



# 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<br>Address: The 1st building of No. 10, Xinqiao GangZai Road, Xinqiao10 Street, Bao'An District ,518125, Shenzhen City,Guangdong Province, P. R. China |
| Product Category                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Sleep Apnoea Breathing Therapy Equipment                                                                                                                                                         |
| Product Model                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | BR-25ST,BR-25S,BR-25A,BR-25C,BR-20ST,BR-20S, BR-20A,BR-20C.                                                                                                                                      |
| Classification - Annex IX                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Class IIa, Rule 11                                                                                                                                                                               |
| Conformity Assessment Route                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Annex II excluding section 4                                                                                                                                                                     |
| <p>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.</p> <p>All supporting documentation is retained at the premises of the manufacturer<br/>ShenZhen Bi-rich Medical Devices Co., Ltd. is exclusively responsible for this EC Declaration of Conformity.</p> |                                                                                                                                                                                                  |
| Notified Body:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | SGS Belgium NV,Notified Body 1639                                                                                                                                                                |
| Identification Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 1639                                                                                                                                                                                             |
| (EC) Certificate(s):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | CN19/41038                                                                                                                                                                                       |
| European Representative:                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | SUNGO Cert GmbH,<br>Add: Lindenstraße 48-52, 40233 Düsseldorf, Germany<br>Tel /Fax: +49 (0)211 97634133<br>E-mail: ec.rep@sungogroup.com                                                         |
| Date of declaration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Shenzhen 2022-09-14                                                                                                                                                                              |
| Signature:                                                                                                                                                                                                                                                                                                                                                                                                        | Name: Steve liu Position: Regulation Manager                                                                                                                                                     |

