



PROWA MEDICAL INSTRUMENTS



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P.O. Box 3036,
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EC DECLARATION OF CONFORMITY

We,
Prowa Medical Instruments
P.O. Box 3036,
9-KM Daska Road,
Sialkot 51310 - Pakistan
Email ID: sales@prowainstruments.com

With the Scope of
Manufacturing And Exporting Of All Sorts Of Non-Active Surgical And Dental Instruments, ENT, Orthopaedic, Ophthalmic, VATS, Electro-Surgical Instruments, Sterilization Containers, Hospital Furniture & Hollowware, Implants And Allied Products

Herewith declare under our responsibility, that all listed medical devices
Instruments of Risk-Class I,

Classified according to Regulation MDR 2017/745 annex VIII chapter 1 into risk class I, have been manufactured under consideration of following Regulation:

European Regulation 2017/745(MDR) + Corrigendum I and II

Applied conformity assessment according Annex IV of MDR 2017/745.

The listed products meet the essential safety- and performance requirements of the European Regulation Annex I of Regulation (EU) 2017/745 and are therefore placed into market with CE

Medical Device Name:

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

Basis-UDI-DI: HIBCC (G672)

EUDAMED SRN: PK-MF-000037852

EU Authorized Representative

CMC Medical Devices & Drugs SL

SRN: ES-AR-000000293

C/ Horacio Lengo N18, 29006, Málaga-Spain



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Whereas our all products are manufactured under the guidelines of the following international standards:

ISO 9001:2015 Quality Management System

EN ISO 13485:2016 Medical Devices Quality Management System

EN ISO 14971:2019 Medical Devices- Application of Risk Management to Medical Devices

ISO 7153-1:2016 Surgical Instruments Metallic Materials - Part-1: Stainless Steel

BS EN 1041:2008+A1:2013 Information Supplied by the Manufacturer with Medical Devices

BS EN ISO 15223-1:2016 Medical Devices, Symbol to be used with Medical Device Labels, labeling and Information to be supplied

ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

ASTM F899-12b Standard Specification for Wrought Metals for Surgical Instruments

CGMP Medical Device Current Good Manufacturing Practice

We herewith declare and certify that the mentioned devices technical documentations meet the provisions of the Medical Device Regulation (EU) 2017/745 with the Annex II, III, IV. The products list is attached in Annex A of this declaration. We shall maintain these documentations for 10 years from the data of their production.

Signed for and on behalf of
Prowa Medical Instruments

Numan Bhatti

Name: Numan Bhatti

Designation: Partner - Int'l Sales Operations

Date of Issue: September 22, 2025

Place of Issue: P.O. Box 3036, 9-KM Daska Road, Sialkot 51310 - Pakistan

