

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 1 of 14

EU DECLARATION OF CONFORMITY

Name and Address of Product Owner:-

LONG LIFE SURGICAL INDUSTRIES

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 Beverages, Daska Road, Sialkot 51310, PAKISTAN.

Call us: +92-52-3562932-1

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E-mail: info@longlife.com.pk

Website: www.longlife.com.pk

Hereby Declare Under Our Sole Responsibility That the Medical Devices Described
 Hereunder

NON-STERILE, REUSABLE, LARYNGOSCOPES BLADES & HANDLES

With following variants;

- **FIBER OPTIC GREEN SYSTEM REUSABLE LARYNGOSCOPES**
- **STANDARD CONVENTIONAL REUSABLE BLADES**
- **REUSABLE SPECIAL BLADES**

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 and, if applicable, with any other relevant Union legislation that provides for the

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 2 of 14

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, Reusable, 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.

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

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 3 of 14

- ☑ EN ISO 14971:2019+A11:2021: 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
- ☑ EN 1041:2008+a1:2013: 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

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

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 4 of 14

For & on behalf of:
Long Life Surgical Industries

Date of Issuance: 31 .08. 2024

Place of Issuance: Sialkot – Pakistan



Irfan Aslam
CEO

“SUPPLEMENT–A” TO EU DECLARATION OF CONFORMITY

NON-STERILE, REUSABLE LARYNGOSCOPES BLADES & HANDLES

With following variants;

- **FIBER OPTIC GREEN SYSTEM REUSABLE LARYNGOSCOPES**
- **STANDARD CONVENTIONAL REUSABLE BLADES**
- **REUSABLE SPECIAL BLADES**
- **GREEN SYSTEM FIBER OPTIC LARYNGOSCOPE SETS AND CONVENTIONAL LARYNGOSCOPE SETS.**

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 5 of 14

BASIC-UDI-DI pattern:

Example:

++A999MODELIDENTIFIER11S8

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

FIBER OPTIC GREEN SYSTEM RESUABLE BLADES

Cat. No. /Code	Item Description	Size	BASIC-UDI-DI
Macintosh Blades English Profile			
AL-1401-00	Premature, 00	68mm	++G126RUMACFOEPLC
AL-1401-0	Neonate, 0	80mm	
AL-1401-1	Infant, 1	92mm	
AL-1401-2	Child, 2	105mm	
AL-1401-3	Medium Adult, 3	135mm	
AL-1401-4	Large Adult, 4	155mm	
AL-1401-5	X-Large, 5	175mm	
Miller Blades English Profile			
AL-1402-00	Premature, 00	65mm	++G126RUMILFOEPS
AL-1402-0	Neonate, 0	78mm	
AL-1402-1	Infant, 1	102mm	
AL-1402-2	Child, 2	154mm	
AL-1402-3	Medium Adult, 3	195mm	
AL-1402-4	Large Adult, 4	205mm	
Macintosh Blades Mega Line			
AL-1403-0	Neonate, 0	80mm	++G126RUMACFOMLLU
AL-1403-1	Infant, 1	93mm	
AL-1403-2	Child, 2	114mm	
AL-1403-3	Medium Adult, 3	135mm	
AL-1403-4	Large Adult, 4	155mm	



Long Life
Surgical Industries

Technical File

EU Declaration of Conformity
[MDR (EU) 2017/745
Annex IV]

Document No.

LLI-TMF-11-10

Issue Date

03-08-2020

Revision
Issue #

01

Page #

Page 6 of 14

AL-1403-5

X-Large, 5

175mm

Miller Blades Mega Line

AL-1404-00

Premature, 0

65mm

AL-1404-0

Neonate, 0

78mm

AL-1404-1

Infant, 1

102mm

AL-1404-2

Child, 2

154mm

AL-1404-3

Medium Adult, 3

195mm

AL-1404-4

Large Adult, 4

205mm

++G126RUMILFOMLT7

MacFlex FO Laryngoscope Blades

AL-1405-2

Child, 2

105mm

AL-1405-3

Medium Adult, 3

135mm

AL-1405-4

Large Adult, 4

155mm

++G126RUMACFOFXLX

Mega MacFlex Blades, FO, German Profile

AL-1424-2

Child, 2

108mm

AL-1424-3

Medium Adult, 3

130mm

AL-1424-4

Large Adult, 4

155mm

++G126RUMACFOMFX3S

Macintosh FO Xenon Laryngoscope Sets, English Profile

AL-1415-1

Set of 4 Blades 1,2,3,4 with 1 Med
Handle, 1 Replacement Lamp, in Plastic
Case,.

AL-1415-2

Set of 5 Blades 0, 1,2,3,4 with 1 Med
Handle, 1 Replacement Lamp, in Plastic
Case, .

AL-1415-3

Set of 6 Blades 0,1,2,3,4,5 with 1 Med
Handle, 1 Replacement Lamp, in Plastic
Case, .

++G126RUMACFOXNEPSETUK

Miller FO Xenon Laryngoscope Sets, English Profile

AL-1417-1

Set of 4 Blades 1,2,3,4 with 1 Med
Handle, 1 Replacement Lamp, in
Plastic Case, .

AL-1417-2

Set of 5 Blades 0,1,2,3,4 with 1 Med
Handle, 1 Replacement Lamp, in
Plastic Case, .

AL-1417-3

Set of 6 Blades 0,1,2,3,4,5 with 1 Med
Handle, 1 Replacement Lamp, in
Plastic Case, .

++G126RUMILFOXNEPSETCK

MacFlex FO Xenon Laryngoscope Set, English Profile

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 7 of 14

AL-1418-1	Set of 2 Blades 3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		++G126RUMACFOXNFXSETWN
MacFlex FO LED Laryngoscope Set, English Profile			
AL-1419-1	MacFlex F.O LED Laryngoscope Set of 2 Blades 3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		++G126RUMACFOXNFXSETWN
Macintosh FO LED Laryngoscope Sets, English Profile			
AL-1420-1	Mac F.O LED Laryngoscope Set of 4 Blades 1,2,3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		++G126RUMACFOLEDSETHK
AL-1420-2	Mac F.O LED Laryngoscope Set of 5 Blades 0,1,2,3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		
AL-1420-3	Mac F.O LED Laryngoscope Set of 6 Blades 0,1,2,3,4,5 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		
Miller FO LED Laryngoscope Sets, English Profile			
AL-1421-1	Miller F.O LED Laryngoscope Set of 4 Blades 1,2,3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		++G126RUMILFOLEDSETXA
AL-1421-2	Miller F.O LED Laryngoscope Set of 5 Blades 0,1,2,3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		
AL-1421-3	Miller F.O LED Laryngoscope Set of 6 Blades 0,1,2,3,4,5 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		
Mega MacFlex FO Xenon Laryngoscope Set, German Profile			
AL-1422-1	Set of 2 Blades 3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		++G126RUMACFOXNMFSET8G
Maga MacFlex LED Laryngoscope Set, German Profile			
AL-1423-1	Set of 2 Blades 3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		++G126RUMACFOXNMFSET8G
Battery Handles FO Xenon, Stainless Steel			
AL-1451-1	Infant, (1xLithium 123 Size)	122mm	++G126RUBATHANDFOLA
AL-1451-2	Stubby, (2xAA Size)	125mm	
AL-1451-3	Pediatric, (2xAA Size)	160mm	
AL-1451-4	Medium, (2xC Size)	160mm	



Long Life
Surgical Industries

Technical File

EU Declaration of Conformity
[MDR (EU) 2017/745
Annex IV]

Document No.

LLI-TMF-11-10

Issue Date

03-08-2020

Revision
Issue #

01

Page #

Page 8 of 14

AL-1451-5	Large, (2xD Size)	175mm	
Battery Handles FO Xenon Brass Chrome Plated			
AL-1452-1	Infant, (1xLithium 123 Size)	122mm	++G126RUBATHANDFOLA
AL-1452-2	Stubby, (2xAA Size)	125mm	
AL-1452-3	Pediatric, (2xAA Size)	160mm	
AL-1452-4	Medium, (2xC Size)	160mm	
AL-1452-5	Large, (2xD Size)	175mm	
Battery Handles FO LED, Stainless Steel			
AL-1453-1	Infant, (1xLithium 123 Size)	122mm	++G126RUBATHANDFOLA
AL-1453-2	Stubby, (2xAA Size)	125mm	
AL-1453-3	Pediatric, (2xAA Size)	160mm	
AL-1453-4	Medium, (2xC Size)	160mm	
AL-1453-5	Large, (2xD Size)	175mm	
Battery Handles FO LED Brass Chrome Plated			
AL-1454-1	Infant, (1xLithium 123 Size)	122mm	++G126RUBATHANDFOLA
AL-1454-2	Stubby, (1xLithium 123 Size)	125mm	
AL-1454-3	Pediatric, (2xAA Size)	160mm	
AL-1454-4	Medium, (2xC Size)	160mm	
AL-1454-5	Large, (2xD Size)	175mm	
Replacement Lamps			
AL-1455-1	Xenon 2.5V		++G126RUREPLAMPFO3E
AL-1455-2	LED 3.0V		
AL-1455-3	Halogen 2.5V		
AL-1455-4	Halogen 3.5V		
Replacement FO light Guides English Profile (4mm)			
AL-1461-00	Miller Blade 00		++G126RUREPFOLGEP45
AL-1461-0	Miller Blade 0		
AL-1461-1	Miller Blade 1		
AL-1461-2	Miller Blade 2		
AL-1461-3	Miller Blade 3		
AL-1461-4	Miller Blade 4		
AL-1462-00	Macintosh Blade 00		
AL-1462-0	Macintosh Blade 0		
AL-1462-1	Macintosh Blade 1		
AL-1462-2	Macintosh Blade 2		
AL-1462-3	Macintosh Blade 3		

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 9 of 14

AL-1462-4	Macintosh Blade 4		
	Spare Box for Laryngoscope Sets for FO		

STANDARD CONVENTIONAL REUSABLE BLADES			
Cat.No./Code	Item Description	Size	BASIC-UDI-DI
Macintosh Blades English Profile			
AL-1201-00	Premature, 00	68mm	++G126RUCONMACEP6X
AL-1201-0	Neonate, 0	80mm	
AL-1201-1	Infant, 1	92mm	
AL-1201-2	Child, 2	105mm	
AL-1201-3	Medium Adult, 3	135mm	
AL-1201-3.5	Medium Adult, 3.5	145mm	
AL-1201-4	Large Adult, 4	155mm	
AL-1201-5	X-Large, 5	175mm	
Miller Blades English Profile			
AL-1202-00	Premature, 00	65mm	++G126RUCONMILEPA4
AL-1202-0	Neonate, 0	78mm	
AL-1202-1	Infant, 1	102mm	
AL-1202-2	Child, 2	154mm	
AL-1202-3	Medium Adult, 3	195mm	
AL-1202-4	Large Adult, 4	205mm	
MacFlex Blades, Con, English Profile			
AL-1215-2	Child, 2	105mm	++G126RUCONMACEPFXMJ
AL-1215-3	Medium Adult, 3	130mm	
AL-1215-4	Large Adult, 4	155mm	
Macintosh Conventional Laryngoscope Sets, English Profile			
AL-1213-1	Mac Conventional Laryngoscope Set of 4 Blades 1,2,3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		++G126RUCONMACSETUB
AL-1213-2	Mac Conventional Laryngoscope Set of 5 Blades 0,1,2,3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		
AL-1213-3	Mac Conventional Laryngoscope Set of 6 Blades 0,1,2,3,4,5 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 10 of 14

Miller Conventional Laryngoscope Sets, English Profile

AL-1214-1	Miller Conventional Laryngoscope Sets Set of 4 Blades 1,2,3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		++G126RUCONMILSETZ2
AL-1214-2	Miller Conventional Laryngoscope Sets Set of 5 Blades 0,1,2,3,4 with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		
AL-1214-3	Miller Conventional Laryngoscope Sets Set of 6 Blades 0,0,1,2,3,4, with 1 Med Handle, 1 Replacement Lamp, in Plastic Case, .		

Battery Handles Stainless Steel

AL-1251-1	Infant, (1xLithium 123 Size)	110mm	++G126RUCONBATHANDKC
AL-1251-2	Stubby, (2xAA Size)	115mm	
AL-1251-3	Pediatric, (2xAA Size)	145mm	
AL-1251-4	Medium, (2xC Size)	150mm	
AL-1251-5	Large, (2xD Size)	165mm	

Battery Handles Brass Chrome Plated

AL-1252-1	Infant, (1xLithium 123 Size)	110mm	++G126RUCONBATHANDKC
AL-1252-2	Stubby, (2xAA Size)	115mm	
AL-1252-3	Pediatric, (2xAA Size)	145mm	
AL-1252-4	Medium, (2xC Size)	150mm	
AL-1252-5	Large, (2xD Size)	165mm	

Replacement Lamp for Conventional Laryngoscope

AL-1253-01	Small, Clear		++G126RUCONREPLAMPVM
AL-1253-02	Adult Clear		
AL-1253-03	Small, Frosted		
AL-1253-04	Adult, Frosted		
	Spare Box for Laryngoscope Sets for Conventional		

REUSABLE SPECIAL BLADES

	Macintosh Blades American Profile	
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	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 11 of 14

Cat.No./Code	Item Description	Size	BASIC-UDI-DI
Fiber Optic System			
AL-1407-00	Neonate, 00	68mm	++G126RUSPMACFOAP37
AL-1407-0	Neonate, 0	80mm	
AL-1407-1	Infant, 1	90mm	
AL-1407-2	Child, 2	108mm	
AL-1407-3	Medium Adult, 3	130mm	
AL-1407-4	Extra Medium Adult, 3.5	145mm	
AL-1407-5	Large Adult,4	160mm	
Conventional System			
AL-1203-0	Neonate, 0	80mm	++G126RUSPCONMACAP48
AL-1203-1	Infant, 1	90mm	
AL-1203-2	Child, 2	108mm	
AL-1203-3	Medium Adult, 3	130mm	
AL-1203-3.5	X Medium Adult, 3.5	145mm	
AL-1203-4	Large Adult, 4	160mm	
	Miller Blades American Profile		
Fiber Optic System			
AL-1408-00	Premature, 00	65mm	++G126RUSPMILFOAP9J
AL-1408-0	Neonate, 0	75mm	
AL-1408-1	Infant, 1	102mm	
AL-1408-1.5	Small Child, 1.5	130mm	
AL-1408-2	Child, 2	155mm	
AL-1408-3	Medium Adult, 3	195mm	
AL-1408-4	Large Adult, 4	205mm	
Conventional System			
AL-1204-00	Premature, 00	65mm	++G126RUSPCONMILAP7D
AL-1204-0	Neonate, 0	75mm	
AL-1204-1	Infant, 1	102mm	
AL-1204-1.5	Small Child, 1.5	130mm	
AL-1204-2	Child, 2	155mm	
AL-1204-3	Medium Adult, 3	195mm	
AL-1204-4	Large Adult, 4	205mm	
	Philips Blades, American Profile		



Long Life
Surgical Industries

Technical File

EU Declaration of Conformity
[MDR (EU) 2017/745
Annex IV]

Document No.

LLI-TMF-11-10

Issue Date

03-08-2020

Revision
Issue #

01

Page #

Page 12 of 14

Fiber Optic System

AL-1412-1	Infant, 1	113mm	++G126RUSPPHILFOAP8T
AL-1412-2	Adult, 2	166mm	

Conventional System

AL-1205-1	Infant, 1	113mm	++G126RUSPCONPHILAPBW
AL-1205-1	Adult, 2	166mm	

Wisconsin Blades, American Profile

Fiber Optic System

AL-1426-2	Child, 2	132mm	++G126RUSPWISCFOPAEG
AL-1426-3	Medium Adult, 3	160mm	
AL-1426-4	Large Adult, 4	200mm	

Conventional System

AL-1206-2	Child, 2	135mm	++G126RUSPCONWISCAPFV
AL-1206-3	Medium Adult, 3	162mm	
AL-1206-4	Large Adult, 4	199mm	

**Macintosh Blades, Improved View,
English Profile**

Fiber Optic System

AL-1406-0	Neonate, 0	80mm	++G126RUSPMACFOEPIV46
AL-1406-1	Infant, 1	92mm	
AL-1406-2	Child, 2	105mm	
AL-1406-3	Medium Adult, 3	135mm	
AL-1406-4	Large Adult, 4	155mm	

Conventional System

AL-1207-0	Neonate, 0	80mm	++G126RUSPCONMACEPIV9T
AL-1207-1	Infant, 1	92mm	
AL-1207-2	Child, 2	105mm	
AL-1207-3	Medium Adult, 3	135mm	
AL-1207-4	Large Adult, 4	155mm	

**Macintosh Blades, Improved View,
American Conventional**

AL-1208-2	Child, 2	108mm	++G126RUSPCONMACIV5C
AL-1208-3	Medium Adult, 3	135mm	
AL-1208-3.5	X Medium Adult, 3.5	145mm	
AL-1208-4	Large Adult, 4	155mm	

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 13 of 14

		Wis-Hipple Blades American Profile		
Fiber Optic System				
AL-1410-00	Premature, 00	65mm	++G126RUSPWISHFOAPG7	
AL-1410-0	Neonate, 0	76mm		
AL-1410-1	Infant, 1	102mm		
AL-1410-1.5	Small Child, 1.5	115mm		
Conventional System				
AL-1209-00	Premature, 00	65mm	++G126RUSPCONWISHAPGN	
AL-1209-0	Neonate, 0	76mm		
AL-1209-1	Infant, 1	102mm		
AL-1209-1.5	Small Child, 1.5	115mm		
	Robertshaw Blades English Profile			
Fiber Optic System				
AL-1413-0	Neonate, 0	95mm	++G126RUSPROBSFOEPDN	
AL-1413-1	Neonate, 1	113mm		
Conventional System				
AL-1210-0	Neonate, 0	95mm	++G126RUSPCONROBSEPF3	
AL-1210-1	Infant, 1	113mm		
	Seward Blades, English Profile			
Fiber Optic System				
AL-1414-1	Infant, 1	106mm	++G126RUSPSEWDFOEPCB	
AL-1414-2	Child, 1	130mm		
Conventional System				
AL-1211-1	Infant, 1	106mm	++G126RUSPCONSEWDEPEA	
AL-1211-2	Child, 2	130mm		
	Polio Blades, English Profile			
Fiber Optic System				
AL-1427-2	Child, 2	105mm	++G126RUSPPOLOFOEPPF6	
AL-1427-3	Medium Adult, 3	130mm		
AL-1427-4	Large Adult, 4	155mm		
Conventional System				
AL-1212-2	Child, 2	105mm	++G126RUSPCONPOLOEPFT	
AL-1212-3	Medium Adult, 3	130mm		
AL-1212-4	Large Adult, 4	155mm		
	Oxford Blade, English Profile			
Fiber Optic System				

	Long Life Surgical Industries	Document No.	Revision Issue #
		LLI-TMF-11-10	01
	Technical File EU Declaration of Conformity [MDR (EU) 2017/745 Annex IV]	Issue Date	Page #
		03-08-2020	Page 14 of 14

AL-1416-1	Infant, 1	102mm	++G126RUSPOXFDFOEPD5
<u>Conventional System</u>			
AL-1216-1	Infant, 1	102mm	++G126RUSPCONOXFDEPFG
	Miller Blades, Oxiport English Profile		
<u>Fiber Optic System</u>			
AL-1409-00	Premature ,00	65mm	++G126RUSPMILOXFOEPKR
AL-1409-0	Neonate, 0	78mm	
<u>Conventional System</u>			
AL-1217-00	Premature, 00	65mm	++G126RUSPCONMILOXEPJU
AL-1217-0	Neonate, 0	78mm	
	Macintosh Blades Reduced Flange, English Profile		
<u>Fiber Optic System</u>			
AL-1411-2	Child, 2	105mm	++G126RUSPMACREDFLNGFOEHR
AL-1411-3	Medium Adult, 3	135mm	
AL-1411-3.5	Extra Medium Adult, 3.5	145mm	
AL-1411-4	Large Adult, 4	155mm	
<u>Conventional System</u>			
AL-1218-2	Child, 2	105mm	++G126RUSPMACCONFLNGEEC
AL-1218-3	Medium Adult, 3	135mm	
AL-1218-3.5	Extra Medium Adult, 3.5	145mm	
AL-1218-4	Large Adult, 4	155mm	