

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-11887

Manufacturer

Name : DZIRE SURGICAL INDIA PVT. LTD.

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FACTORY ADDRESS: - 251, 252-KRISHNA INDUSTRIAL
ESTATE, NEAR ANJANI INDUSTRIES, GOTHAN SAYAN
ROAD, SURAT - 394130 GUJARAT, INDIA

Product Name : GAMJEE ROLL, SOFTROLL, CREPE BANDAGES, ELASTIC ADHESIVE
PLAST, CANNULA FIXATOR, GAUZE CLOTH, GAUZE SWAB, COMBINE DRESSING, EYE PAD,
UNDERPAD, SURGEON GOWN, APRON, BIO WASTE CARRY BAG, ALL TYPES OF EXAMINATION &
SURGICAL GLOVES (LATEX / NITRILE / PLASTIC / VINYL), FACEMASK (1PLY, 2PLY, 3PLY, 4PLY,
5PLY), N95, KN95, SURGEON CAP, BOUFFANT CAP, SHOE COVER, SAFETY GOGGLES, ALL TYPES
OF KITS (HIV PROTECTION/ DELIVERY/ BABY/ PPE/ OT/ SURGICAL), SURGICAL DRAPES,
PARAFFIN GAUZE, POST MORTEM COVER, ABSORBENT COTTON, MICROPOROUS PAPER TAPE,
ADHESIVE TAPES, SURGICAL (NON WOVEN / COTTON / GAUZE) PRODUCTS, GAUZE BANDAGES,
MEDICAL PLASTIC PRODUCTS, FACESHIELD, ALLIED PRODUCTS & SURGICAL BLADE

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.

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	21 st December 2020
1 st Surveillance Audit Due	20 th December 2021
2 nd Surveillance Audit Due	20 th December 2022
Certification Expiry (subject to the company maintaining its system to the required standard)	20 th December 2023

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

