Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

# EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

**No. G2 095325 0009 Rev. 01**

**Manufacturer:**

**Guangdong JINME Medical Technology Co., Ltd.**
A15 Guangdong New Light Source Industrial Base
Luocun Langsha, Shishan Town
Nanhai District
528226 Foshan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):**

**Dental High Speed Turbine Handpiece,**
**Dental Low Speed Turbine Handpiece,**
**Electric Motor, Integral Dental Unit**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 095325 0009 Rev. 01

**Report No.:** SH211040EXT01

**Valid from:** 2021-03-29
**Valid until:** 2024-05-26

**Date,** 2021-03-29

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

# Declaration of Conformity
# To council Directive 93/42/EEC

**Manufacturer:** Guangdong JINME Medical Technology Co., Ltd.
Address of manufacturer: A15 Guangdong New Light Source Industrial Base, Luocun Langsha, Shishan Town, Nanhai District, 528226 Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Product: Dental High Speed turbine handpiece;
Dental Low Speed turbine handpiece;
Electric Motor

Model: T, S, M, TU, SU, MU, TP, SP, TUP, SUP, TUQ, SUQ, TUQP, SUQP, 45-T, 45-TU, 45-TUQ, TUQL, LN, L, E1, EN1 & Dr. Mayer (F111, F111 Plus, F3, F3 Plus, F4, F5, F45, F45 LED, F6, F1, F10, F15, F20, F90, Z50, F11, F12, F11 20:1, F11 1:5, F30, F22, F117, F55, F55FO, E1, EN1)
Classification: **IIa, According to MDD 93/42/EEC Annex V, Rule 9**

Conformity assessment route: **MDD 93/42/EEC, Annex V**

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC
Notified Body: TÜV SÜV Product Service GmbH,
Ridlerstraβe.65, 80339 MÜnchen, Germany

Identification number: CE **0123**
(EC) Certificate(s): G2 095325 0009 Rev. 01
Valid from: 2021-03-29
Vlad until: 2024-05-26

EC REP

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175, Fax: 0049-40-255726

Place, Date of issue: Foshan, Guangdong, People's Republic of China, 2018-11-07
Signature:

Name: Catherine
Date: 2021-03-29

Guangdong Jinme Medical Technology Co, Ltd 广东精美医疗科技有限公司

Catherine