

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-3375

Manufacturer

Name : OMEX MEDICAL TECHNOLOGY

Address : Plot No. 1, Shivalik Industrial Park, Near Mehsana Highway,
At- Kotadi, Ta-Vijapur, Dist-Mehsana, India

Products : UROLOGY, INFUSION & TRANSFUSION THERAPY, GASTROENTEROLOGY, ANESTHESIA CARE PRODUCTS, SURGERY, ORTHOPEDIC, BODY BELTS & BRACES, AND MISCELLANEOUS, RANGE SURGICAL HAND GLOVES, SURGICAL GOWN, AND COVERALL SUIT, PPE KIT, HIV KIT, DELIVERY KIT, NEBULIZER KIT, CAP, NRB MASK, OXYGEN MASK AND ALL TYPE MASK

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system 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.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the referenced models.
5. 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.co.uk/verify

Date of initial registration	06 th July 2021
Date of this Certificate	06 th July 2021
Certificate Expiry	05 th July 2024
Recertification Due (subject to the company maintaining its system to the required standard)	05 th July 2024

Daniel..

Authorised Signatory

