

CERTIFICATE



CERTIFICATE OF COMPLIANCE

CE DECLARATION OF CONFORMITY

Certificate No:- QACS-CE-PE-923

M/S.PREMIER ENTERPRISES

REGISTERED OFFICE: S.F.NO.39/2, SOUTH STREET, SANKARAPANDIAPURAM,
CHATRAPATTI – 626102, TAMIL NADU, INDIA

WORKS: S.F.NO.30, SRIVILLIPUTTUR ROAD, SANKARAPANDIAPURAM,
CHATRAPATTI – 626 102, TAMIL NADU, INDIA

That the following described product in our delivered version complies with the applicable basic safety and health requirements of the Medical Devices Directive 93/42/EEC ("MDD") as amended as Medical Device Regulation (EU) 2017/745 based on its design and type, as brought into circulation by us. In case of alteration of the product not agreed upon by us, this declaration will lose its validity

This is to certify that the technical documentation for the -

PRODUCT:-

STERILE GAUZE SWAB PLAIN, STERILE LAP SPONGE WITH LOOP, STERILE OPEN WOVE BANDAGE, STERILE CUT GAUZE, STERILE GAMJEE PAD, STERILE DRESSING KIT, STERILE X-RAYDETECTABLE GAUZE SWABS, STERILE X-RAYDETECTBALE LAPAROTOMY SPONGES, STERILE DIALYSIS KIT, STERILE ABSORBENT COTTON GAUZE, STERILE COMBINED DRESSING PAD (CURE PAD), STERILE GAUZE BALL, STERILE X-RAYDETECTABLE GAUZE BALL, STERILE X-RAY DETECTABLE ABSORBENT COTTON RIBBON GAUZE, STERILE ABSORBENT COTTON RIBBON GAUZE

The manufacturer's technical documentation, as required for class 1s devices, has been reviewed and found to comply with the requirements in Annexure IX

Certificate Issue Date: 25-11-2020

Certificate Expiry Date: 26-11-2023

Revision Date: 03-06-2022

- This certificate is issued under the following conditions:-*
1. It applies only to the quality system maintained in the trading of above referenced products and it does not substitute
 2. The design or type examination procedure, if requested.
 3. The certificate remains valid until the trading conditions or the quality systems are changed.
 4. The certificate validity is conditioned by positive results or surveillance audits.
 5. After fulfilling the relevant EU legislation, the trader shall affix to each product, of the referenced products. the CE mark as shown above can be used, under the responsibility of the trader, after completion of an EC declaration of conformity and compliance with all relevant EC directives. The statement is based on a single evaluation of the sample of above mentioned product. It does not imply an assessment of the whole trading facility.

Authorised Signatory

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