Zhongxing Road, Xiuxin Community, Kengzi street office, Pingshan District, Shenzhen, 518122, Guangdong, P.R. China

New Manufacturer address: 101,201,301, Building A, No. 35, Zhuqing Rd., Shijing Community, Shijing Street, Pingshan District, Shenzhen, 518118 Guangdong, P.R. China

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
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Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

Best regards,



Samuel Qin
Certification body

TÜV Rheinland LGA Products GmbH • 51105 Köln

Shenzhen Yurucheng Dental Materials Co., Ltd.
101,201,301, Building A,
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518118 Guangdong,
P.R. China

Contact

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

Date January 30, 2024

Notified Body Confirmation Letter

Reference. : 10924117

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 Yurucheng Dental Materials Co., Ltd.
101,201,301, Building A,
No. 35, Zhuqing Rd., Shijing Community, Shijing Street,
Pingshan District, Shenzhen,
518118 Guangdong,
P.R. China
SRN Number (if available): CN-MF-000011505

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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Dr. Jörg Schlösser

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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
Dental Zirconia Block(White) Basic UDI-DI: 697424268ZirconiaWhiteSZV	Class IIa	N/A	Certificate # DD 2031977-1 NB #0197
Dental Zirconia Block(Color) Basic UDI-DI: 697424268ZirconiaColorSV9	Class IIa	N/A	Certificate # DD 2031977-1 NB #0197
Dental Zirconia Block(Multilayer) Basic UDI-DI: 697424268ZirconiaMLS	Class IIa	N/A	Certificate # DD 2031977-1 NB #0197

Table 2: Devices covered by this letter and for which the NB is NOT 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
2024/01/30	10924117	Initial issue

Certificate

Quality Management System EN ISO 13485:2016

Registration No.	SX 2031977-1
Certificate Holder	Shenzhen Yurucheng Dental Materials Co., Ltd. 101, 201, 301, Building A, No. 35, Zhuqing Rd., Shijing Community, Shijing Street, Pingshan District, Shenzhen, 518118 Guangdong P.R. China
Scope	Manufacture and Distribution of Zirconia Dental Ceramics

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.	10922420-100
Effective date	2023-07-04
Expiry date	2025-07-29
Issue date	2023-07-04
Replaces certificate SX 2031977-1 issued 2022-07-08	

This certificate can be validated on <https://www.certipedia.com>



Samuel Qin
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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