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-4369

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, XEPI GEL 70E, XEPI RUB CIP, XEPI SKIN PREP, XEPI RUB IPA, SSEPI RUB ET, XEPI SCRUB CHG 4%, SANIDERM SURGIBATH, SANGUARD BED BATH WIPES, SANMEDIN 5 %, SANMEDIN 10%, XEPI SCRUB PVP 7.5%, SANMEDIN GARGLE, SANMETOL, DEZSEP CCI, DEZSEP HC, DEZSEP SC, FACEIN COMBO, FACEIN ECO, FACEIN POWER 256, FACEIN SPRAY, FACEIN KLEEN, FACEIN PRO, STRUMEN G 2%, STRUMEN G 2.45%, STRUMEN MULTIZYME, STRUMEN OPA, STRUMEN HYPA, STRUMEN TRI ACID, STRUMEN RAPID, STRUMEN HP, STRUMEN SP, SODIUM HYPOCHLORITE, STRUMEN OPA TEST STRIPS, STRUMEN G 2.0% & STRUMEN G 2.45% TEST STRIPS"**

Applicable Standard: **Medical Devices – Class II, EN 1276, EN14476, EN 1500, EN 12791, EN 1499, EN 13727, EN 14348, EN 13624, EN 14561**

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the 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	08th September 2023
1st Surveillance Audit Due	07th September 2024
2nd Surveillance Audit Due	07th September 2025
Certificate Expiry (subject to the company maintaining its system to the required standard)	07th September 2026

Authorised Signatory

UK Certification & Inspection Ltd.

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