



Certificate of Compliance

Confirm that the Products technical file & spares of class I according to the Medical Device Directive 93/42/EEC

Certificate No. IMC25KP570IN

Manufacture

Name : KONKORE PACKAGING PRIVATE LIMITED

Address : Surevey . 833/1, Kothari Estate Street, Near Kothari Cross Roads,
Rakanpur-Santej, Kalol, Gandhinagar-382721, Gujarat, India

Product : "Manufacturing & Supply of Medical Packaging Materials, Devices, CSSD & Surgical Products"

Complies with the requirements applicable to it

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 the Medical Device Directive 93/42/EEC

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 EU legislation, the manufacturer shall affix to each device, of the above referenced models.
5. 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.gaafs.us

Initial Registration Date

12 February 2025

Issuance Date

12 February 2025

1st Surveillance Due

11 February 2026

2nd Surveillance Due

11 February 2027

Certificate Expiry (Subject to the company maintaining its system
To the required standard)

11 February 2028



Authorized Signatory



Validity of this Certificate is subject to Annual Surveillance audits done successfully

This certificate remains the property of QCAS and must be returned whenever demanded QCAS is an independent system product and personal assessment body QCAS is accredited by Global Accreditation Assessment Forum Series (GAAFS)



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This Certificate referred above covers the following Products.

S. NO	PRODUCT NAME
01	Sterillization Flat Reels and Pouches
02	Sterillization Tyvek Reels and Pouches
03	Sterillization Gusseted Reels and Pouches
04	Sterillization Self- Seal Pouches
05	Paper to Paper Pouches
06	Aluminum Foil Pouches
07	Header Bags
08	Medical Crepe Paper Wrapping Sheet
09	Medical Non-Woven SMS, SMMS, SMMMS Wrapping Sheet
10	Chemical Indicator Strip and Tapes
11	ETO Indicator Strips/ and Tapes
12	Bowie Dick Test Pack/ A4 Sheet
13	Documentation Label, All Label & Gun
14	Helix PCD & Devices
15	Plasma Indicators Strips and Tapes
16	Sterillization Control Products
17	All CSSD & Surgical Products



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