Guangzhou Fengdan Medical Equipment Co., Ltd.
No. 286 Caixin Road, Lanhe Town, Nansha District, Guangzhou City, Guangdong Province, 8620 511480, P.R. China

18th, April., 2023

Confirmation Letter Reference: CLNB1639 – CN/CAN/14864MDD

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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

Guangzhou Fengdan Medical Equipment Co., Ltd.
No. 286 Caixin Road, Lanhe Town, Nansha District, Guangzhou City, Guangdong Province, 8620 511480, P.R. China
SRN Number (if available): CN-MF-000019472

Authorized representative:
Wellkang Ltd
Enterprise Hub, NW Business Complex, 1 Beraghmore Rd.
Derry, BT48 8SE,
Northern Ireland

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 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 SGS Belgium NV 1639,

Ian How
PP
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**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
Integral Dental Units (Except for dental turbine handpiece, toothdrill and the suction head) for Dental	**Class IIa**	**N/A**	**Certificate CN19/41121; NB 1639**

Device name / Basic UDI-DI	**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
Examination, Dental Treatment and Dental Surgery (Model: QL2028IV, QL2028III, QL2028II, QL2028I, QL2028, BZ636, BZ637, BZ638, BZ639) **Basic UDI-DI: 697510373A00001UY**			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/MM/DD	Version 1	Initial issue

EC Certificate Production Quality Assurance System: Certificate CN19/41121

The management system of

Guangzhou Fengdan Medical Equipment Co., Ltd.

No. 286 Caixin Road, Lanhe Town, Nansha District, Guangzhou City, Guangdong Province, 511480, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Integral Dental Units(Except for dental turbine handpiece, toothdrill and the suction head) for Dental Examination, Dental Treatment and Dental Surgery (Model: QL2028IV, QL2028III, QL2028II, QL2028I, QL2028, BZ636, BZ637, BZ638, BZ639)

For placing on the market of Class IIb covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 16 December 2019 until 16 March 2023
And remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 16 March 2012
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN/CAN/ 14864MDD

Authorised by

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