



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, Xinqia10 Street, Bao' An District ,518125, Shenzhen City,Guangdong Province, P. R. China SRN:CN-MF-000023061
Product Name	Phlegm suction machine
Model	BR-SM181
Intended Use	The Phlegm Suction machine is a portable, AC-powered device intended to be used to remove phlegm from a patient ' s airway. Unfit thoracic drainage and gynecological drainage.
Basic UDI	697507091SM37
Classification - Annex IX:	Class IIa
Conformity Assessment Route	Annex II excluding section 4
We, the manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; including, at 21 March 2010, the amendments by Council Directive 2007/47/EEC, and Article 120 of Medical Device Regulation 2017/745. All supporting documentation is retained at the premises of the manufacturer ShenZhen Bi-rich Medical Devices Co., Ltd. is exclusively responsible for this EC Declaration of Conformity.	
Notified Body:	SGS Belgium NV,Notified Body 1639
Identification Number	1639
(EC) Certificate(s):	CN19/41038
European Representative:	SUNGO Europe B.V. Add: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands E-mail: ec.rep@sungogroup.com SRN:NL-AR-000000247
Applied Standard & Common Specification	EN ISO 13485:2016, EN ISO 15223 -1:2020, EN 1041:2008+ A1:2013, EN ISO 14971: 2012, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-11:2015, EN 60601-1-6:2010 +A1:2015, EN 62366-1:2015 ,ISO10079-1 etc.
Date of declaration	Shenzhen 2024-09-20
Signature: 	Name: Steve liu Position: Regulation Manager

