

Scala Surgical Limited declares that the Surgical Instruments listed and coded within the company catalogue are manufactured in accordance with our quality management system which is certified to ISO 13485 (2016) and follow the guidance of MDD 93/42 EEC as amended by 2007/47 EEC.

Where applicable, our products are manufactured from materials and are suitable for sterilisation in accordance with the requirements of one or more of the recognised standards and guidance documents listed below:

BS EN ISO 13485 (2016)	Quality management system for medical devices - certification standard
MDD 93/42/EEC as amended by 2007/47 EEC	Guidance of the 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)	Specifies the materials used to manufacture 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 7741 : 1986	Scissors and shears - General requirements and test methods
ISO 7740 : 1985	Scalpels with detachable blades - Fitting dimensions
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 sterilisation
ASTM A967	Specification for chemical passivation treatment for stainless steel parts

For and on behalf of Scala Surgical Ltd

Signature: *Haroon ibn Islam*

Name: Haroon ibn Islam
 Position: Director
 Date: 16/08/2018