

EC Declaration of Conformity for Medical Class I (Surgical Instruments)

Notified Body: Technical Standards Institute - Blokland 52 2 th 2620 Albertslund, Denmark

Doc #: ECD-01, Rev 02

We declare, under our sole responsibility, that the product listed below conforms to the provisions of European Council Directive 93/42/EEC of 14 June 1993, as updated directive 2007/47/EEC concerning medical devices.

**Manufacturer's
Name & Business
Address:**

Implant Surgical Company
Fateh Ghar Road, Bila Sweet Streets, 51310,
Sialkot – Pakistan.

EC	REP
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Syed Awais Ayyub
Theodor-Heuss-Straße 7
71642 Neckarweihingen
GERMANY

**MDD Annex:
Classification:
Classification Rule:**

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Standards Applied:

ISO 9001:2008	Quality Management Systems
EN ISO 13485:2012	Medical Devices - Quality Management Systems
ISO 7153:2001	Material Composition for Surgical Instruments
BS 5194:Part 2:1989	Specification for instruments with pivot joints (excluding cutting instruments)
BS 5194:Part 3:1985	Specification for Dissecting Forceps
BS 5194:Part 4:1985	Specification for scissors, shears, and other jointed cutting instruments
ISO 7151:1988	Surgical instruments – non-cutting, articulated instruments – general requirements & test methods
ISO 7740:2004	Scalpels with detachable blades - Fitting dimensions
ISO 7741:1986	Scissors and shears - General requirements and test methods
ISO 6508 - 1:2005	Specifies the method for Rockwell and Rockwell superficial hardness tests for metallic materials.
ISO 14971:2012	Medical Devices – Application of risk management to medical devices.
DIN 58298:2010-09	Medical instruments - Materials, finish and testing.
DIN 58299:1964-01	Serrations for surgical instruments; profile angles, groove distances.
DIN 58300:1982-02	Joints for surgical instruments.
ISO 15223-1:2012	Symbols for use in the labeling of medical devices
EN 1041:2008	Information supplied by the Manufacturer

Authorized Signatory:

*Muhammad
Azeem*

03-05-2018

Date

Managing Director



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