

CERTIFICATE OF COMPLIANCE

No: CE -1801

Certificate
Holder

PREMIER ENTERPRISES

Registered office: 39/2, South Street, Sankarapandiapuram,
Chatrapatti – 626 102, Tamil Nadu, India.

Factory: SF/30, Srivilliputhur Road, Sankarapandiapuram,
Chatrapatti – 626 102, Tamil Nadu, India.

Product(s)

Gauze Swabs with X-ray thread
Lap Sponges with X-ray thread
Nasal Pack with X-ray thread
Neuro Gauze
Cotton Balls
Dressing Kit
Dialysis Kit

Brand Name

PREMIER

Verification to:

Standard:

EN ISO 13485:2016, EN 14079:2003, ISO 14971:2019,
EN ISO 15223-1:2016, EN 1041:2008, ISO 10993-1:2018,
ISO 10993-4:2017, ISO 10993-5:2009, ISO 10993-10:2010,
ISO 11737-1:2018, ISO 14644-1:2015, ISO 14644-2:2015,
ISO 14644-3:2019

Related to Directive:

93/42/EEC + 2007/47/EC (Medical Devices)

Class I (rule 4)

As per Annex VII

Issue date: 11 MARCH 2021

Expiry date: 10 MARCH 2022

Remark: Based on the successful review of technical construction file documentation of the above mentioned products, UCAS confirms manufacturer ability to keep permanently the required safety and quality level. The manufacturer is obligated to assure that all medical devices of the respective models conform to the type approved by this certificate. The certificate remains valid until the manufacturing conditions and quality system as per the technical documentation are maintained or relevant legislation are changed. The product liability rests with the manufacturer or his representative in accordance with applicable Directive and Standard, after fulfilling the relevant EU legislation requirements, the manufacturer shall affix CE mark to each medical device of the above reference models.



Authorised Signatory

UNIVERSAL CERTIFICATION ASSESSMENT SERVICES

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