



深圳市百瑞琪仪器设备有限公司
Shenzhen Bi-Rich Medical Devices Co., Ltd

EC Declaration of conformity

As the manufacturer, we declare with sole responsibility that below listed product(s) comply with the basic requirements and provisions of Council Directive 93/42/EEC. The product(s) therefore fulfill all essential requirements for the application of the CE-conformity mark.

Manufacturer: Shenzhen Bi-rich Medical devices co.,Ltd

Address: No. 10th, Hongqian 2nd Road ,ShangNan, Shajing street, Bao'An district, 518125 Shenzhen City, Guangdong Province, P.R.China

European Representative: Trinium

Address : Hakakatu 16 A 1 90120 OULU FINLAND



Product Name : Compressor Nebulizer

Model Number: UN-014(UN-014A-ECxB) (identical with BR-CN116)

Brand: AND

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

Conformity Assessment Route : On medical device,Annex II excluding section 4

We herewith 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.



No.10th,Hongqian 2nd Road, ShangNan, Shajing street, Bao'An district,518125, Shenzhen City, Guangdong province, P.R. China 地址：深圳市宝安区沙井街道上南宏前二路 10 号
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Directives

Medical device directive : COUNCIL DIRECTIVE 93/42/EEC as amended by 2007/47/EC.

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 harmonized standards used or references to the specifications in relation to which

conformity is declared: EN13544-1:2007, EN980:2008, EN60601-1 :2006/AC:2010 EN60601-1-11 : 2010, EN60601-1-2:2007/AC:2010 etc.

Notified Body : SGS United Kingdom Limited

Unit 202B, Worle Parkway,

Weston-super-Mare, Somerset, BS22 6WA

Country : United Kingdom

Certificate number : CN11/30784

Issued Date: 14 November 2014

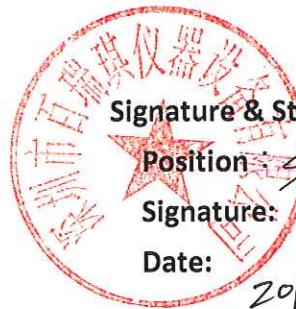
Expire date of the Certificate : 14 July 2019

Place, date of issue : Unit 202B, Worle Parkway,

Weston-super-Mare, Somerset, BS22 6WA

Country : United Kingdom

Tel: +44 0 1934 522917 Fax:+44 01934 522137 www.sgs.com



Signature & Stamping :

Position :

Signature :

Date :

Sales Manager
Richard
2017- April-13th