

EC Certificate Full Quality Assurance System: Certificate CN19/41038

The management system of

SHENZHEN BI-RICH MEDICAL DEVICES CO. LIMITED

The 1st Building of No. 10, Xinqiao Gangzai Road, Xinqiao Street,
Bao'An District, Shenzhen City, Guangdong Province, 518125, P.R. China
has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

**Compressor Nebulizer for use on conscious patients with tracheitis,
bronchitis and lung disease (Model : BR-CN001, BR-CN003, BR-CN116,
BR-CN118, BR-CN126, BR-CN136, BR-CN133, BR-CN143, BR-CN151,
BR-CN152, BR-CN161, BR-CN166, BR-CN168, BR-CN171, BR-CN176,
BR-CN183, BR- CN188, BR-CN191, BR-CN195)
Phlegm Suction machine (Model:BR-SM153, BR-SM181)
Mesh Ultrasonic Nebulizer (BR-MN199)
Sleep Apnoea Breathing Therapy Equipment (Model:BR-20C, BR-20A,
BR-20S, BR-20ST, BR-25C, BR-25A, BR-25S, BR-25ST)**

Where the above scope includes class III medical device(s), a valid EC Design Examination
Certificate according to Annex II (Section 4) is a mandatory requirement for each device in
addition to this certificate to place that device on the market.

This certificate is valid from 11 May 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 14 July 2011.

Certification is based on reports numbered CN/SZX 13714

Authorised by



Global Medical Devices Head of Notified Body

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