Declaration of Conformity

For the following products:
Disposable Nebulizer Kit, Sterile

(Product Name)

SJI;SJII;SJIII;SJI-K;SJII-K;SJIV;SJV;SJVI;SJIV-K;SJV-K;SJVII;SJVIII;SJIX;SJVII-K;SJVIII-K;SJX;
SJXI;SJXII;SJM-1;SJM-2;SJM-3;SJK;SJB.
Class: IIa

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)
Applicable harmonized standards are:
EN ISO14971:2012;EN ISO15233-1:2016;EN 1041:2008;EN ISO10993-1:2009/AC:2010;EN ISO 10993-5:2009; EN ISO 10993-7:2008/AC:2009; ISO 10993-10:2010;ISO11135-2014.EN ISO 11737 -1:2006/AC:2009;EN 62366:2008;EN ISO 11607-1:2009; EN ISO 11607-2:2006;

Conformity Assessment Route:
Annex II excluding section 4 of Medical Device Directive

Notified Body:
DNV GL Presafe AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway

IDENTIFICATION NUMBER: CE 2460

(EC) CERTIFICATE(S): 10000421974-PA-NA-CHN

The following European Authorized Representative is stated to the declaration:

Company Name: Prolinx GmbH

Company Address: Brehmstr. 56, 40239, Duesseldorf

The following manufacturer is exclusively responsible for making this declaration:

Company Name: Weihai Shengjie Medical Technology CO.,Ltd.

Company Address: *No.58-3, Chuhe South Road, High-tech Industrial Development Zone, Weihai City, Shandong Province, China*

WEIHAI SHENGJIE MEDICAL TECHNOLOGY CO., LTD 威海医疗科技有限公司

Zan Jing
(Legal Signature)

General Manager
(Position/title)

2019.8.15
(Date)