EC Certificate

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

TÜVRheinland®

Registration No.: DD 60151346 0001

Report No.: 17050363 010

Manufacturer:
Foshan COXO Medical Instrument
Co., Ltd.
BLDG 4, District A
Guangdong New Light Source
Industrial Base, South of Luocun Avenue
Nanhai District
Foshan
528226 Guangdong
P.R. China

Products:
Active dental devices
(see attachment for products included)

Replaces EC Certificate No. DD 60150762 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: 2020-12-06

Date: 2020-12-06

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Shengkui Zhong

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60151346 0001
Report No.: 17050363 010

Manufacturer:
Foshan COXO Medical Instrument Co., Ltd.
BLDG 4, District A
Guangdong New Light Source Industrial Base, South of Luocun Avenue
Nanhai District
Foshan
528226 Guangdong
P.R. China

Products:

- Root Apex Locators
- Endo Motors
- Pulp Testers
- High-speed Air Turbine Handpieces
- Straight Handpieces
- Geared Angle Handpieces
- Air Motors
- Dental Implantation Systems
- Dental Electrical Motors
- Endodontic Obturation Systems

Notified Body

Shengkui Zhong

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-12-06

Business Stream Products
Certification Department

TÜVRheinland®
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TÜV Rheinland LGA Products GmbH • 51105 Köln

Foshan COXO Medical Instrument Co., Ltd.
No. 17, Guangming Ave., New Light Source Industrial
Base, Nanhai National High-tech Zone,
Foshan 528226, Guangdong,
P.R. China

Contact

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

Date January 11, 2024

Notified Body Confirmation Letter
Reference. : 10923571

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:

Foshan COXO Medical Instrument Co., Ltd.
No. 17, Guangming Ave., New Light Source Industrial
Base, Nanhai National High-tech Zone,
Foshan 528226, Guangdong,
P.R. China
SRN Number (if available): CN-MF-000001682

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

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Fax +49 911 655 5226
service@de.tuv.com
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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
2024.01.11
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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
Root Apex Locators Model: C-Root I, C-Root I(III), C-Root I(V), C-Root I(VI), C-Root i+ **Basic UDI-DI:** 69742678903ZU	Class IIa	N/A	Certificate # DD 60151346 0001 NB #0197
Endo Motor Model: C-Smart-Mini, C-Smart-Mini 2, C-Smart-Mini Ap **Basic UDI-DI:** 6974267890403FG	Class IIa	N/A	Certificate # DD 60151346 0001 NB #0197
Endo Motor Model: C-Smart-I Pro, C-Smart, C-Smart-I, C-Smart-II, C-Smart-III, C-Smart-V **Basic UDI-DI:**	Class IIa	N/A	Certificate # DD 60151346 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
69742678904ZW			
High-speed air turbine handpieces Model: CX207, CX207-G, CX207-2, CX207-A, CX207-A-2, CX207-B, CX207-B-2, CX207-C, CX207-C-2, CX207-F, CX207-W, CX207-W-2 **Basic UDI-DI:** 6974267890523	Class IIa	N/A	Certificate # DD 60151346 0001 NB #0197
Dental implantation system **Model:** C-Sailor, C-Sailor+, C-Sailor Pro+ **Basic UDI-DI:** 69742678910ZR	Class IIa	N/A	Certificate # DD 60151346 0001 NB #0197 Note: model C-Sailor Pro+ is not covered by MDD certificate.
Geared angle handpieces **Model:** CX235-1B, CX235-1C, CX235-1E, CX235-1F, CX235-1G, CX235C1, CX235C2, CX235C3, CX235C4, CX235C5, CX235C6, CX235C7, CX235C8, CX235-2S, CX235-2S1 **Basic UDI-DI:** 6974267891201F9	Class IIa	N/A	Certificate # DD 60151346 0001 NB #0197
Straight handpieces Model: CX235-2, CX235-2A, CX235-2B, CX235-2F, CX235-2G, CX235-2C, CX235-2S2 **Basic UDI-DI:** 6974267891202FB	Class IIa	N/A	Certificate # DD 60151346 0001 NB #0197
Air motors **Model:**	Class IIa	N/A	Certificate # DD 60151346 0001

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
CX235-3B, CX235-3F, CX235-3C **Basic UDI-DI:** 6974267891203FD			NB #0197
Dental Electrical Motors Model: C-Puma **Basic UDI-DI:** 6974267891322	Class IIa	N/A	Certificate # DD 60151346 0001 NB #0197
Endodontic Obturation System Model: C-Fill **Basic UDI-DI:** 697426789172A	Class IIa	N/A	Certificate # DD 60151346 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
2024-01-11	10923571	Initial issue

Business Stream Products
Certification Department

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Foshan COXO Medical Instrument Co., Ltd.
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Contact

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

Application for: QMS

Certificate No.	: DD 60151346 0001
Requirement	: MDD 93/42/EEC Annex V
Confirmation letter ID	: DOC_2024-01-26_ DD 60151346 0001
Report no.	: 10922746-100

Dear Madame or Sir,

Update of information to Certificate no. DD 60151346 0001, issued on 06.12.2020

The change notification received on 20.07.2023 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:	BLDG 4, District A, Guangdong New Light Source Industrial Base, South of Luocun Avenue, Nanhai District, Foshan, 528226, Guangdong, P.R. China
New Manufacturer address:	No. 17, Guangming Ave., New Light Source Industrial Base, Nanhai National High-tech Zone, Foshan 528226, Guangdong P.R. China

Best regards,

Samuel Qin
Certification body

TÜV Rheinland
LGA Products GmbH

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