



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: **General Surgical Instruments, Dental Instruments, Microsurgical Instruments, Orthopedic Surgical Instruments, Ophthalmic Surgical Instruments, Otology & Rhinology Surgical Instruments, Laryngoscopes (Conform to ISO 7376 Standard), Wall Mounted Diagnostic Systems, Vital Signs Monitors, Blood Pressure Measuring Devices, Dermatoscopes, Otoscope (Both Rechargeable and Battery Operated), Ophthalmoscopes (Both Rechargeable and Battery Operated), Stethoscopes, Neurological Hammers and Sterilization Containers.**

Certificate Number: TCE/CA04/01021401
Company Name: **Cross Instruments Inc.**
Company Address: 4004 Aspen Drive East N.W., Edmonton, AB T6J 2A8 CANADA
Applicable EC Directives has been found to comply with the council directive 93/42/EEC for medical devices and EU essential health & 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: 05 September 2018
Issue Date: 17 September 2021
Expiry Date: 16 September 2022
Revision: 00



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