

## DECLARATION OF CONFORMITY

### Full Quality Assurance Procedure

No: TD01-02-01/ 20211114-000

<b>Manufacturer</b>	Surgical Instruments Group Holdings (SIGH) LTD
<b>Manufacturer's Address</b>	Unit 6, Thronton Chase, Linford Wood, Milton Keynes MK14 6FD
<b>Medical Device Product Name</b>	General Instruments, Sterilisation Container Systems
<b>Classification</b>	Annexe VIII, Chapter 3 Rule 1, Class I
<b>Annexes</b>	Annexe I, Device UDI-DI Description.

#### Global Medical Device Nomenclature

Code	Code Term	Code	Code Term
[13730]	Sterilization Container	[35732]	Rigid endoscopic biopsy forceps
[35362]	Indicator, chemical/physical	[36249]	Orthopaedic burr
[44411]	StainlessSteel Lid, basket, reusable	[32764]	Ophthalmic Diamond knife
[35048]	Rreusable Bone lever/elevator	[66306]	Neurosurgical curette
[62467]	Surgical soft-tissue forceps, alligator	[46830]	Laryngoscope handle
[45181]	Surgical retraction system	[45918]	Hand-held surgical retractor
[45182]	Self-retaining surgical retractor	[35326]	Flexible endoscopic scissors
[12235]	Resuable Scalpel handle	[37472]	Dermatome & blades

We declare under our sole responsibility, that the medical device of class I, to which this declaration relates are in conformity with the provisions of the European Medical Device Regulation 2017/745 EU and Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002). Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied. Medical devices comply with the EU regulation, Annex I General safety and performance requirements and Part II of the UK MDR 2002, Annex X. A Technical File has been created for the Medical Device in accordance with the Annex-II and UK MDR 2002 Technical Documentation section. This declaration of conformity has been prepared in accordance with Annex-IV EU Declaration of Conformity.

#### Standards and Directives Applied

• 2017/745 EU	• EN ISO 13485:2016	• IEC 62366-1:2015	• EN ISO 11607-2:2019
• UK MDR 2002	• EN ISO 14971:2020	• EN ISO 11607-1:2019	• EN1041+A1:2013
• MEDDEV 2.7.1	• MEDDEV 2.12-1	• MEDDEV 2.12-2	• EN 868-8:2018
• ISO 11737-2:2020	• EN 285:2015	• EN ISO 17664:2017	• EN ISO 14937:2009
• ISO 17665-1:2006	• ISO 18472:2018	• EN ISO 11140-1:2014	• EN ISO 15223-1:2016

**Company Director:**

EN ISO 13485: 2016 Certificate (GB97/11493)

Authorized Signatory

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