

Document #:	DC0019
Revision #:	AC
COF #:	2495

## Declaration of Conformity Form

**Legal Manufacturer Name:**  
Teleflex Medical

**Subcontractor Site Name:**  
Foremount Enterprise Co., Ltd

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

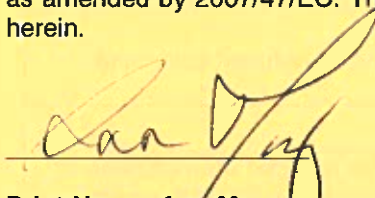
**Address:**  
No. 17, Alley 15, Lane 5, Shenan Street,  
Shengang Hsiang,  
Taichung, 42944 Taiwan ROC

**Notified Body:** BSI

**Notified Body Number:** CE 2797

Product Name	Product Classification	Classification Rule	Conformity Pathway	CE Certificate Number	Design Certificate Number
Guedel Airway (sterile)	Is	Annex IX Rule 5.2	Annex V	540596	N/A
Guedel Airway (non-sterile)	I	Annex IX Rule 5.2	Annex VII	N/A	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:** VP Global Distribution & Quality Systems

ATHLONE 16 May 2019  
IRELAND Place and Date of Issue

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Template # ATH-FRM0079	Revision: 00	Issue Date: See Agile	Parent Document: ATH-WI0083
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**Approvals**

Function [Print Function Titles]	Approval	Date
Originator	Jeanette Kelly	See COF 2495
Quality Systems	Ida Foley	See COF 2495
Regulatory Affairs (RA) and Quality Engineering (QE)	Sinead Egan	See COF 2495

**Change History for Declaration of Conformity:**

COF#	Revision	Date	Reason for Revision
825	AA	23 <sup>rd</sup> April 2013	Initial Release
1385	AB	11 February 2016	Bring form to current revision.
2495	AE	13 June 2019 <i>AP 13 June 2019</i>	Change Notified Body number from 0086 to 2797.

**Change History for ATH-FRM0079:**

Change Order Number	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.
DCO-035047	00	SEE AGILE	Upload to AGILE
DCO-036090	01	See Agile	Notified body number to be updated from CE0086 to CE2797. Header and footer to be updated to align with Global form.

**Attachment 1 to Declaration of Conformity**

Product Name	Product Code	Manufacturing Site & Address	Date CE Mark Affixed by Teleflex Medical
Guedel Airway (sterile)	124900-000001	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang,	23 <sup>rd</sup> April 2013

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Template # ATH-FRM0079	Revision: 00	Issue Date: See Agile	Parent Document: ATH-WI0083
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		Taichung, 42944 Taiwan ROC	
Guedel Airway (sterile)	124900-000002	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (sterile)	124900-000003	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (sterile)	124900-000010	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (sterile)	124900-000020	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (sterile)	124900-000030	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (sterile)	124900-000040	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (sterile)	124900-000050	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124700-000001	Foremount Enterprise Co., Ltd	23 <sup>rd</sup> April 2013

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		No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	
Guedel Airway (non-sterile)	124700-000002	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124700-000003	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124700-000010	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124700-000020	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124700-000030	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124700-000040	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124700-000050	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013

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		ROC	
Guedel Airway (non-sterile)	124700-000060	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124786-000030	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124786-000040	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	124786-000050	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	672901-000002	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	672901-000003	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	672901-000010	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	672901-000020	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5,	23 <sup>rd</sup> April 2013

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		Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	
Guedel Airway (non-sterile)	672901-000030	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	672901-000040	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013
Guedel Airway (non-sterile)	672901-000050	Foremount Enterprise Co., Ltd No. 17, Alley 15, Lane 5, Shenan Street, Shengang Hsiang, Taichung, 42944 Taiwan ROC	23 <sup>rd</sup> April 2013

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