



Certificate of Compliance

Technical file of the company mentioned below has been observed 93/42/EEC for Medical device directive has been taken as references for the processes.

Product Requirements of the organization has been assessed in accordance with the Directive applicable of product for: **Surgical & Dental Instruments (Reusable and Non-Powered)**

Certificate Number: TCE/PK342/04400404
Company Name: **Surgicon (Pvt.) Ltd**
Company Address: P. O. Box No. 244, Khadim Ali Road, Sialkot - 51310, Pakistan

Applicable EC Directives & Annex: 93/42/EEC & Annex V / 2007/47EEC Module A Annex VII for Class 1 Medical Devices & Essential Health and safety requirements

Applicable Harmonized Standards: EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008+A1:2013
ISO 17664-1:2021, ISO 11197:2019, ISO 13485:2016

This certificate permits the above named organization to issue declarations of performance in support of CE Marked product with to the scope of certification as stated within this certificate; thereby confirming to interested parties the above named organization has produced the product to the agreed specification.

European Authorized Representative (EC REP)

CMC MEDICAL DEVICES & DRUGS, S.L
C/ Horacio Lengo n18
C. P 29006
Malaga-Spain

Issue Date: 04 April 2025
Expiry Date: 03 April 2026



This Certificate is issued against the product sample conforming to the essential requirements as per the Directive. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

After preparation of necessary technical documentation as well as the EC conformity declaration the required CE marking can be affixed on the product. Other relevant directives have to be observed.



To verify the certificate please scan the above QR code.

Approved on Behalf of the Certification Board



Signature By Scheme Manager