

Certificate



Application of Council Directive 93/42/EEC OF 14 June 1993 as updated directive 2007/47EEC for Class I Medical Devices

This is certify that the products submitted are:

MEDICAL DEVICES CLASS I
(Surgical, Dental & Orthodontic Instruments)
Certificate No: CL/PK/989206

Manufactured By:
SACRED INTERNATIONAL
Harrar, Rorus Road, Sialkot - Pakistan.

Comply with the applicable requirements of the Directive 93/42/EEC as updated directive 2007/47/EEC The Technical file of the devices have been assessed according to the procedure of conformity Assessment described in the Module A, Annexure VII.

Limitations:

The manufacturer must inform CL of any substantial changes occurred in the Product or process in order to examine whether this certificate remains valid.

SCHEME MANAGER

Certificate Issue Date: February 28, 2023 - **Certificate Expiry Date:** February 27, 2024
This Certificate of Registration is Granted subject to the Regulations approved by the Board.

Certlink Certification Services.

Info@cert-link.com
www.cert-link.com



EC DECLARATION OF CONFORMITY

We,

Manufacturer's Name: Sacred International
Address: Harrur Roras Road, Sialkot - Pakistan
Email ID: info@sacred.com.pk

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:

Our products are Class I Medical Device, as the following:

CROWN INSTRUMENTS	BONE FILES
DENTAL SYRINGE	CEMENT SPATULA
IMPRESSION TRAYS	EXPLORERS
MIRROR HANDLES	MOUTH MIRRORS
RETRACTORS	SCALPEL HANDLES

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ISO 9002
ISO 13485
FDA APPROVED **CE**



SCISSORS	BONE RONGEURS
NEEDLE HOLDER	ROOT ELEVATORS
FORCEPS	FILLING INSTRUMENTS
MATRIX RETAINERS	AMALGAM CARRIERS
COTTON & DRESSING PLIERS	RUBBER DAM INSTRUMENTS
ELEVATORS	BUR HOLDERS
PROBES & EXPLORERS	PLIERS
SCALER CURETTES	TWEEZERS
BRACKET HOLDER & POSITIONER	MOLAR BRACKET PLACER
HEIGHT VERIFICATION BLOCK	ORTHODONTIC INSTRUMENTS
IMPLANT INSTRUMENTS	NITI CHILLI PEN

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 Council Directive for Medical Devices
amended 2007/47/EC
- 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

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cGMP	Medical Devices – Current Good Manufacturing Practices
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

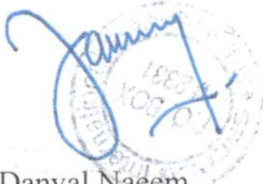
We prepare and maintain technical documentation for each device as requires by applicable classification rules and Annex-VII of the directive. Records are maintained for 10 years.

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
Email: info@cmcmedicaldevices.com

Signed for and on behalf of: Sacred International



Name: Danyal Naeem
Designation: Partner
Place of Issue: Harrur Roras Road, Sialkot - Pakistan
Date of Issue: 25-07-2023

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ISO 9002
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