

DECLARATION OF CONFORMITY CLASS 1 SURGICAL INSTRUMENTS

Notified Body: SGS United Kingdom Ltd, Rossmore Business Park, Ellesmere Port, Cheshire CH65 3EN, United Kingdom

Surtex Instruments Ltd. medical devices are designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing, or ligating and other similar procedures. They may also be used to facilitate the insertion of surgical implants.

Surtex Instruments Ltd. declares that the Class 1 Surgical Instruments listed and coded within the Company catalogue are manufactured in accordance with our Quality Management System certified to ISO9001:2012, ISO13485:2016 and Council Directive 93/42/EEC of June 1993 C, in conjunction with registration by the manufacturer with the UK Competent Authority in accordance with Article 14 of the directive concerning medical devices. Where applicable, our products are manufactured in accordance with and from materials suitable for sterilization in accordance with the requirements of one or more of the recognized standards and guidance documents listed below:

Standard	Details
BS EN ISO 9001:2008	Quality Management Systems certification standard.
BS EN ISO 13485:2003	Medical Devices – Quality Management Systems certification standard.
MDD 93/42/EEC, Annex II, Section 3.2	Medical Device Directive, 'EC Declaration of Conformity' (full quality assurance system).
MDD 93/42/EEC, Annex I	Essential Requirements for Medical Devices.
BS EN ISO 7153- 1:2001 (BS 5194:Part 1:1991)	Surgical Instruments – Metallic materials part 1 - Stainless Steel
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 (DIN 50103-3:1995)	Specifies the method for Rockwell and Rockwell superficial hardness tests for metallic materials.
BS EN 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.
HTM 2010	Recommendations for sterilization
AS/NZ 4187-2003	Cleaning, disinfecting & sterilising of re-usable surgical instruments

For and on behalf of Surtex Instruments Ltd.



Anwar Khaliq – CEO – 1st October 2018

