

EC Certificate



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

Registration No.: DD 2039342-1

Manufacturer: Shenzhen Perfect Medical Instruments
Co., Ltd.
1st Floor, Building C, No.3
Jixia Zao He Keng Industrial Zone,
Nanwan Road, Longgang District,
Shenzhen
518100 Guangdong
P.R. China

Products: Orthodontic wires, Dental Root-Canal Instruments, Dental Burs, Endo
Motors

Replaces Approval, Registration No.: DD 60144004 0001

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.

Report No.: 10917853-100

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25



A blue ink signature of Shengkui Zhong.
Shengkui Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate



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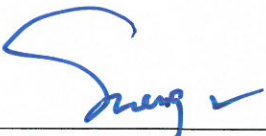

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Shenzhen
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The scope of certification includes the following manufacturing site:

No.	Location	Product groups manufactured
/01	Shanwei Perfect Medical Instruments Co., Ltd No. 29, South side of Sanhe Road, West District, Hongcaoyuan District, High-tech Zone, Shanwei, 516600 Guangdong P.R. China	Orthodontic wires, Dental Root-Canal Instruments, Dental Burs, Endo Motors

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