

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-5043

Manufacturer

Name : **Sanmed Healthcare Pvt. Ltd.**

Address : **Plot No 56, TSIIC, Biotech Park, Phase III, Karakapatla Village Murkuk Mandal, Siddipet District, 502279 Telangana, India.**

Products : **XEPI RUB M, XEPI RUB CET, XEPI RUB ET, SANMEDIN 5 %, SANMEDIN 10%, XEPI SCRUB PVP 7.5 %, XEPI SCRUB CHG 4%, SANMETOL & SODIUM HYPOCHLORITE**

Applicable Standard : **EN 1276 & EN 14476**

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.
4. After fulfilling the relevant Standard testing performance, the manufacturer shall affix to each device, of the referenced models.

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	15 th September 2020
1 st Surveillance Audit Due	14 th September 2022
2 nd Surveillance Audit Due	14 th September 2023
Certificate Expiry (subject to the company maintaining its system to the required standard)	14 th September 2023

Daniel..



Authorised Signatory