Add：C-4# Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
E-mail：Info@welllead.com.cn
Tel：+86 20 84758878
Fax：+86 20 84758224

Declaration of Conformity

MANUFACTURER:
Well Lead Medical Co., Ltd.
Address: C-4# Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China

FACILITY:
Well Lead Medical Co., Ltd.
Address: No.47 Guomao Avenue South,511434 Panyu,Guangzhou, People's Republic of China

AUTHORIZED REPRESENTATIVE:
Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestraβe 80, 20537 Hamburg, GERMANY

MEDICAL DEVICE:
Model Name: Spigots
Type or size: Universal size
Classification: I Sterile (Rule 1, Annex IX, MDD 93/42/EEC amended 2007)
UMDNS code: 15850
Conformity Assessment Procedure: Annex V

We herewith declare in our own responsibility that the above-mentioned product(s) meet(s) the provisions of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer (head of Quality department).

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC.

Applicable standard(s):
ENISO13485:2012/ENISO14971:2012/ ENISO 11135-1:2007/ EN980:2008/ ENISO15223-1:2016/ EN1041:2008/ ENISO11737-1:2006/AC:2009/ ENISO11737-2:2009/ENISO11607-1:2009/ ENISO11607-2:2006/ ENISO10993-1:2009/AC:2010/ ENISO10993-5:2009/ ISO10993-10:2010/ ENISO10993-7:2008/AC:2009/EN556-1:2001/AC:2006/ISO11138-1:2017/ENISO11138-2:2009

Notified Body: TÜV SÜD Product Service GmbH
Address: Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany
Identification No.: 0123

EC Certificate(s): G2S 17 07 38814 065
EC certificate(s) valid until: 09.24, 2022

Person keeping the technical documentation: Yolanda Guo (Quality Manager)
C-4# Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China. / 2017.09.25
(Place and date of issue of this certificate)*

广州维力医疗器械股份有限公司

Yolanda Guo
(Signature and title of authorized person)*