

	<u>Quality Record</u>	FRM0079    Rev: AD
	<b>Declaration of Conformity Form</b>	DC0015    Rev. AG
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**Legal Manufacturer Name:**  
Teleflex Medical

**Subcontractor Site Name:**  
Tianjin Medis Medical Device Co. Ltd.

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

**Address:**  
10-A Tianzhi Industrial Center  
No. 12 Hong Yuan Road,  
Xiqing Economic Development Area,  
300385 Tianjin City  
People's Republic of China

**Notified Body:** BSI

**Notified Body Number:** CE0086

Product Name	Product Classification	Classification Rule	Conformity Pathway	CE Certificate Number	Design Certificate Number
LMA Unique™ (Silicone Cuff)	IIa	Rule 5	Annex II.3	CE 540595	N/A
LMA Unique™ (Silicone Cuff) Cuff Pilot™	IIa	Rule 5	Annex II.3	CE 540595	N/A
SureSeal Laryngeal Mask	IIa	Rule 5	Annex II.3	CE 540595	N/A

Teleflex Medical declares that above documented product(s) meets the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC. The declaration authorizes Teleflex Medical to affix the CE-marking to the products listed herein.



**Print Name:** Ann Murray  
**Title:** QA Director for QS & Distribution, International

*Annex II / FEB / 2016*  
**Place and Date of Issue**

**Approvals**

Function <small>(Print Function Titles)</small>	Approval	Date
Originator	Michael Conneally	Per FRM0001 COF1385
Quality Systems	Ida Foley	Per FRM0001 COF1385
Regulatory Affairs (RA) and Quality Engineering (QE)	Jillian Connery	Per FRM0001 COF1385

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**Change History for Declaration of Conformity:**

COF#	Revision	Date	Reason for Revision
COF0101	AA	27 April 2010	Initial Release
COF0179	AB	13 Sept 2010	Update to include additional Laryngeal Mask product codes for reusable products.
COF0190	AC	29-Oct-2010	Update to clarify typo error for referencing the classification rule under the conformity pathway section and clarify subcontractor address in line with CE Certificate address.
COF 0336	AD	17 – May-2011	Update to correct the header description of the Reinforced Laryngeal mask with cuff pilot balloon 100% silicone. Changing the description “standard” with “Cuff”. Removal of Date and reference to date in CE Certificate Number section. Update the Teleflex Medical Logo to Teleflex.
COF1224	AE	04-September-2015	Updated to change product names for 105200 and 105300 product codes. Form also updated to align with FRM0079 format, addresses updated and approver name updated.
COF1234	AF	08-Sep-2015	Updated to add SureSeal Laryngeal Mask product name on page 1.
COF1385	AG	11 February 2016	Bring form to current revision.

**Change History for FRM0079:**

COF#	Revision	Date	Reason for Revision
0824	AC	23 <sup>rd</sup> April 2013	Update to provide more detail in Teleflex Medical Address as per regulatory requirements and introduction of change history table for FRM0079
1366	AD	12 <sup>th</sup> January 2016	Update to include notified body and notified body number, Change “Manufacturing Site Name” to “Subcontractor Site Name”, Added “Manufacturing Site & Address” column to attachment 1.

**Attachment 1 to Declaration of Conformity**

Product Name	Size	Product Code	Manufacturing Site & Address	Date CE Mark Affixed by Teleflex Medical
<b>LMA Unique™ (Silicone Cuff) Cuff Pilot™ – 105200-0000xx</b>				
LMA Unique™ (Silicone Cuff) Cuff Pilot™	1	105200-000010	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road,	11 June 2010

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			Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	
LMA Unique™ (Silicone Cuff) Cuff Pilot™	1.5	105200-000015	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff) Cuff Pilot™	2	105200-000020	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff) Cuff Pilot™	2.5	105200-000025	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff) Cuff Pilot™	3	105200-000030	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of	11 June 2010

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			China	
LMA Unique™ (Silicone Cuff) Cuff Pilot™	4	105200-000040	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff) Cuff Pilot™	5	105200-000050	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff) Cuff Pilot™	6	105200-000060	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
<b>LMA Unique™ (Silicone Cuff) – 105300-0000xx</b>				
LMA Unique™ (Silicone Cuff)	1	105300-000010	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff)	1.5	105300-000015	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial	11 June 2010

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			Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	
LMA Unique™ (Silicone Cuff)	2	105300-000020	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff)	2.5	105300-000025	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff)	3	105300-000030	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff)	4	105300-000040	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development	11 June 2010

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			Area, 300385 Tianjin City People's Republic of China	
LMA Unique™ (Silicone Cuff)	5	105300-000050	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
LMA Unique™ (Silicone Cuff)	6	105300-000060	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
<b>SureSeal Single Use Laryngeal Mask with Cuff Pilot Balloon 100% Silicone – 105210-0000xx</b>				
Sure Seal Single Use Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	1	105210-000010	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	1.5	105210-000015	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010

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Sure Seal Single Use Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	2	105210-000020	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	2.5	105210-000025	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	3	105210-000030	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	4	105210-000040	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	5	105210-000050	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan	11 June 2010

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			Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	
Sure Seal Single Use Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	6	105210-000060	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
<b>SureSeal Single Use Laryngeal Mask with Standard Pilot Balloon 100% Silicone – 105310-0000xx</b>				
Sure Seal Single Use Laryngeal Mask with Standard Pilot Balloon 100% Silicone	1	105310-000010	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Standard Pilot Balloon 100% Silicone	1.5	105310-000015	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Standard Pilot Balloon 100% Silicone	2	105310-000020	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area,	11 June 2010



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			300385 Tianjin City People's Republic of China	
Sure Seal Single Use Laryngeal Mask with Standard Pilot Balloon 100% Silicone	2.5	105310-000025	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Standard Pilot Balloon 100% Silicone	3	105310-000030	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Standard Pilot Balloon 100% Silicone	4	105310-000040	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Standard Pilot Balloon 100% Silicone	5	105310-000050	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Laryngeal Mask with Standard Pilot Balloon	6	105310-000060	Tianjin Medis Medical Device Co. Ltd.	11 June 2010

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100% Silicone			10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	
<b>SureSeal Single Use Reinforced Laryngeal Mask with Cuff Pilot Balloon 100% Silicone – 105220-0000xx</b>				
Sure Seal Single Use Reinforced Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	1	105220-000010	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	1.5	105220-000015	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	2	105220-000020	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	2.5	105220-000025	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road,	11 June 2010

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			Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	
Sure Seal Single Use Reinforced Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	3	105220-000030	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	4	105220-000040	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	5	105220-000050	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with Cuff Pilot Balloon 100% Silicone	6	105220-000060	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010

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			China	
<b>SureSeal Single Use Reinforced Laryngeal Mask with standard Pilot Balloon 100% Silicone – 105320-0000xx</b>				
Sure Seal Single Use Reinforced Laryngeal Mask with standard Pilot Balloon 100% Silicone	1	105320-000010	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with standard Pilot Balloon 100% Silicone	1.5	105320-000015	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with standard Pilot Balloon 100% Silicone	2	105320-000020	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with standard Pilot Balloon 100% Silicone	2.5	105320-000025	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with standard Pilot	3	105320-000030	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial	11 June 2010

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Balloon 100% Silicone			Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	
Sure Seal Single Use Reinforced Laryngeal Mask with standard Pilot Balloon 100% Silicone	4	105320-000040	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with standard Pilot Balloon 100% Silicone	5	105320-000050	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
Sure Seal Single Use Reinforced Laryngeal Mask with standard Pilot Balloon 100% Silicone	6	105320-000060	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	11 June 2010
<b>SureSeal Reusable Laryngeal Mask, 100% Silicone – 105000-0000xx</b>				
Sure Seal Reusable Laryngeal Mask 100% Silicone	1	105000-000010	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic	13 <sup>th</sup> September 2010

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			Development Area, 300385 Tianjin City People's Republic of China	
Sure Seal Reusable Laryngeal Mask 100% Silicone	1.5	105000-000015	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone	2	105000-000020	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone	2.5	105000-000025	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone	3	105000-000030	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010

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Sure Seal Reusable Laryngeal Mask 100% Silicone	4	105000-000040	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone	5	105000-000050	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone	6	105000-000060	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
<b>SureSeal Reusable Laryngeal Mask, 100% Silicone Reinforced – 105010-0000xx</b>				
Sure Seal Reusable Laryngeal Mask 100% Silicone Reinforced	1	105010-000010	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone Reinforced	1.5	105010-000015	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center	13 <sup>th</sup> September 2010

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			No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	
Sure Seal Reusable Laryngeal Mask 100% Silicone Reinforced	2	105010-000020	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone Reinforced	2.5	105010-000025	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone Reinforced	3	105010-000030	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone Reinforced	4	105010-000040	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area,	13 <sup>th</sup> September 2010



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			300385 Tianjin City People's Republic of China	
Sure Seal Reusable Laryngeal Mask 100% Silicone Reinforced	5	105010-000050	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010
Sure Seal Reusable Laryngeal Mask 100% Silicone Reinforced	6	105010-000060	Tianjin Medis Medical Device Co. Ltd. 10-A Tianzhi Industrial Center No. 12 Hong Yuan Road, Xiqing Economic Development Area, 300385 Tianjin City People's Republic of China	13 <sup>th</sup> September 2010

