surgimax™
saving lives

EC DECLARATION OF CONFORMITY

We Surgimax Instruments, located at Harrar Roras Road Sialkot-51310-Pakistan hereby under sole responsibility declares that below mentioned medical devices manufactured by us have been classified as Class I according to the classification rules stated in the Chapter III of Annex – IX and conform to the Essential Requirements as laid out in the Annex-I of the EU MDD 93/42/EEC as amended by 2007/47/EC and the CE marking may be affixed.

Conformity Assessment procedure:

Annex I and Annex VII of EU MDD 93/42/EEC as updated by 2007/47/EC

Medical Device Name:

Non-sterile, reusable, non-active Surgical and Dental Instruments

List of Products:

See List of Instruments (Annex I- Agreement 310719)

This declaration related is in conformity with the following standard(s) used or other normative document(s) / guideline(s)

ISO 9001	Quality Management Systems
ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purpose
MDD 93/42/EEC as amended 2007/47/EC	Council Directive for Medical Devices
ISO 14971	Medical Devices–Application of Risk Management to Medical Devices
ISO 17664	Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied part-1 – general requirements
cGMP	Medical Devices – Current Good Manufacturing Practices

Certifications ISO 13485 ISO 9001:2015 cGMP CE

surgical
dental
orthopedic

since 1984

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ASTM-F899	Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments
ISO 7153-1	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel
ISO 21850-1	Dentistry – Materials for dental instruments – part 1: Stainless Steel

We prepare and maintain technical documentation for each device as requires by applicable classification rules and Annex-VII of the directive. Records are maintained for 10 years.

We have appointed the EU Authorized Representative as below:

CMC Medical Devices & Drugs, S.L.

C/ Horacio Lengo n18
C. P 29006, Málaga-Spain
Tel: +34 951 214 054

Signed for and on behalf of Surgimax Instruments

Name: Zulifiqar Ali
Designation: QA Manager
Place of Issue: Harrar Roras Road Sialkot-51310-Pakistan
Date of Issue: 22nd May, 2021

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