

Certificate of Compliance



Confirms that the Class 1 complies according to the directive Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-10202

Manufacturer

Name : RECKON BIRETTA PRIVATE LIMITED

Address : C-47, Sector -63, Noida, Noida GB Nagar, Gautam Buddha Nagar, Uttar Pradesh – 201301, India

Product Name : Medical Equipment- Ventilator Circuits, HME Filters, CCV, face Mask- NIV, Anti Viral, Surgical, Pollution, PPE Kits, Connectors, Elbows and Other Devices

The manufacturer's technical documentation as required for Medical Council according to the directive 93/42/EEC has been reviewed and found to comply with the requirements for Class I Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC. Any significant changes in the design or construction of the product, not agreed upon by us, this declaration will lose its validity.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	09th April 2020
1st Surveillance Audit Due	08th April 2021
2nd Surveillance Audit Due	08th April 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	08th April 2023



Authorised Signatory

