



PROWA MEDICAL INSTRUMENTS



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sales@prowainstruments.com
www.prowainstruments.com

P.O. Box 3036,
9-KM Daska Road
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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

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 (EUAR Agreement)

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





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SO 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

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
Prowa Medical Instruments



Name: NUMAN WAHEED

Designation: Partner

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

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