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

TÜV SÜD
Product Service

Certificate

No. Q5 072067 0012 Rev. 00

Holder of Certificate: **GUANGZHOU CLEAN MEDICAL PRODUCTS MANUFACTURING CORP.**
No.9 Guangcong Road
Conghua Development District
510990 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): GUANGZHOU CLEAN MEDICAL PRODUCTS MANUFACTURING CORP.
No.9 Guangcong Road, Conghua Development District, 510990 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

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

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). See also notes overleaf.

Report No.: GZ1801501

Valid from: 2019-04-24
Valid until: 2021-12-31

Digitally signed by Iarovoi Petru
Date: 2020.06.23 14:39:58 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2019-04-24

Stefan Preiß

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. * REPUBLICA MOLDOVA * Sogno S.R.L. IDNO 1004600013854

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

TÜV®

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

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 072067 0013 Rev. 01

Manufacturer:

GUANGZHOU CLEAN MEDICAL PRODUCTS MANUFACTURING CORP.
No.9 Guangcong Road
Conghua Development District
510990 Guangzhou
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. See also notes overleaf.

Report No.: GZ1901502

Valid from: 2020-02-12
Valid until: 2024-05-26

Date, 2020-02-12

Christoph Dicks
Head of Certification/Notified Body

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. * REPUBLICA MOLDOVA * Sogno S.R.L. IDNO 1004600013864

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

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Benannt durch/Designated by
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TÜV SÜD 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 072067 0013 Rev. 01

Facility(ies):

GUANGZHOU CLEAN MEDICAL PRODUCTS MANUFACTURING CORP.
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FIRMA DE PRODUCERE SI COMERT "SOGMO" S.R.L. * REPUBLICA MOLDOVA * IDNO 1004600013854 S.R.L. Sogmo

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