



Certificate of compliance

This is to certify that

PRIME HEALTHCARE PRODUCTS PRIVATE LIMITED

PLOT NO. - 111 & 112, SECTOR-53, PH-V, HSIIDC INDUSTRIAL AREA
KUNDLI, SONIPAT - 131028 HARYANA (INDIA)

has been assessed and Certified by KBN Certification System

CE MARK

For the following scope of activities:

PRODUCTS:- DISPOSABLE STERILE SINGLE USE MEDICAL DEVICES VIZ. I.V. CANNULA, SAFETY I.V. CANNULA, 3-WAY STOP COCK, 3-WAY STOP COCK WITH EXTENSION TUBE, EXTENSION TUBE, INFUSION SET, BLOOD TRANSFUSION SET AND M.V. SET.

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.

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 relevant 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 relevant EC Directives in product. The statement is based on a single evaluation of one sample of above mentioned products. It dose not imply assessment of the whole production.

Date of Registration: 29/09/2021 1st Surveillance Date : 28/09/2022
Re-Certification Due : 28/09/2024 2nd Surveillance Date : 28/09/2023

Certificate No:- 2611301021

To Verify this certificate please visit at www.kbncertification.com



Authorised Signatory

KBN Certification System



Validity of this Certificate is Subject to annual Surveillance audits done successfully

this certificate of Registration remains the property of KBN Certification System and shall be returned immediately Upon request

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Uttam Nagar, New Delhi - 110059 (INDIA).

Address:- 305, High Street, Purley, London, United Kingdom.

Email:- info@kbncertification.com Website:- www.kbncertification.com