

## **EC Declaration of Conformity**

*Manufacturer:*

**JDI Electronics Factory**  
Sima Industrial Zone, Chang Ping Town,  
Dongguan, Guangdong, China  
Tel: (86) 0769 8339 2420  
Fax: (86) 0769 83972224

*whose single Authorized Representative:*

**Cepartner4U B.V.**  
ESDOORNLAAN 13, 3951 DB MAARN  
THE NETHERLANDS  
Tel: +31 343 442 524  
Fax: +31 343 442 162

We, the manufacturer, herewith declare that the product

### **Disinfecting Device for Ventilation Pipeline and Mask of Positive Airway Pressure (PAP) Respirator/System (Model:SC1200)**

GMDN-Code: 61383

Our Product Code: SC1200

meet the provisions of Directive 93/42/EEC and 2007/47/EC which apply to them.

The medical device has been assigned to class IIa according to Annex IX Rule 15 of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured under a quality management system according to Annex II of Directive 93/42/EEC excluding section 4, Electromagnetic Compatibility (EMC) Directive 2014/30/EU, Low Voltage (LVD) Directive 2014/35/E, Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU, Directive (EU) 2015/863, Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, Regulation (EC) 1907/2006 and following applicable harmonized standards:

EN ISO13485:2016, EN ISO14971:2012, EN-61010-2-040:2015, EN-61010-1:2010+A1:2017, EN 61326-1-2013, EN 1041:2008, EN 62304:2006+A1:2015, EN 61326-1-2013, EN 62366-1:2015+AC:2015, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 15223-1:2016,

MEDDEV 2.7/1 rev.4, MEDDEV 2.12-1 rev8, MEDDEV 2.12/2 rev2

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

**SGS Belgium Ltd, Notified Body 1639**

EC Certificate No.: HK19/41031

The certificate is valid from 31 October 2019 until 13 September 2023

and remains valid subject to satisfactory surveillance audits.

Issue 1.Certified Since 21 August 2014

and first Certified by SGS Belgium on 31 October 2019

Following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC excluding section 4, and Directive 2007/47/EC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.


Date that CE Marking affixed: 21<sup>st</sup> August 2014

The above mentioned declaration of conformity is exclusively under the responsibility of

**JDI Electronics Factory**  
Sima Industrial Zone, Chang Ping Town,  
Dongguan, Guangdong, China, 523570

Date of Issue: 5 March 2020

Place of Issue: Dongguan, Guangdong, China

  
2020.03.05  
Jacob Wong

Quality System and Regulatory Manager