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 004911 0001 Rev. 00

Manufacturer: **TP Orthodontic Appliance(Wuxi) Co., Ltd.**
L2, A2 Building, Liyuan Economic Zone
214072 Wuxi, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
TP Orthodontic Appliance(Wuxi) Co., Ltd.
L2, A2 Building, Liyuan Economic Zone, 214072 Wuxi, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Metal Bracket, Ceramic Bracket, Crimpable Hook and Stop**

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. See also notes overleaf.

Report No.: SH18135201

Valid from: 2018-10-25
Valid until: 2023-10-24

Date, 2018-10-25

Stefan Preiß

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

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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17