EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60144008 0001

Report No.: 17047780 009

Manufacturer:

Aidite (Qinhuangdao) Technology
Co., Ltd.
No. 9 Dushan Road, Economic And
Technological Development Zone
Qinhuangdao City
066004 Hebei
China

Products:

- Dental Zirconia Ceramics
- Dental Glass Ceramics
- Coloring Liquid Specializeds for Aidite Zirconia Material
- Porcelain Powder
- PMMA Blocks for Dental Use

Replaces Approval, Registration No.: HD 60139224 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-02

Date: 2019-12-02

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Fuxin Sheng

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.

Business Stream Products
Certification Department

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LGA
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TÜV Rheinland LGA Products GmbH • 51105 Köln

Aidite (Qinhuangdao) Technology Co., Ltd.
No.9 Dushan Road, Economic And Technological Development Zone,
Qinhuangdao City,
066004, Hebei,
P.R. China

Contact

Tel. +49 911 655-5225
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Date April 29, 2024

Notified Body Confirmation Letter
Reference. : 10924287

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:

Aidite (Qinhuangdao) Technology Co., Ltd.
No.9 Dushan Road, Economic And Technological Development Zone,
Qinhuangdao City,
066004, Hebei,
P.R. China
SRN Number (if available): CN-MF-000015573

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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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 Ceramics **Model: HT,SHT,ST,AT** Basic UDI-DI: 697645949ZCW39	Class IIa	N/A	Certificate # HD 60144008 0001 NB #0197
Dental Zirconia Ceramics **Model: Color,ST-COLOR,FC** Basic UDI-DI: 697645949ZCCZW	Class IIa	N/A	Certificate # HD 60144008 0001 NB #0197
Dental Zirconia Ceramics **Model: SHT-Plus,,Multilayer,Multilayer-3D,Multilayer-3T,MC,GC,EC** Basic UDI-DI: 697645949ZCM2M	Class IIa	N/A	Certificate # HD 60144008 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
Dental Glass Ceramics **Models: HT** Basic UDI-DI: 697645949GCHTUQ	Class IIa	N/A	Certificate # HD 60144008 0001 NB #0197
Dental Glass Ceramics **Models: LT** Basic UDI-DI: 697645949GCLTV4	Class IIa	N/A	Certificate # HD 60144008 0001 NB #0197
Dental Glass Ceramics **Models: ST** Basic UDI-DI: 697645949GCSTVR	Class IIa	N/A	Certificate # HD 60144008 0001 NB #0197
Coloring Liquid Specialized for Aidite Zirconia Material **Model: 25ml,50ml,100ml,250ml** Basic UDI-DI: 697645949CL6S	Class IIa	N/A	Certificate # HD 60144008 0001 NB #0197
Porcelain Powder **Models: Dentine** Basic UDI-DI: 697645949PPDZM	Class IIa	N/A	Certificate # HD 60144008 0001 NB #0197
Porcelain Powder **Models: Enamel/ Modifier** Basic UDI-DI: 697645949PPEMXZ	Class IIa	N/A	Certificate # HD 60144008 0001 NB #0197
Porcelain Powder **Models: Stain/Glaze** Basic UDI-DI: 697645949PPSGYX	Class IIa	N/A	Certificate # HD 60144008 0001 NB #0197
PMMA Blocks for Dental Use **Models: Color** Basic UDI-DI: 697645949RMCZL	Class IIa	N/A	Certificate # HD 60144008 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
PMMA Blocks for Dental Use **Models: Multilayer** Basic UDI-DI: 697645949RMM2B	Class IIa	N/A	Certificate # HD 60144008 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
2024-04-29	AIDIT_CL607_2024-04-29	Initial issue

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 2041251-1
Certificate Holder:	Aidite (Qinhuangdao) Technology Co., Ltd. No.9 Dushan Road, Economic And Technological Development Zone, Qinhuangdao City, 066004 Hebei P.R. China
Scope:	Design and Development, Manufacture and Distribution of Dental Zirconia Ceramics, Dental Glass Ceramics, Dental Coloring Materials, Porcelain Powders, PMMA Blocks for Dental use, Progressive Orthodontic Appliance Systems, Dental Foils, Denture Base Resins, Dental Ceramic Blocks, Dental Resins for Additive Manufacturing, Intraoral Scanners, Dental Base Cements, Dental Bonding Agents, Head Lamps, Binocular Loupes, Dental Waxes, Firing Pastes for dental applications

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.:	10926025-100
Effective date:	2025-06-13
Expiry date:	2027-07-09
Issue date:	2025-06-13

Replaces certificate SX 2041251-1 issued 2024-07-09

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

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2041251-1

Certificate Holder: Aidite (Qinhuangdao) Technology Co., Ltd.
No.9 Dushan Road, Economic And Technological Development Zone,
Qinhuangdao City,
066004 Hebei
P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Aidite (Qinhuangdao) Technology Co., Ltd. No.9 Dushan Road, Economic And Technological Development Zone, Qinhuangdao City, 066004 Hebei P.R. China	Design and Development, Manufacture and Distribution of Dental Zirconia Ceramics, Dental Coloring Materials, Dental Base Resins, Dental Ceramic Blocks, Dental Resins for Additive Manufacturing, Intraoral Scanners, Dental Base Cements, Dental Bonding Agents Design and Development, and Distribution of Dental Glass Ceramics, Porcelain Powders, PMMA Blocks for Dental Use, Progressive Orthodontic Appliance Systems, Dental Foils, Head Lamps, Binocular Loupes, Dental Waxes, Firing Pastes for dental applications
/02	c/o Aidite (Qinhuangdao) Technology Co., Ltd. No. 56 Tianchi Road, Economic And Technological Development Zone, Qinhuangdao City, 066004 Hebei P.R. China	Manufacture of Dental Glass Ceramics, Porcelain Powders, PMMA Blocks for Dental use, Dental Resins for Additive Manufacturing, Progressive Orthodontic Appliance Systems, Dental Foils, Head Lamps, Binocular Loupes, Dental Waxes, Firing Pastes for dental applications

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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