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 107765 0002 Rev. 00

Manufacturer:

Guangzhou Clean Medical Products Manufacturing Corp.
No.163 Meidu Road, Chengjiao
Conghua District
510900 Guangzhou, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Disposable Electronically Pulsed Lavage Suction Apparatus

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 107765 0002 Rev. 00

Report No.: GZ2001502

Valid from: 2021-04-26
Valid until: 2024-05-26

Date, 2021-04-26

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Iarovoi Petru
Date: 2022.10.25 14:35:58 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 107765 0001 Rev. 01

Holder of Certificate: **Guangzhou Clean Medical Products Manufacturing Corp.**
No.163 Meidu Road, Chengjiao
Conghua District
510900 Guangzhou, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Disposable Electronically Pulsed Lavage Suction Apparatus and Bone Cement Mixing System**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 107765 0001 Rev. 01

Report No.: GZ2101502

Valid from: 2022-01-01
Valid until: 2024-12-31

Date, 2021-12-02

Christoph Dicks
Head of Certification/Notified Body

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 107765 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Guangzhou Clean Medical Products Manufacturing Corp.
No.163 Meidu Road, Chengjiao, Conghua District, 510900
Guangzhou, Guangdong, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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

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