



Certificate of Compliance



Confirms that the products of class I according to the Medical Council Directive 93/42/EEC of June 1993.

Certificate No.: CE-2135

Manufacturer

Name : DR. SURGICAL

H.OFFICE : B -8 & 9, ADITYA COMMERCIAL COMPLEX, NANGAL RAYA, NEW DELHI-110046, INDIA

WORKS : J-1023 & 1024, I.I.D. KHUSHKHERA INDUSTRIAL AREA, BHIWADI, ALWAR, RAJASTHAN-301707, INDIA.

Products : AS PER APPENDIX-I, II & III

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 the medical Council directive 93/42/EEC of June 1993.

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.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the referenced models.
5. 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.nficertification.co.uk/Validity

Date of Initial registration

11th January 2021

Date of this certification

11th January 2021

Certificate Expiry

08th January 2022

Recertification Due (subject to the company maintaining its system to the required standard)

08th January 2023

Authorised Signatory



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Appendix-I

Appendix to Certificate no.: CE-2135

Manufacturer Name : DR.SURGICAL

H.OFFICE :- B -8 & 9, ADITYA COMMERCIAL COMPLEX, NANGAL RAYA,
NEW DELHI-110046, INDIA.

WORK UNIT:- J-1023 & 1024,I.I.D. KHUSHKHERA INDUSTRIAL AREA, BHIWADI,
ALWAR, RAJASTHAN-301707, INDIA.

CE

This certificate referred to above covers the following products like:

Products :- **MEDICAL DISPOSABLE DEVICES.**

- HIGH PRESSURE STOP COCK/ THREE WAY STOP COCK
- HIGH PRESSURE MANIFOLD
- ANGIO RADIAL BAND
- HEMOSTASIS Y-ADAPTOR & CATH LAB KIT ACCESSORY
- GUIDING CATHETER/ DIAGNOSTIC CATHETER
- HYDROPHILIC COATED GUIDE WIRE
- CONTROL SYRINGE/ COLOURED SYRINGE
- P.T.C.A.KIT/ ANGIO KIT/ CATH LAB KIT & ACCESSORIES
- INTRODUCER SHEATH RADIAL/ FEMORAL/ PEELWAY SHEATH
- TEMPORARY PACING LEADS/ BALOON TIP
- INFLATION DEVICE
- ANGIOGRAPHIC/ INTRODUCER NEEDLE
- HIGH PRESSURE LINE
- FEMORAL ANGIO BAND
- HEART STABILIZER
- VENOUS CANNULA PLASTIC TIP & METAL TIP
- CARDIOPLEGIO SYSTEM WITH TUBING
- MIST BLOWER
- HEMO CONCENTRATORS WITH TUBING
- CHEST DRAINAGE CATHETER/ TROCAR
- THERMODILUTION CATHETER/FLEX SHEATH
- PRESSURE MONITORING LINE
- EXTENSION LINE WITH 3 WAY STOP COCK
- CENTRAL VENOUS CATHETER
- ARTERIAL CANNULA PLASTIC TIP & METAL TIP
- VESSEL CANNULA



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Appendix-II

Appendix to Certificate no : CE-2135

Manufacturer Name : DR.SURGICAL

H.OFFICE :- B -8 & 9, ADITYA COMMERCIAL COMPLEX, NANGAL RAYA, NEW DELHI-110046, INDIA.

WORK UNIT:- J-1023 & 1024,I.I.D. KHUSHKHERA INDUSTRIAL AREA, BHIWADI, ALWAR, RAJASTHAN-301707, INDIA



This certificate referred to above covers the following products like:

Products :- MEDICAL DISPOSABLE DEVICES.

- HEART ASPIRATOR & SUCKER
- CUSTOM PACK AND ACCESSORIES
- PRE BY PASS FILTER
- CORONARY ARTERY OSTIAL CANNULA
- AROTIC ROOT CANNULA & CARDIOPLEGIA CANNULA
- ARTERIAL FILTER
- DOUBLE LUMEN LEFT HEART CATHETER
- STRAIGHT CONNECTOR
- Y-CONNECTOR
- EMBOLECTOMY CATHETER
- DIALYSIS CATHETER
- ASPIRATION CATHETER
- BALLOON DILATATION CATHETER
- GUIDE EXTENSION CATHETER
- MICRO CATHETER
- DISPOSABLE CORONARY SHUNT
- DISPOSABLE PRESSURE MONITORING KIT
- CLOSED SUCTION CATHETER
- FISTULA NEEDLE
- BLOOD TUBING
- FLOW REGULATOR
- RF NEEDLE/CANNULA
- KYPHOPLASTY & VERBTROPLASTY KIT
- BONE MARROW BIOPSY NEEDLE
- ONCO CARE KIT
- ONE WAY CHECK VALVE/RELEASE VALVE
- PPE KIT
- 3 PLY FACE MASK
- N95 FACE MASK

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Appendix-III

Appendix to Certificate no : CE-2135

Manufacturer Name : DR.SURGICAL

H.OFFICE :- B -8 & 9, ADITYA COMMERCIAL COMPLEX, NANGAL RAYA, NEW DELHI-110046, INDIA.

WORK UNIT:- J-1023 & 1024,I.I.D. KHUSHKHERA INDUSTRIAL AREA, BHIWADI, ALWAR, RAJASTHAN-301707, INDIA



This certificate referred to above covers the following products like:
Products: - MEDICAL DISPOSABLE DEVICES.

- LEFT HEART CATHETER (VENT LINE)
- PAEDIATRIC ONE PIECE ARTERIAL CANNULA
- SUMP
- TUBING ORGANIZER
- TOURNIQUET & SNUGGER SET
- CARDIOPLEGIA ADAPTER
- ISOLATOR
- EPIDURAL ANESTHESIA SET
- FEMORAL CATHETER
- TRANSDUCER PROTECTOR
- YANKUR SUCTION SET
- COMPONENTS
- PTCA CARRY WIRE
- PTCA BALLOON WINNER WIRE
- GUIDE WIRE PTFE COATED & SS
- CHEST DRAINAGE CATHETER
- VENOUS CANNULA TWO STAGE & THREE STAGE

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