SHENZHEN PERFECT MEDICAL INSTRUMENTS CO., LTD
ADD: 1F, Bldg. C, No.3, Jixia Zaohekeng Industrial Zone,
Nanwan St., Longgang Dist., Shenzhen, China
TEL: +86-755-28540953
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EC Declaration of Conformity

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

EC-Representative:
SUNGO Europe B.V
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands

We, the manufacturer, herewith declare that the products

Orthodontic Wires, Dental Root-Canal Instruments, Dental Burs, Endo Motors
(including system components and accessories,)
IJMDNS-Code: **16670； 16668； 31878; 40529**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex V of the Directive 93/42/EEC.
It bears the mark CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 2017/745.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Product GmbH
Tilly street 2 90431 Nurnberg
Certificate No.: DD 2039342-1
Issue date: 2021-05-25
Expiry date: 2024-05-26

Following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

For Class Is/Im product only: Application of the above mentioned Annexes and the intervention by the Notified Body is limited to:
the aspects of manufacture concerned with securing and maintaining sterile conditions.

The above mentioned declaration of conformity is exclusively under the responsibility of
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

June.24, 2022

Place, date

Legally binding signature, Function
Tim Shi