DECLARATION

To whom It May Concern

The European Parliament And The Council Regulation (EU) 2023/607 of 15 March 2023 Amending Reulation (EU) 2017/745 And Regulation (EU) 2017/746 Concerns Transitional Provisions for Certain Medical Devices and In Vitro Diagnostic Medical Devices

Manufacturer; Sinol Dental Limited
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***MDD CE Certificate Notified Body;* TÜV SÜD Product Service GmbH**
Notified Body Number: 0123
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Tel: +49 89 50084-747
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Name and Title of Authorized; Mr. Michael Mauermeir / Application Reviewer
Mr. Wenjing Zhou / Conformity Assessment Responsible (CARE)

Products within the scope of the certificate;

Device name	**Risk class**	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification	**MDD Certificate Date of expiration**
High Speed Air Turbine Handpiece	IIa	Certificate No.: G1 099406 0008 Rev.01; NB 0123	22.01.2024
High Speed Air Turbine Handpiece			
Dental Low Speed Handpiece including Air motor, Straight and Geared Angle Handpiece			
Dental Unit With Chair			

We, Sinol Dental Limited declare,

- For the above-mentioned medical devices we produce, regulated by "; **TÜV SÜD Product Service GmbH** "; The validity period of the **"Certificate No: G1 099406 0008 Rev.01 - Full Quality Assurance System** (Assessed according to the conformity assessment procedure described in Annex II, excluding section 4, of the Council Directive 93/42/EEC on Medical Devices, as amended)" expired on **22.01.2024.** (The certificates are not suspended or has not been withdrawn.)

- Our products continue to comply with the conformity assessment procedure as defined in Annex II (excluding section 4) of the Council Directive 93/42/EEC on Medical Devices, as amended.

- The compliance / audit of the existing quality management system with the quality management system defined in Annex IX, Chapter 1, Article 10(9) of Regulation 2017/745 will be implemented before 26.05.2024.

- An official application has been made to TÜV SÜD Product Service GmbH, which is a notified Body for EC Certification in accordance with Regulation 2017/745 (MDR) and identified in NANDO with the number 0123, and a written agreement has been signed on 10.01.2024.

- Our products are in the process of transitioning to MDR according to the Notified Body Confirmation Letter reference **CL 099406 0010 Rev. 00** - attached.

- Our products are under the control and supervision of the notified body TÜV SÜD Product Service GmbH

- No significant changes have been made in the design or purpose of use of the devices in the MDD EC Certificate.

- No changes have been made in the quality system affecting production.

- The devices do not pose an unacceptable risk to the health or safety of patients, users or other persons or for other matters relevant to the protection of public health.

- There are no reports of serious incidents and field safety corrective actions identified in the post-market phase;

Date, Place: 2024-01-22, Xianyang

Authorized Name and Title: Tian Geng, General Manager

Signature / Stamp: