By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 769823 R000

Manufacturer: Teleflex Medical

Address:
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Single Registration Number: IE-MF-000015868

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-06-20**

Current Issue Date: **2025-10-10**

Starting Validity Date: **2025-10-10**

Expiry Date: **2028-06-19**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Humidification Systems	Class IIa
Intraosseous Infusion Devices and Accessories	Class IIa
Temperature Sensors	Class IIa
Respiratory Mask	Class IIa
Laryngeal Masks	Class IIa
Endotracheal Tubes	Class IIa
Anaesthesia and Resuscitation Connector	Class IIa
Endobronchial Tubes	Class IIa
Lubricant Spray	Class IIa
Stabilizer Dressing	Class Is
Intubation Device	Class Is
Nasopharyngeal Tubes	Class Is
Endotracheal Tube Accessories	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-06-20	3831486	Issued
2023-11-08	30006522	Supplemented – Addition of Respiratory Mask, Laryngeal Masks, Anaesthesia and Resuscitation Connector, Endobronchial Tubes Amended – Update of Rüsch Bronchoflex Reinforced Endotracheal Tube (cuffed/uncuffed) to Endotracheal Tubes Amended – Administrative update to certificate history
2025-01-21	30289274	Supplemented – Addition of Intraosseous Infusion Devices and Accessories, Stabilizer Dressing, and Temperature Sensors
2025-04-09	30381125	Supplemented – Addition of Lubricant Spray
Current	30423243	Supplemented – Addition of Humidification Systems, Nasopharyngeal Tubes, and Endotracheal Tube Accessories Amended – Addition of subcontractor for sterilization of Endobronchial Tubes, addition of subcontractors for manufacture, packaging, and sterilization of EZ-IO Needle Sets and Stabilizer Dressing.

First Issue Date: **2023-06-20**

Current Issue Date: **2025-10-10**

Starting Validity Date: **2025-10-10**

Expiry Date: **2028-06-19**

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EU DECLARATION OF CONFORMITY

Legal Manufacturer	Name: Teleflex Medical Address: IDA Business and Technology Park Dublin Road, Athlone, Co. Westmeath, Ireland Single Registration Number (SRN): IE-MF-000015868
Authorized Representative	Name: N/A Address: N/A Single Registration Number (SRN): N/A
Notified Body	Name: BSI Group the Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam Netherlands Identification Number: NB 2797

Product Name	Product Classification	Classification Rule	Conformity Assessment Route (s)	EC Certificate(s) No
LMA® Gastro™ Cuff Pilot™	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Fastrach™ SU	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Fastrach™ ETT	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Proseal™	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Classic™	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Fastrach™	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Flexible™	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Protector™ and	Class IIa	Rule 5	Annex IX	MDR 769823

LMA® Protector™ Cuff Pilot™				
LMA® Supreme™	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Unique™ (Silicone Cuff) & LMA® Unique™ (Silicone Cuff) Cuff Pilot™	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Flexible PreCurved™ & LMA® Flexible PreCurved™ Cuff Pilot™	Class IIa	Rule 5	Annex IX	MDR 769823
LMA® Flexible™ Single Use	Class IIa	Rule 5	Annex IX	MDR 769823

Teleflex Medical declares that the documented product(s) meets the provisions of Regulation (EU) 2017/745. This declaration is made in accordance with Annex IX, Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation, on the basis of the CE Certificate(s) issued by NB 2797, listed above. This declaration is issued under the sole responsibility of Teleflex Medical and authorizes Teleflex Medical to affix the CE-marking to the products listed herein.

Intended Purpose:
The LMA® Gastro™ Cuff Pilot® is intended to facilitate oxygenation and ventilation along with access to the intestinal tract for upper gastrointestinal endoscopy procedures.

LMA® Fastrach™ and LMA® Fastrach™ Single Use are intended to be used as a guide for blind intubation and to facilitate oxygenation and ventilation.

LMA® Fastrach™ ETT is intended to be used for tracheal intubation to facilitate oxygenation and ventilation.

The LMA® ProSeal™, LMA® Classic™, LMA® Flexible™, LMA® Supreme™, LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™, LMA® Flexible PreCurved™ and LMA® Flexible PreCurved™ Cuff Pilot™ and LMA® Flexible™ Single Use are intended to facilitate oxygenation and ventilation.

The LMA® Protector™ and LMA® Protector™ Cuff Pilot™, are intended to facilitate oxygenation and ventilation along with access to the intestinal tract for the drainage of gastric contents.

Basic UDI-DI	Product Name	Product Code	EMDN/CND Code	Manufacturing Site & Address	Date CE Mark Affixed by Teleflex Medical
08019020000000000010 2JZ	LMA® Gastro™ Cuff Pilot™ Size 3	1E5030	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1,	29 September 2016

				Kulim Hi-Tech Park, Kedah, 09090 Malaysia	
08019020000 00000000010 2JZ	LMA® Gastro™ Cuff Pilot™ Size 4	1E5040	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	29 September 2016
08019020000 00000000010 2JZ	LMA® Gastro™ Cuff Pilot™ Size 5	1E5050	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	29 September 2016
08019020000 00000000013 9KQ	LMA® Fastrach™ Single Use size 3	135130	R010201	Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II, Zon Perdagangan Bebas, 30020 Ipoh, Perak, Malaysia	12 December 2014
08019020000 00000000013 9KQ	LMA® Fastrach™ Single Use size 4	135140	R010201	Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II, Zon Perdagangan Bebas, 30020 Ipoh, Perak, Malaysia	12 December 2014
08019020000 00000000013 9KQ	LMA® Fastrach™ Single Use size 5	135150	R010201	Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II, Zon Perdagangan Bebas, 30020 Ipoh, Perak, Malaysia	12 December 2014
08019020000 00000000009 9L5	LMA® Fastrach™ ETT size 6	131060	R0103	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000009 9L5	LMA® Fastrach™ ETT size 6.5	131065	R0103	Arrow Medical Ltd. Hatton Garden Industrial Estate,	12 December 2014

				Kington, Hereford, HR5 3RB, United Kingdom	
08019020000 00000000009 9L5	LMA® Fastrach™ ETT size 7	131070	R0103	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000009 9L5	LMA® Fastrach™ ETT size 7.5	131075	R0103	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000009 9L5	LMA® Fastrach™ ETT size 8	131080	R0103	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000010 0JV	LMA® Proseal™ size 1	150010	R010201	Parker Hannifin CSS Merrillville 1201 East 86th Place, Merrillville, IN, 46410, United States	12 December 2014
08019020000 00000000010 0JV	LMA® Proseal™ size 1.5	150015	R010201	Parker Hannifin CSS Merrillville 1201 East 86th Place, Merrillville, IN, 46410, United States	12 December 2014
08019020000 00000000010 0JV	LMA® Proseal™ size 2	150020	R010201	Parker Hannifin CSS Merrillville 1201 East 86th Place, Merrillville, IN, 46410, United States	12 December 2014
08019020000 00000000010 0JV	LMA® Proseal™ size 2.5	150025	R010201	Parker Hannifin CSS Merrillville 1201 East 86th Place, Merrillville, IN, 46410, United States	12 December 2014
08019020000 00000000010 0JV	LMA® Proseal™ size 3	150030	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000010 0JV	LMA® Proseal™ size 4	150040	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014

08019020000 00000000010 0JV	LMA® Proseal™ size 5	150050	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000021 2K9	LMA® Classic™size 1	100010	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000021 2K9	LMA® Classic™ size 1.5	100015	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000021 2K9	LMA® Classic™ size 2	100020	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000021 2K9	LMA® Classic™ size 2.5	100025	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000021 2K9	LMA® Classic™ size 3	100030	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000021 2K9	LMA® Classic™ size 4	100040	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000021 2K9	LMA® Classic™ size 5	100050	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000021 2K9	LMA® Classic™ size 6	100060	R010201	Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe, Seychelles	12 December 2014
08019020000 00000000013 8KN	LMA® Fastrach™ size 3	130030	R010201	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000013 8KN	LMA® Fastrach™ size 4	130040	R010201	Arrow Medical Ltd. Hatton Garden Industrial Estate,	12 December 2014

				Kington, Hereford, HR5 3RB, United Kingdom	
08019020000 00000000013 8KN	LMA® Fastrach™ size 5	130050	R010201	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000014 0K9	LMA® Flexible™ size 2	110020	R010201	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000014 0K9	LMA® Flexible™ size 2.5	110025	R010201	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000014 0K9	LMA® Flexible™ size 3	110030	R010201	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000014 0K9	LMA® Flexible™ size 4	110040	R010201	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000014 0K9	LMA® Flexible™ size 5	110050	R010201	Arrow Medical Ltd. Hatton Garden Industrial Estate, Kington, Hereford, HR5 3RB, United Kingdom	12 December 2014
08019020000 00000000014 0K9	LMA® Flexible™ size 6	110060	R010201	Parker Hannifin CSS Merrillville 1201 East 86th Place, Merrillville, IN, 46410, United States	12 December 2014
08019020000 00000000010 1JX	LMA® Protector™ size 3	195030	R010201	The Laryngeal Mask Company (M) Sdn. Bhd	12 December 2014

				Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	
08019020000 00000000010 1JX	LMA® Protector™ size 4	195040	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	12 December 2014
08019020000 00000000010 1JX	LMA® Protector™ size 5	195050	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	12 December 2014
08019020000 00000000010 1JX	LMA® Protector™ Cuff Pilot™ size 3	192030	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	23 November 2015
08019020000 00000000010 1JX	LMA® Protector™ Cuff Pilot™ size 4	192040	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	23 November 2015
08019020000 00000000010 1JX	LMA® Protector™ Cuff Pilot™ size 5	192050	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	23 November 2015
08019020000 00000000021 3KB	LMA® Supreme™ size 1	175010	R010201	The Laryngeal Mask Company (M) Sdn. Bhd	06 november 2015

				Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	
08019020000 00000000021 3KB	LMA® Supreme™ size 1.5	175015	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	08 March 2016
08019020000 00000000021 3KB	LMA® Supreme™ size 2	175020	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	17 December 2015
08019020000 00000000021 3KB	LMA® Supreme™ size 2.5	175025	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	23 March 2016
08019020000 00000000021 3KB	LMA® Supreme™ size 3	175030	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	12 December 2014
08019020000 00000000021 3KB	LMA® Supreme™ size 4	175040	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	12 December 2014
08019020000 00000000021 3KB	LMA® Supreme™ size 5	175050	R010201	The Laryngeal Mask Company (M) Sdn. Bhd	12 December 2014

				Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) size 1	105300-000010	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) size 1.5	105300-000015	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) size 2	105300-000020	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) size 2.5	105300-000025	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) size 3	105300-000030	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) size 4	105300-000040	R010201	The Laryngeal Mask Company (M) Sdn. Bhd	11 June 2010

				Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	
08019020000 00000000021 4KD	LMA® Unique™ (Silicone Cuff) size 5	105300-000050	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000 00000000021 4KD	LMA® Unique™ (Silicone Cuff) size 6	105300-000060	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000 00000000021 4KD	LMA® Unique™ (Silicone Cuff) Cuff Pilot™ size 1	105200-000010	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000 00000000021 4KD	LMA® Unique™ (Silicone Cuff) Cuff Pilot™ size 1.5	105200-000015	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000 00000000021 4KD	LMA® Unique™ (Silicone Cuff) Cuff Pilot™ size 2	105200-000020	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000 00000000021 4KD	LMA® Unique™ (Silicone Cuff) Cuff Pilot™ size 2.5	105200-000025	R010201	The Laryngeal Mask Company (M) Sdn. Bhd	11 June 2010

				Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia, Kedah, Malaysia	
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) Cuff Pilot™ size 3	105200-000030	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) Cuff Pilot™ size 4	105200-000040	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) Cuff Pilot™ size 5	105200-000050	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000000000021 4KD	LMA® Unique™ (Silicone Cuff) Cuff Pilot™ size 6	105200-000060	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	11 June 2010
08019020000000000021 5KF	LMA® Flexible PreCurved™ size 2	1B5020	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	07 December 2016
08019020000000000021 5KF	LMA® Flexible PreCurved™ size 2.5	1B5025	R010201	The Laryngeal Mask Company (M) Sdn. Bhd	07 December 2016

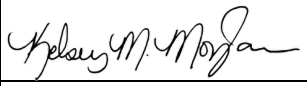
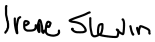
				Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	
08019020000 00000000021 5KF	LMA® Flexible PreCurved™ size 3	1B5030	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	07 December 2016
08019020000 00000000021 5KF	LMA® Flexible PreCurved™ size 4	1B5040	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	07 December 2016
08019020000 00000000021 5KF	LMA® Flexible PreCurved™ size 5	1B5050	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	07 December 2016
08019020000 00000000021 5KF	LMA® Flexible PreCurved™ Cuff Pilot™ size 2	1B2020	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	07 December 2016
08019020000 00000000021 5KF	LMA® Flexible PreCurved™ Cuff Pilot™ size 2.5	1B2025	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	07 December 2016
08019020000 00000000021 5KF	LMA® Flexible PreCurved™ Cuff Pilot™ size 3	1B2030	R010201	The Laryngeal Mask Company (M) Sdn. Bhd	07 December 2016

				Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	
08019020000 00000000021 5KF	LMA® Flexible PreCurved™ Cuff Pilot™ size 4	1B2040	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	07 December 2016
08019020000 00000000021 5KF	LMA® Flexible PreCurved™ Cuff Pilot™ size 5	1B2050	R010201	The Laryngeal Mask Company (M) Sdn. Bhd Lot 19, Jalan Hi-Tech 3, Zon Industri Fasa 1, Kulim Hi-Tech Park, Kedah, 09090 Malaysia	07 December 2016
08019020000 00000000014 1KB	LMA® Flexible™ Single Use size 2	115020	R010201	Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II, Zon Perdagangan Bebas, 30020 Ipoh, Perak, Malaysia	12 December 2014
08019020000 00000000014 1KB	LMA® Flexible™ Single Use size 2.5	115025	R010201	Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II, Zon Perdagangan Bebas, 30020 Ipoh, Perak, Malaysia	12 December 2014
08019020000 00000000014 1KB	LMA® Flexible™ Single Use size 3	115030	R010201	Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II, Zon Perdagangan Bebas, 30020 Ipoh, Perak, Malaysia	12 December 2014
08019020000 00000000014 1KB	LMA® Flexible™ Single Use size 4	115040	R010201	Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II, Zon Perdagangan Bebas, 30020 Ipoh, Perak, Malaysia	12 December 2014

08019020000 00000000014 1KB	LMA® Flexible™ Single Use size 5	115050	R010201	Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II, Zon Perdagangan Bebas, 30020 Ipoh, Perak, Malaysia	12 December 2014

** Indicates the item is within the scope of and in compliance with European Directive 2011/65/EU, the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment.*

Approvals

Name and Title of Approver:	**Kelsey Moylan** **Senior Manager, Regulatory Affairs**
Signature of Approver:	
Date Approved:	**22-Nov-2023**
Place of Issue:	**Morrisville, North Carolina, USA**
Name and Title of Approver:	**Irene Slevin** **Manager, Quality Systems**
Signature of Approver:	
Date Approved:	**22-Nov-2023**
Place of Issue:	**Athlone, Ireland**

Change History for Declaration of Conformity:

Revision	Date	Reason for Revision
00	See Agile	Initial release of EU MDR Declaration of Conformity