EC Certificate

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

Registration No.: DD 60147804 0001

Report No.: 17057065 008

Manufacturer:

Shenzhen Denco Medical Co., Ltd.
Room 301, No. 8 1st road of Xiawei
Industrial Zone, Zhangkengjing Community
Guanhu Street, Longhua District
518110 Shenzhen
P.R. China

Products:

Dental Root Canal Instruments

Replaces Approval, Registration No.: DD 60134120 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: 2020-08-07

Date: 2020-08-07

Notified Body

Fuxiu 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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Shenzhen Denco Medical Co., Ltd.
Room 301, No. 8 1st road of Xiawei Industrial Zone,
Zhangkengjing Community, Guanhu Street, Longhua District,
518110, Shenzhen,
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Contact

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Date March 11, 2024

Notified Body Confirmation Letter
Reference. : 10924190

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 Denco Medical Co., Ltd.
Room 301, No. 8 1st road of Xiawei Industrial Zone,
Zhangkengjing Community, Guanhu Street, Longhua District,
518110, Shenzhen,
P.R. China
SRN Number (if available): CN-MF-000014271

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 Root Canal Instruments Files Basic UDI-DI: **69705149101MDA9**	Class IIa	N/A	Certificate # DD 60147804 0001 #0197
Dental Root Canal Instruments Reamers Basic UDI-DI: **69705149102SHB8**	Class IIa	N/A	Certificate # DD 60147804 0001 #0197
Dental Root Canal Instruments Barbed broaches Basic UDI-DI: **69705149106BB9V**	Class IIa	N/A	Certificate # DD 60147804 0001 #0197
Dental Root Canal Instruments Spreaders Basic UDI-DI: **69705149103SCB3**	Class IIa	N/A	Certificate # DD 60147804 0001 #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 Root Canal Instruments Pluggers Basic UDI-DI: **69705149103NCAL**	Class IIa	N/A	Certificate # DD 60147804 0001 #0197
Dental Root Canal Instruments Paste carrier Basic UDI-DI: **69705149106PCB9**	Class IIa	N/A	Certificate # DD 60147804 0001 #0197
Dental Root Canal Instruments Enlarger Basic UDI-DI: **69705149107EEAH**	Class IIa	N/A	Certificate # DD 60147804 0001 #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
2024/03/11	10924190	Initial issue