

EC DECLARATION OF CONFORMITY

We,

Darleys Surgical Co.

Address: 2-A Kutchery Road, Sialkot Pakistan

Tel: Tel +92-52-4269230, Fax +92-52-4586215

Email: info@darleypsurgical.com

Web: www.darleypsurgical.com

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

➤ **Surgical Instruments**

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 5 years.

The Authorized European Representative with in the community is:

MAXCERT GERMANY

Heidelbergerstr 79, 69190,

Walldorf Germany

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Manufacturer of Surgical Instruments Since 1992

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

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:

Qasim Idrees Dodhy

Partner **Darleys Surgical Co.**

Partner 

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