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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 074840 0012 Rev. 00

Manufacturer:

Shanghai Handy Medical Equipment Co., Ltd.
Floor 2, Building No. 11, Lane 177, Fulian Er Road
Baoshan District
201906 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shanghai Handy Medical Equipment Co., Ltd.
Floor 2, Building No. 11, Lane 177, Fulian Er Road, Baoshan District, 201906 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Digital Dental X-Ray Imaging System

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH19646EXT01

Valid from: 2019-10-30
Valid until: 2024-05-26

Date, 2019-10-30

Christoph Dicks
Head of Certification/Notified Body

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

A4 / 07.17

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

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

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