

We,  
Falcon surgical so. (pvt.) ltd.  
Wazirabad Road, village Golophala, Sialkot 51310-Pakistan

declare under our own responsibility that all surgical and dental instruments  
manufactured by us

- Fall into Class 1 according classification rules described in Annex VII of Medical Devices Directive 93/42/EEC.
- And meet the essential requirement of Medical Device Directive 93/42/EEC as amended by 2007/47/EC.

## List of applicable standards and directives

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

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For Falcon Surgical co. (pvt.) ltd.

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