深圳市百瑞琪医疗器械有限公司

Shenzhen Bi-Rich Medical Devices Co.,Ltd

EC Declaration of conformity

Manufacturer: Shenzhen Bi-rich Medical Devices Co.,Ltd

Address: The 1st building of No. 10, Xinqiao GangZai Road, Xinqiao Street, Bao'An District ,518125, Shenzhen City,Guangdong Province, P. R. China

European Representative: SUNGO Cert GmbH,

Add: Lindenstraße 48-52, 40233 Düsseldorf, Germany

Tel/Fax: +49 (0)211 97634133

E-mail: ec.rep@sungogroup.com

CE 1639

Product Name : Compressor Nebulizer

Model : BR-CN001 / BR-CN003 / BR-CN116 /BR-CN126/ BR-CN118/BR-CN133/BR-CN136 / BR-CN143/BR-CN151/ BR-CN152/ BR-CN161/BR-CN166/BR-CN168/BR-CN171/BR-CN176/BR-CN183/BR-CN188/BR-CN191/BR-CN195.

CE Certificate:CN19/41038.

Classification (MDD , 93/42/EEC) : Class II a

Conformity Assessment Route : Annex II excluding section 4 .

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards .All supporting documentations are retained under the premises of the manufacturer.

Directives

General applicable directives :

Medical device directive : COUNCIL DIRECTIVE 93/42/EEC as amended by 2007/47/EC and **Article 120 of Medical Device Regulation 2017/745.**

Standard applied :

The object of the declaration described above is in conformity with the relevant Community harmonization legislation , Has been assessed as

meeting the Essential Requirements and relevant provisions of EC Directive 93/42/EEC as amended by 2007/47 for Medical Devices , References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

co-ordination and international standards list

1	Council Directive 93/42/EEC	1993	concerning medical devices OJ L 169 of 12 July 1993
2	EN ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
3	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
4	EN ISO10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
5	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
6	EN ISO 10993-10	2010	Biological evaluation of medical devices. Tests for irritation and skin sensitization
7	ISO15223	2016	Medical devices-symbols to be used with medical devices labels, labeling and information to be supplied-part1:Gerneral requirements
8	EN ISO 2234	2002	Packaging - Complete, filled transport packages and unit loads - Stacking tests using a static load
9	EN22248	1993	Complete, filled transport packages — Method for determination of resistance to vertical impact by dropping
10	ISO 2859-1	1999	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
11	MEDDEV 2.12-1 rev 8	2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
12	EN 13544-1	2009	Respiratory therapy equipment - Part 1: Nebulizing systems and their components
13	EN62366-1 , EN60601-1-6:2011 + A1:2015	2015	Medical electrical -- Part 1: Application of usability engineering to medical devices
14	EN 60601-1:2006/A1:2013 IEC 60601-1:2005/A1:2012	2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

15	EN 60601-1-2 /AC:2010 , IEC60601-1-2，2014	2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
16	EN 60601-1-11	2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
17	MEDDEV.2.7.1 Rev 4_2016	2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
18	RoHs DIRECTIVE 2011/65/EU	2011	Directive 2011/65/EU of the european parliament and of the council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
19	REACH REGULATION 1907/2006	2006	Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
20	Regulation （EU） 2017/745	2017	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Notified Body : SGS Belgium NV ,Notified body 1639

Identification number：CE 1639
(EC)certificates: CN19/41038,
Expire date of the certificate:24 May,2024
Start of CE marking:14th,July,2011.
Issue1. Certified since 20 July 2011 and First certified by SGS Belgium NV since 16 December 2019
SGS House Noorderlaan 87 2030 Antwerp Belgiam
T +32(0) 3545 48 48 f +32(0)3545 48 49 www.sgs.com

Signature & Stamping :

Position : Regulation manager

Signature: Steve Liu

Place/Date:Shenzhen 2022-06-25