



Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirement of Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-32209

Manufacturer

Name : HEMANT SURGICAL INDUSTRIES LIMITED

Address : Regd Office:- 502, 6th Floor, Ecstasy, City of Joy Commercial Complex,
JSD Road, Mulund West Mumbai-400080, Maharashtra, India
Factory:- Plot No. 19/1. 187/1/1, Opposite at Gaon Station, At gaon (East)
Taluka Shahpur, Thane, India

Products : As per appendix page-I

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

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	06 th March 2020
1 st Surveillance Audit Due	05 th March 2021
2 nd Surveillance Audit Due	05 th March 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	05 th March 2023



Authorised Signatory



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Certificate of Compliance

Appendix-I

Appendix to Certificate no.:- CE-32209

Manufacturer :

Hemant Surgical Industries Limited

Address:

Regd Office:- 502, 6th Floor, Ecstasy, City of Joy Commercial Complex, JSD Road, Mulund West Mumbai-400080, Maharashtra, India

Factory:- Plot No. 19/1, 187/1/1, Opposite At Gaon Station, At gaon (East) Taluka Shahpur, Thane, India



This certificate referred to above covers the following products like:

Products:-

- **AERO:** PREVENTIVE PROTECTION EQUIPMENT (PPE KIT), PREVENTIVE FACE SHIELD, 3 PLY FACE MASK, PISTON NEBULIZER (REGULAR), PISTON NEBULIZER (COMFORT), MESH NEBULIZER (AIR PRO), ANTI DECUBITUS MATTRESS, PULSE OXIMETER, DIGITAL THERMOMETER, SKIN STAPLER, ECG ELECTRODE, OXYGEN CONCENTRATOR, BLOOD LINE TUBING, A.V. FISTULA, TRANSDUCER PROTECTOR, INFUSION SET, ON AND OFF KIT, PATIENT MONITOR, FETAL DOPPLER, INFUSION PUMP, SYRINGE PUMP, ECG MACHINE, IV CANNULA, 3 WAY STOP COCK, BLOOD PRESSURE MONITOR, INFRARED THERMOMETER.
- **HEMANT SURGICAL:** REFURBISHED 4008S DIALYSIS MACHINE, REFURBISHED 4008H DIALYSIS MACHINE, REFURBISHED DIALOG+ DIALYSIS MACHINE, STAINLESS STEEL RO PLANT, PVC RO PLANT, DIALYSIS BICARB MIXTURE, DIALYZER CLEANING MACHINE, STABILIZER (3KVA), DIALYSIS FLUID (ACIDIC), DIALYSIS POWDER (ACIDIC), DIALYSIS POWDER (BICARB)
- **CITRO-H:** HOT STERILANT
- **COMFORT:** DIALYSIS CHAIR
- **DIACLEAN:** COLD STERILANT
- **ECOSIL:** SILICONE FOLEY CATHETER
- **FATHER:** SKIN GRAFTING BLADE
- **FEROBEST:** IRON SUCROSE INJECTION
- **SWS:** SWS 4000A DIALYSIS MACHINE
- **JMS:** ADHESIVE SURGICAL MICROPOROUS TAPE, BLOOD TRANSFUSION SET, SCALP VEIN SET, INFUSION SET, PEDIATRIC INFUSION SET, BURETTE SET.
- **JOYLIFE:** MESH NEBULIZER (AIR ANGEL)
- **SAFECATH:** SILICONE FOLEY CATHETER, DOUBLE LUMEN CATHETER
- **SEPTICLEAN:** HAND SANITIZER

Authorised Signatory



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