

Certificate of Compliance



We hereby declare that the technical file of product confirms with the requirement of Protective Equipment 89/686/EEC as Amended Regulation (EU) 2016/425 & Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-4606

Manufacturer

Name : SK IMPEX

Address : A-1, 3rd Floor, Sardar Mall, Nr. IDBI Bank, Nikol Gam Road, Ahmedabad-382350, Gujarat, India

Product Name : N 95 Folding Mask, 3 Ply Mask, Anti Bacterial Sleeves and Socks, Surgeon and Bouffant Cap, Surgical Face and Cup Mask, Non Woven Fabric Surgical Items, Hosiery Items and Socks, Textile Garments, Plastic and Metal Nose Wire for Mask, Elastic for All Type of Face Mask, Plastic Shoes Cover, Shoes Cover Dispensers, Dust Mask, Apron and Gloves, Beared Mask, Textile Machinery, Medical Pharma Machinery, Hand Gloves From Cotton Hosiery, Safety Goggles, PPE KIT (Personal Protective Equipment)

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 of Protective Equipment 89/686/EEC as Amended Regulation (EU) 2016/425 & 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.

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

Date of Certification	13 th May 2020
1 st Surveillance Audit Due	12 th May 2021
2 nd Surveillance Audit Due	12 th May 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	12 th May 2023

Daniel..

Authorised Signatory

