

EC DECLARATION OF CONFORMITY

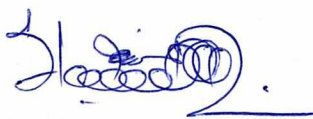
April 19, 2022

We Surgimax Instruments Limited England hereby declare that we fall within manufacturers of Class – I devices and the instruments produced by us are as under: –

General | Cardiovascular | ENT | Neuro | Gynecology | Ophthalmology | Plastic | Orthopedic | Laryngoscopes | Liposuction and Infiltration | Cranio–Maxillo–Facial (CMF) | Mammoplasty | Podiatry | Dental

Above products meet the essential requirement of Directive No. 93/42/EEC as amended 2007/47/EC and also registered with Medicines and Healthcare Products Regulatory Agency (MHRA) UK. We prepare and maintain technical documentation for each device as requires by Annex–VII of the directive 93/42/EEC as amended 2007/47/EC. To which this declaration related is in conformity with the following International standard(s) or other normative documents.

ISO 9001:2015	Quality Management Systems
ISO 13485:2016	Medical Devices–Quality Management Systems–Requirements for Regulatory Purpose
ISO 14971:2007	Medical Devices–Application of Risk Management to Medical Devices
ISO 17664:2004	Sterilization of Medical Devices–Information to be provided by the manufacturer for the processing of re–sterilizable medical devices
EN 980:2008	Graphical Symbols for Use in the Labeling of Medical Devices
cGMP	Medical Devices; Current Good Manufacturing Practice
93/42/EEC	Council Directive for Medical Devices
ASTM–F899–09	Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments
ISO 7153–1	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel



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