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CERTIFICATE

CE

CERTIFICATE OF COMPLIANCE

CE DECLARATION OF CONFORMITY

Certificate No:- QACS-CE-PE-937

M/S. PREMIER ENTERPRISES

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

UNIT-A: DOOR NO.135A/9, 135B/9, 136B/9 & 140/9, SOUTH STREET, SANKARAPANDIAPURAM, CHATRAPATTI-626102, TAMIL NADU, INDIA

UNIT-B: S.F.No.30, DOOR NO.532B,532C,532B, 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:-

GAUZE SWABS, X-RAY DETECTABLE GAUZE SWABS, ABDOMINAL PAD (LAP SPONGES), X-RAY DETACTABLE ABDOMINAL PAD (LAPAROTOMY SPONGES), CUT GAUZE, GAUZE BALL, OPEN WEAVE BANDAGE (ROLLER BANDAGE), ABSORBENT COTTON RIBBON GAUZE (NASAL PACK), X-RAY DETECTABLE RIBBON GAUZE (X-RAY DETECTABLE NASAL PACK), ABSORBENT COTTON GAUZE ROLL, ABSORBENT COTTON GAUZE (NEURO GAUZE), COTTON BALL (ABSORBENT COTTON), DRESSING KIT, DIALYSIS KIT & POST SURGERY DRESSING PAD (COMBINE DRESSING PAD)

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

Certificate Issue Date:- 02-04-2022
Certificate Expiry Date:- 01-04-2025

This certificate is issued under the following conditions:-

1. ***İt 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 decleration of confirmity and compliane with all relevant EC directives. The statement is based on a single evaluation of the sample of above mentioned product. İt does not imply an assessment of the whole trading facility.***

Authorised Signatory

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