

EC Declaration Of Conformity

We, Surgins Surgical Ltd, Concorde House Trinity Park Solihull B37 7UQ UK

hereby declare that we fall within manufacturers of Class 1 devices, and the devices produced by us which are:

**“Surgical, Dental, Veterinary, Manicure, Pedicure”
(S/S Reusable, Single use and Titanium Surgical Instruments)**

meet the essential requirement of Directive No. 93/42/EEC and updated directive 2007/47/EEC.

We prepare and maintain technical documentation for each device as required by Annex-VII of the directive.

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

93/42/EEC:	Council directive for medical Devices
cGMP:	Medical Devices, Current Good manufacturing Practice
BS EN ISO 13485:	Medical device Quality Management systems requirements for regulatory purpose
BS EN ISO 14971:	Medical Devices Application of Risk management to Medical Devices
BS EN ISO 17664:	Sterilisation of Medical Devices information to be provided by the manufacturer for the processing of re-sterilisable devices
BS EN ISO 7153-1:	Surgical instruments- Metallic materials-Part 1 Stainless Steel
BS EN ISO 13402:2001, BS 7891:1997:	Surgical and dental hand instruments. determination of resistance against autoclaving, corrosion and thermal exposure
BS EN ISO 7153-1:2001, BS 5194-1:1991:	Surgical instruments. Metallic materials. Stainless steel

ASTM-F899:	Standard specification for Stainless Steel Billet, Bar, and wire for surgical instrument
ASTM F1611 - 00(2009):	Standard Specification for Intramedullary Reamers
ASTM F116 - 00(2009):	Standard Specification for Medical Screwdriver Bits
ASTM F1026 - 86(2008)e1:	Standard Specification for General Workmanship and Performance Measurements of Hemostatic Forceps
ASTM F1079 - 87(2008)e1:	Standard Specification for Inserted and Noninserted Surgical Scissors
ASTM F1613 - 95(2008)e1:	Standard Specification for Surgical Tissue/Dressing/Pick-Up Forceps (Thumb Type)
ASTM F1325 - 91(2008)e1:	Standard Specification for Stainless Steel Suture Needle Holders-General Workmanship Requirements and Corresponding Test Methods
ASTM F899 – 11:	Standard Specification for Wrought Stainless Steels for Surgical Instruments
BS 2982:1992:	Specification for materials and packaging of surgical scalpels with detachable blades
BS 5194-2:1989:	Surgical instruments. Specification for instruments with pivot joints (excluding cutting instruments)
BS 5194-3:1985:	Surgical instruments. Specification for dissecting forceps
BS 5194-4:1985:	Surgical instruments. Specification for scissors, shears and other jointed cutting instruments.
BS EN 27740:1992, ISO 7740:1985:	Specification for dimensions of surgical scalpels with detachable blades
BS EN 980:	Graphic Symbols for use in the labelling of Medical Devices