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 ŞI COMERT "SOGNO" S.R.L. REPUBLICA MOLDOVA IDNO 1004600013854 S.R.L.

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

TÜV®

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 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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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.
No.9 Guangcong Road, Conghua Development District, 510990 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

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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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CLEAN Medical Products 佳林医疗用品

Declaration of Conformity
To Council Directive 93/42/EEC Concerning Medical Devices

Manufacturer:

Name: Guangzhou Clean Medical Products Manufacturing Corp.
Address: No.9 Guangcong Road, Conghua Development District, Guangzhou, China.
Zip code: 510990

Medical Device:

Name: Disposable Electronically Pulsed Lavage Suction Apparatus
Model No.: W-203 **UMDNS code:** 12306
Classification- Annex IX: Class IIa, Rule 11 **MD code: MD1104_1, MDS7006_1**
Conformity Assessment Route: Annex V

We, Guangzhou Clean Medical Products Manufacturing Corp., herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices;
All supporting documentation is retained at the premises of the manufacturer.
The manufacturer is exclusively responsible for the Declaration of Conformity.

Standards applied:

EN 556-1:2001/AC:2006, EN 1041:2008+A1:2013, EN ISO 10993-1:2018 (ISO 10993-1:2018), EN ISO 10993-5:2009 (ISO 10993-5:2009), EN ISO 10993-7:2008/AC:2009 (ISO 10993-7:2008/Cor 1:2009), EN ISO 10993-10:2010 (ISO 10993-10:2010), EN ISO 11135:2014 (ISO 11135:2014), EN ISO 11138-1:2017 (ISO 11138-1:2017), EN ISO11138-2:2017 (ISO 11138-2:2017), EN ISO 11607-1:2019 (ISO 11607-1:2019), EN ISO 11607-2:2019 (ISO 11607-2:2019), EN ISO 11737-1:2018 (ISO 11737-1:2018), EN ISO 11737-2:2009 (ISO 11737-2:2009), EN ISO 13485:2016 (ISO 13485:2016), EN ISO 14155:2011 (ISO 14155:2011), EN ISO 14971:2012 (ISO 14971:2007), EN ISO 15223-1:2016 (ISO 15223-1:2016), EN 15986:2011, EN 60601-1:2006 /AC:2010 /A1:2013 (IEC 60601-1:2005 /A1:2012), EN 60601-1-2:2015 (IEC 60601-1-2:2014), EN 62366-1:2015 (IEC 62366-1:2015)

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstrasse 65, D-80339 München, Germany
Identification Number: 0123
(EC) Certificate(s): G2 072067 0013

EC REP **European Representative:**
Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Start of CE-marking: 2013-11-08

Place, Date of Declaration: Guangzhou, China., 2020-02-15
Signature:

2020.02.15

Name: Margin Yu（余裕富）
Position: Management Representative

FIRMA DE PRODUCERE SI COMERT SOGMO S.R.L. REPUBLICA MOLDOVA