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EU DECLARATION OF CONFORMITY

Name and Address of Product Owner:-

LONG LIFE SURGICAL INDUSTRIES

03-km, Bab-e-Sialkot, Fazalabad Stop, Opposit King Beverages, Daska Road,
 Sialkot 51310, PAKISTAN. Tel: 0092 52 3308177-78-79-80

E-mail: info@longlife.com.pk

Website: www.longlife.com.pk

Single Registration Number PK-MF-000010701.

Hereby Declare Under Our Sole Responsibility That Medical Devices Described
 Hereunder

NON-STERILE, SINGLE USE, LARYNGOSCOPES BLADES & HANDLES
 with following variants;

- **FIBER OPTIC GREEN SYSTEM DISPOSABLE BLADES**
- **CONVENTIONAL DISPOSABLE BLADES**
- **DISPOSABLE METALLIC KITS (BATTERY INCLUDED)**
- **DISPOSABLE METALLIC KITS (W/O BATTERY)**

Details of all catalogue codes, description and their basic UDI-DI are given in
Supplement-A to this declaration of conformity.

To which this declaration relates have been classified as **Class I** by the rule of 5 set out in Medical Device Regulation (EU) 2017/745, [Annex VIII, and Chapter III]. Are in conformity with the General Safety and Performance Requirement (GSPR) (Annex-I) And, the Commission delegated directive (EU) 2015/863, also called RoHS 3, amending Annex II of the RoHS directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) device that is covered by the present declaration is in conformity with this Regulation

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and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity; Are In Conformity With The National / International Standard(s) Transposing Harmonized Standard(s);

The intended use and purpose of the device of Long Life Surgical Laryngoscope, which is a two-part, hand held device consisting of a handle that contains batteries and a detachable blade. it is used to visualize and examine the upper airway of a patient and to guide placement of the endotracheal tube during intubation procedures. Long Life Surgical Laryngoscopes are used to provide direct vision of the larynx prior to intubation, enabling the user to insert a tube into the trachea, avoiding the oesophagus and minimizing trauma to the vocal cords.

Risk Classification:

Non Sterile, Single Us, Laryngoscopes Blades and Handles manufactured by Long Life Surgical Industries are classified in **Class I** by the rule of 5 set out in Medical Device Regulation (EU) 2017/745, [Annex VIII, Chapter III], class I if they are intended for transient use ;('Transient' means normally intended for continuous use for less than 60 minutes.)"- falls in low risk device class. Rules 1 – 4 cover non-invasive devices. But laryngoscope is an invasive device with body orifice, so these rules are not applicable. Rules 5 – 8 focus on invasive devices. Rule 5 covers the medical Devices invasive in body orifices, due to which rule 5 is applicable to laryngoscope, but rule 6 to 8 is for surgically invasive device which is not applicable. Rules 9 – 13 cover the active therapeutic and medicinal device which are not applicable on the laryngoscope. Rules 14 – 22 cover special rules. These are rules which cannot be categorised into the other sets previously mentioned. but all these rules are not complied with the Device.

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Harmonized Standards:-

Devices are in conformity with the national / international standards transposing harmonized standards;

- ☑ EN ISO 13485:2016: Medical Devices – Quality Management Systems - Requirements for regulatory purposes
- ☑ ISO 9001:2015: Quality Management System-Requirements
- ☑ EN ISO 14971:2019: Medical devices - Application of risk management to medical devices
- ☑ ISO 7376:2020(E): Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation
- ☑ EN ISO 15223-1:2021: Medical devices – Symbols to be used with medical device labels, labelling & information to be supplied – Part 1: General requirements
- ☑ ISO 20417:2021: Information supplied by the manufacturer of medical devices
- ☑ EN ISO 10993-1:2020: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ☑ ISO 7153-1: 2016: Surgical Instruments – Metallic Materials – Part 1: Stainless Steel
- ☑ IEC 60601-1-11:2015/AMD1 : 2020 Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

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Conformity Assessment Route:

Conformity Assessment Route adopted as per Article 52 (7).MDR (EU) 2017/745. Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III. CE mark could be affixed by self-Declaration.

The device is registered in EU territory /Union market and has allowed its authorized representative to fulfil the tasks mentioned in Article 11(3).

European Authorized Representative:

According to the provision of Article 11, MDR (EU) 2017/745.Long Life Surgical Industries has designated **MDSS GmbH** as an Authorized Representative in European community. **MDSS GmbH** can be reached as:

MDSS GmbH

Schiffgraben 41, 30175 Hannover, Germany

For & on behalf of:
Long Life Surgical Industries

Date of Issuance: 14 .10. 2023

Place of Issuance: Sialkot – Pakistan



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Irfan Aslam
CEO

“SUPPLEMENT–A” TO EU DECLARATION OF CONFORMITY

NON-STERILE, SINGLE USE, LARYNGOSCOPES BLADES & HANDLES
with following variants;

- **FIBER OPTIC GREEN SYSTEM DISPOSABLE BLADES**
- **CONVENTIONAL DISPOSABLE BLADES**
- **DISPOSABLE METALLIC KITS (BATTERY INCLUDED)**
- **DISPOSABLE METALLIC KITS (W/O BATTERY)**

BASIC-UDI-DI pattern:

Example:

++A999MODELIDENTIFIER11S8

++	A999	MODELIDENTIFIER11	S8
HIBCC Basic UDI-DI Flag	LIC	Model Identifier	Check Character

FO GREEN SYSTEM DISPOSABLE BLADES

Cat.No./Code	Item Description	Size	BASIC-UDI-DI
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FO GREEN SYSTEM DISPOSABLE BLADES

	Macintosh Blades, FO Acrylic, Semimetal		
AL-1801-0	Neonate, 0	80mm	++G126SUMACFOSMN7
AL-1801-1	Infant, 1	92mm	
AL-1801-2	Child, 2	102mm	
AL-1801-3	Medium Adult, 3	135mm	
AL-1801-3.5	Medium Adult, 3.5	145mm	
AL-1801-4	Large Adult, 4	155mm	
AL-1801-5	X-Large, 5	175mm	
	Miller Blades, FO Acrylic, Semimetal		
AL-1802-00	Premature, 00	65mm	++G126SUMILFOSMUJ
AL-1802-0	Neonate, 0	78mm	
AL-1802-1	Infant, 1	102mm	
AL-1802-2	Child, 2	154mm	
AL-1802-3	Medium Adult, 3	195mm	
AL-1802-4	Large Adult, 4	205mm	
	Macintosh Blades FO Acrylic, Metallic		
AL-1803-0	Neonate, 0	80mm	++G126SUMACFOFMLY
AL-1803-1	Infant, 1	92mm	
AL-1803-2	Child, 2	102mm	
AL-1803-3	Medium Adult, 3	130mm	
AL-1803-3.5	Medium Adult, 3.5	145mm	
AL-1803-4	Large Adult, 4	155mm	
AL-1803-5	X-Large, 5	175mm	
	Miller Blades FO Acrylic, Metallic		
AL-1804-00	Premature, 00	65mm	++G126SUMILFOFMTB
AL-1804-0	Neonate, 0	78mm	
AL-1804-1	Infant, 1	102mm	
AL-1804-2	Child, 2	154mm	
AL-1804-3	Medium Adult, 3	195mm	
AL-1804-4	Large Adult, 4	205mm	
	Macintosh Blades, FO Acrylic, Semimetal		
AL-1801-00E	Premature, 00	67mm	

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FO GREEN SYSTEM DISPOSABLE BLADES

AL-1801-0E	Neonate, 0	80mm	++G126SUMACFOSME54
AL-1801-1E	Infant, 1	92mm	
AL-1801-2E	Child, 2	102mm	
AL-1801-3E	Medium Adult, 3	135mm	
AL-1801-3.5E	Medium Adult, 3.5	145mm	
AL-1801-4E	Large Adult, 4	155mm	
AL-1801-5E	X-Large, 5	175mm	
	Miller Blades, FO Acrylic, Semimetal		
AL-1802-00E	Premature, 00	65mm	++G126SUMILFOSMECZ
AL-1802-0E	Neonate, 0	78mm	
AL-1802-1E	Infant, 1	102mm	
AL-1802-2E	Child, 2	154mm	
AL-1802-3E	Medium Adult, 3	195mm	
AL-1802-4E	Large Adult, 4	205mm	
	Macintosh Blades FO Acrylic, Metallic		
AL-1803-0E	Neonate, 0	80mm	++G126SUMACFOFME33
AL-1803-1E	Infant, 1	92mm	
AL-1803-2E	Child, 2	102mm	
AL-1803-3E	Medium Adult, 3	130mm	
AL-1803-3.5E	Medium Adult, 3.5	145mm	
AL-1803-4E	Large Adult, 4	155mm	
AL-1803-5E	X-Large, 5	175mm	
	Miller Blades FO Acrylic, Metallic		
AL-1804-00E	Premature, 00	65mm	++G126SUMILFOFMEAY
AL-1804-0E	Neonate, 0	78mm	
AL-1804-1E	Infant, 1	102mm	
AL-1804-2E	Child, 2	154mm	
AL-1804-3E	Medium Adult, 3	195mm	
AL-1804-4E	Large Adult, 4	205mm	
	Macintosh Blades, FO Acrylic, Full-Plastic		
AL-1805-1	Infant, 1	95mm	++G126SUMACFOFPM6
AL-1805-2	Child, 2	115mm	
AL-1805-3	Medium Adult, 3	135mm	



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FO GREEN SYSTEM DISPOSABLE BLADES

AL-1805-4	Large Adult, 4	155mm	
	Miller Blades FO Acrylic, Full-Plastic		
AL-1806-0	Neonate, 0	80mm	++G126SUMILFOFPTH
AL-1806-1	Infant, 1	105mm	
AL-1806-2	Child, 2	155mm	
AL-1806-3	Medium Adult, 3	195mm	
AL-1806-4	Large Adult, 4	205mm	
	MacFlex Blades, FO Acrylic, Full-Metalic		
AL-1807-2	Child, 2	105mm	++G126SUMACFOFXMN
AL-1807-3	Medium Adult, 3	130mm	
AL-1807-4	Large Adult, 4	155mm	
	Battery Handles FO LED, Semimetal with Batteries		
AL-1851-2	Infant,	115mm	++G126SUBATHANDFOSMFB
AL-1851-3	Pediatric	150mm	
AL-1851-4	Medium	150mm	
	Battery Handles FO LED, Metallic with Batteries		
AL-1852-2	Infant	115mm	++G126SUBATHANDFOFME4
AL-1852-3	Pediatric	150mm	
AL-1852-4	Medium	150mm	
	Battery Handles FO LED, Semimetal without Batteries		
AL-1858-2	Infant	115mm	++G126SUWOBATHANDFOSMGN
AL-1858-3	Pediatric	150mm	
AL-1858-4	Medium	150mm	
	Battery Handles FO LED, Metallic without Batteries		
AL-1859-2	Infant,	115mm	++G126SUWOBATHANDFOFMFF
AL-1859-3	Pediatric	150mm	
AL-1859-4	Medium	150mm	
	Disposable Metallic Kits (Battery Included)		



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FO GREEN SYSTEM DISPOSABLE BLADES

AL-1853-00	Miller Blade 00 with Battery Handle Med		++G126SUMETKITMILBTINC9W
AL-1853-0	Miller Blade 0 with Battery Handle Med		
AL-1853-1	Miller Blade 1 with Battery Handle Med		
AL-1853-2	Miller Blade 2 with Battery Handle Med		
AL-1853-3	Miller Blade 3 with Battery Handle Med		
AL-1853-4	Miller Blade 4 with Battery Handle Med		
AL-1854-0	Mac Blade 0 with Battery Handle Med		++G126SUMETKITMACBTINCZW
AL-1854-1	Mac Blade 1 with Battery Handle Med		
AL-1854-2	Mac Blade 2 with Battery Handle Med		
AL-1854-3	Mac Blade 3 with Battery Handle Med		
AL-1854-4	Mac Blade 4 with Battery Handle Med		
AL-1854-5	Mac Blade 5 with Battery Handle Med		
	Disposable Metallic Kits (W/O Batteries)		
AL-1855-00	Miller Blade 00 with Battery Handle Med		++G126SUMETKITMILWOBTTN
AL-1855-0	Miller Blade 0 with Battery Handle Med		
AL-1855-1	Miller Blade 1 with Battery Handle Med		
AL-1855-2	Miller Blade 2 with Battery Handle Med		
AL-1855-3	Miller Blade 3 with Battery Handle Med		
AL-1855-4	Miller Blade 4 with Battery Handle Med		
AL-1856-0	Mac Blade 0+Battery Handle Med		++G126SUMETKITMACWOBTMB
AL-1856-1	Mac Blade 1+Battery Handle Med		
AL-1856-2	Mac Blade 2+Battery Handle Med		
AL-1856-3	Mac Blade 3+Battery Handle Med		
AL-1856-4	Mac Blade 4+Battery Handle Med		
AL-1856-5	Mac Blade 5+Battery Handle Med		
AL-1857-1	Replacement LED capsule		++G126SUREPLEDHT



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CONVENTIONAL SYSTEM DISPOSABLE

	Macintosh Blades LED, Semimetal		
Cat.No./Code	Item Description	Size	BASIC-UDI-DI
AL-1601-1	Infant, 1	92mm	++G126SUCONMACLEDSMPY
AL-1601-2	Child, 2	102mm	
AL-1601-3	Medium Adult, 3	130mm	
AL-1601-4	Large Adult, 4	155mm	
AL-1601-5	X-Large, 5	175mm	
	Miller Blades LED, Semimetal		
AL-1602-00	Premature, 00	65mm	++G126SUCONMILLEDSMXV
AL-1602-0	Neonate, 0	78mm	
AL-1602-1	Infant, 1	102mm	
AL-1602-2	Child, 2	154mm	
AL-1602-3	Medium Adult, 3	195mm	
AL-1602-4	Large Adult, 4	205mm	
	Macintosh Blades LED, Metallic		
AL-1603-1	Infant, 1	92mm	++G126SUCONMACLEDFMNR
AL-1603-2	Child, 2	102mm	
AL-1603-3	Medium Adult, 3	130mm	
AL-1603-3.5	Medium Adult, 3.5	145mm	
AL-1603-4	Large Adult, 4	155mm	
AL-1603-5	X-Large, 5	175mm	
	Miller Blades LED, Metallic		
AL-1604-00	Premature, 00	65mm	++G126SUCONMILLEDFMWN
AL-1604-0	Neonate, 0	78mm	
AL-1604-1	Infant, 1	102mm	
AL-1604-2	Child, 2	154mm	
AL-1604-3	Medium Adult, 3	195mm	
AL-1604-4	Large Adult, 4	205mm	
	Battery Handles Con, Semimetal		
AL-1651-2	Infant	115mm	++G126SUCONBATHANDSMNU
AL-1651-3	Pediatric	150mm	
AL-1651-4	Medium	150mm	
	Battery Handles Con, Metallic		
AL-1652-1	Infant,	115mm	++G126SUCONBATHANDFMMM

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CONVENTIONAL SYSTEM DISPOSABLE			
Macintosh Blades LED, Semimetal			
Cat.No./Code	Item Description	Size	BASIC-UDI-DI
AL-1652-3	Pediatric	150mm	
AL-1652-4	Medium	150mm	