

EC DECLARATION OF CONFORMITY

We,

Falcon Surgical Co. (Pvt.) Ltd

Address: Wazirabad Road, Village Golophala, Sialkot 51310-Pakistan

Mob: +923008610049

Email ID: adnanhayat.falcon@gmail.com

Hereby declare that we fall within manufacturers of Class – I devices and the devices produced by us are

➤ **See List of Instruments (Annex I- Agreement 051120/83)**

Meet the essential requirement of Medical Device Directive 93/42/EEC as amended by 2007/47/EC. 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 are 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

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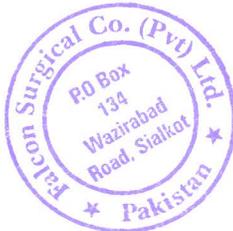
To which This declaration related is in conformity with the following standard(s) or other normative document(s)

- | | |
|----------------------|---|
| ISO 9001 | Quality Management Systems |
| ISO 13485 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purpose |
| 93/42/EEC as amended | 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 |
| 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 |

Signature:

Name: Azmat Rasool

Designation: Q A Manager



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