



Certificate of Compliance

Technical file of the company mentioned below has been observed 93/42/EEC for Medical 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 & Veterinary Instruments**
(Reusable, Non-Powered & Non Invasive)

Certificate Number: TCE/PK35/0133
Company Name: **SIGAL MEDCO**
Company Address: Nasri Street No.9, Fateh Garh, 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 1639:2009, EN ISO 14971:2012, EN ISO 15223-1:2016
EN 1041:2008, EN ISO 17664:2004, ISO 11197:2019

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.

Initial Certification Date: 25 Aug 2022
Issue Date: 31 Aug 2022
Expiry Date: 31 Aug 2023
Revision: 02



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