

COMPLIANCE CERTIFICATE

We certify that the Technical Documentation of the below mentioned products (Surgical Instruments & Medical Devices Directive 2007/47/EC) According to the Council Directive 93/42/EEC as amended (2007/47/EC).

VAISHALI PHARMA PVT. LTD.

706 - 709 , 7TH FLOOR, ARAVALI BUSINESS CENTRE , R.C.PATEL ROAD , OFF. SODAWALA LANE , BORIVALI (W) , MUMBAI - 400 092 , INDIA

has been assessed and conforms to:



Applicable to products : As Pre Annexure 1st

Complies with the applicable requirements of the Directive 93/42/EEC as amended (2007/47/EC)

Referring to the intended use, the Certification body has conducted with successful results the review of the Manufacturer's Technical documentation of the certified product according to the above mentioned Directive and appropriate Harmonized European Standards.

This Certificate is issued under the following conditions:-

- ❖ The Manufacturer's Technical Documentation, as required for Surgical Instruments & Medical Devices 2007/42/EC, has been reviewed & found to comply with the requirements in Annexure IX, Section 3.
- ❖ It applies only to the above mentioned Surgical Instruments & Medical Devices.
- ❖ The Manufacturer is obligated to assure conformity of all the Surgical Instruments & Medical Devices of the respective model to the type assessed by the mean of this certificate.
- ❖ Any significant changes in the design or process use to manufacture the product or revision to the directive or standards referred above may require special audit.

Certificate Number : CE-16-3052

Original Certification Date : 22/03/2016 1st Surveillance Due on : 20/03/2017

Certificate Expiration Date : 21/03/2019 2nd Surveillance Due on: 18/03/2018



Deutsche Accreditation Board

Otto-Hahn-Ring 6, D-81739 Muenchen, Germany

E-mail: info@dabaccreditation.com Website : www.dabaccreditation.com


Certification Manager

The validity of this certificate is contingent upon the condition that the client has understood & shall abide by contract agreement, certification agreement for certification services and logo rules as given on our website www.dabaccreditation.com. The client is request to check the above certificate details at our above mentioned website and also on www.dabaccreditation.com under the heading of Register & Sub heading of certified organization by entering their certificate number and inform us in case of any discrepancy at our above email id

VAISHALI PHARMA PVT. LTD.

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Scope as per CE Annexure:-

Annexure 1st

- **SURGICAL GLOVES (STERILE & NON STERILE)**
- **EXAMINATION GLOVES**
- **INFUSION SET (WITH & WITHOUT AIR VENT)**
- **BLOOD TRANSFUSION SET (WITH & WITHOUT AIR VENT)**
- **I V CANNULA**
- **SCALP VAIN SET**
- **GAUZE SWAB & GAUZE ROLL**
- **ABSORBENT COTTON ROLL (100 GRM , 200 GRM , 250 GRM , 500 GRM)**
- **FOLLEY BALLOON CATHETER**
- **DISPOSABLE SYRINGES (2ML, 5ML ,10ML)**
- **DISPOSABLE OXYGEN MASK**
- **SUCTION CATHETERS**
- **FEEDING TUBE**
- **RYLES TUBE**
- **URINE BAG**
- **DISPOSABLE CAP MASK**
- **DISPOSABLE H.I.V. KITS**
- **DISPOSABLE DELIVERY KIT**
- **DISPOSABLE CAESAREAN KIT**
- **DISPOSABLE TOTAL KNEE REPLACEMENT KIT**
- **DISPOSABLE OPERATION THEATER KIT**
- **DISPOSABLE OPERATION THEATER GOWN**