



# Certificate of Compliance

This is to certify that

## WIRKSAM PHARMA PRIVATE LIMITED

H-519A, RIICO INDUSTRIES AREA JOTHWARA EXTN. II,  
SARNA DUNGER, JAIPUR -302012, RAJASTHAN, INDIA.

has been assessed and Certified by KBN Certification System

### CE Mark

For the following scope of activities:

PRODUCTS: INFUSION SET (NON VENTED INFUSION SET , VENTED INFUSION SET , MICRO DRIP INFUSION SET , INFUSION SET WITH Y CONNECTOR & LUER LOCK), MEASURED VOLUME INFUSION SET, BLOOD TRANSFUSION SET , RYLE'S TUBE , INFANT FEEDING TUBE, SUCTION CATHETER , URETHRAL CATHETER ( K-90/K-91), UMBILICAL CORD CLAMP, SCALP VEIN SET, IV CANULLA, IV CANULLA FIXATOR, MUCUS EXTRACTOR, FOLEY BALLON CATHETER, URINE BAGS, URINE CULTURE BOTTLE, NEBULIZER MASK KIT , OXYGEN MASK KIT , GUEDEL AIRWAYS, VENTRI CIRCUIT (PLAIN/SWT/DWT) , CATHETER MOUNT , HME FILTER, BVF FILTER, SURGICAL GLOVES (STERILE/NON STERILE) , EXAMINATION GLOVES (STERILE/NON STERILE) AND MORE DRUG /NON DRUG DISPOSABLE SURGICAL PRODUCTS ) MEDICAL DEVICES ( STRILE /NON STERILE )

The Certification body has performed a Technical File Review of the above product Technical file covering the design, manufacturer and final inspection of the certified products. The technical File has been assessed approved and is subject to continuous surveillance according to Directive Medical Device products Directive : EU 93/42/EEC, 93/68/EEC, 98/79/EC

This Certificate issued the following conditions:

1. It apply to the technical file maintained in the manufacturer of the about referenced models and it does not substitute the design or type examination procedures, if requested
2. The certificate remain valid until the manufacturing condition or the technical file are changed.
3. The certificate validity is conditioned by positive result or surveillance audit.
4. After fulfilling the relevent EU legislation of Directive the manufacturer shall affix to each device of the referenced work.
5. The CE mark as shown above can be used, under the responsibility of the manufacturer after the completion of an EU declaration of conformity and compliance with all relevent EC Directives in product. The statement is based on a single evaluation of one sample of above mentioned products. It dose not simply assessment of the whole production.

Date of Registration : 02/03/2019  
Re Certification Date : 01/03/2022

1st Surveillance Date : 01/03/2020  
2nd Surveillance Date : 01/03/2021

**Certificate No :- 1805020319**

To Verify this certificate please visit at [www.kbncertification.com](http://www.kbncertification.com)



  
Authorised Signatory



**KBN Certification System**

Validity of this Certificate is Subject to annual Surveillance audits done successfully  
5 JUPITER HOUSE, CALLEVA PARK, ALDERMASTON, READING BERKSHIRE RG7  
8NN. UK Email:- [info@kbncertification.com](mailto:info@kbncertification.com) Website:- [www.kbncertification.com](http://www.kbncertification.com)