

Declaration of Conformity To Council Directive 93/42/EEC of 14 June 1993 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 and Accessories
Model No.: W-202, W-203 **UMDNS code:** 12306

Classification- Annex IX: Class IIa, Rule 11


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 of 14 June 1993 concerning medical devices;
All supporting documentation is retained at the premises of the manufacturer.

Standards applied:

EN 556-1:2001/AC:2006, EN ISO 15223-1:2012, EN 1041:2008,
EN ISO 10993-1:2009/AC:2010(ISO 10993-1:2009), EN ISO 10993-5:2009(ISO 10993-5:2009),
EN ISO 10993-7:2008/AC:2009(ISO 10993-7:2008), EN ISO 10993-10:2010(ISO 10993-10:2010),
EN ISO 11135-1:2007, EN ISO11138-1:2006, EN ISO11138-2:2009, EN ISO 11607-1:2009,
EN ISO 11607-2:2006, EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2009,
EN ISO 13485:2012/AC:2012(ISO 13485:2003), EN ISO 14155:2011, EN ISO 14971:2012,
EN 15986:2011, EN 60601-1:2006/AC:2010, EN 60601-1-2:2007/AC:2010, YZB/YUE 0683-2011

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr 65, D-80339 München, Germany

Identification Number:  0123
(EC) Certificate(s): G 2121072067007

EC REP

European Representative:

Name: Wellkang Ltd (www.CE-marking.eu)
Address: Suite B, 29 Harley Street, LONDON, W1G 9QR, U.K

Start of CE-marking: 2010-01-25

Place, Date of Declaration: Guangzhou, China., 2013-08-05

Signature:

Name: Ziyi Zhong
Position: Management Representative

