

Certificate of Compliance



We hereby declare that the technical files of all the items in each product group of complied with the requirements of the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-3339

Manufacturer

Name : SKY MEDICAL

Address : 139 SARPAT PALLY JAISHREE BANSDRONI NEAR JAISHREE KALIBARI, KOLKATTA WEST BENGAL - 700070, INDIA

Product : VENTILATOR BREATHING CIRCUIT, BAIN CIRCUIT, AIRWAY MANagements PRODUCTS, BREATHING FILTERS, BIPAP/CPAP FULL FACE MASK (VENTED/NIV), BIPAP/CPAP TUBING, CPAP NASAL MASK, OXYGEN & AEROSOL MASK, SPO2 PROBE, ECG CABLE & ACCESSORIES, NIBP CUFF AND ACCESSORIES, MULTIPARAMETER MONITOR, RADIANT WARMER TEMPERATURE PROBE, ESU ACCESSORIES, NEBULIZER, DIGITAL BP MACHINE, INFRARED THERMOMETER, FINGERTIP PULSE OXIMETER, HFNC CANNULA, HFNC CANNULA SET, OTHER CRITICAL CARE ACCESSORIES & ANESTHESIA ACCESSORIES.

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

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 21st July 2022

1st Surveillance Audit Due 20th July 2023

2nd Surveillance Audit Due 20th July 2024

Certificate Expiry (subject to the company maintaining its system to the required standard) 20th July 2025

Daniel..



Authorised Signatory

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851