surgimax™
saving lives

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) | Mammaplasty | 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

Shahbaz Ahmed
Managing Director

surgimax™
saving lives
+44 (0) 161302 2744
sales@surgimax.co.uk
www.surgimax.co.uk
surgical
dental
orthopedic

SURGIMAX INSTRUMENTS LIMITED 923193