

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



Manufacturer:

Name: Guangzhou Clean Medical Products Manufacturing Corp.
Address: No.163 Meidu Road, Chengjiao, Conghua District, Guangzhou, Guangdong, China.
Zip code: 510900
SRN: CN-MF-000008926

Medical Device:

Name: Disposable Electronically Pulsed Lavage Suction Apparatus
Model No.: W-203 **UMDNS code:** 12306
Basic UDI-DI (GS1, GMN) code: 69512337W203U1CH
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 ISO 10993-1:2009/AC:2010 (ISO 10993-1:2009/Cor 1:2010), EN ISO 10993-5:2009 (ISO 10993-5:2009), EN ISO 10993-7:2008/AC:2009 (ISO 10993-7:2008/ A1:2019), 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 ISO 11138-2:2017 (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 11737-2:2020 (ISO 11737-2:2019), EN ISO 13485:2016 (ISO 13485:2016), EN ISO 14971:2019 (ISO 14971:2019), EN ISO 15223-1:2021 (ISO 15223-1:2021), EN ISO 20417:2021 (ISO 20417:2021), 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 • 80339 Munich • Germany.

Identification Number: 0123

EC Certificate No.: G2 107765 0002, Rev.00

EC

REP

European Representative:

Name: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands.

Start of CE-marking: 2013-11-08

Place, Date of Declaration: Guangzhou, China., 2023-03-02

Signature:

Name: Margin Yu (余裕富)

Position: Management Representative