



# Declaration of Conformity

15 Hampshire St.  
Mansfield, MA 02048  
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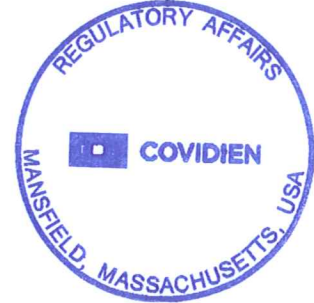
Technical File: **SDG-59**

The undersigned declares that the products named and listed on this certificate meet the provisions of the European Communities Council Directive 93/42/EEC, as amended by Directive 2007/47/EC, and the Essential Principles and classification rules according to Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, which apply to them and the CE mark may be affixed.

General Product Name: **Suction Catheters, Mucus and Specimen Traps**

Manufacturer: **Covidien llc  
15 Hampshire Street  
Mansfield, MA. 02048 USA**

EC Representative: **Covidien Ireland Limited  
IDA Business and Technology Park  
Tullamore**



Intended Use: The suction catheters and mucus traps are used for the purpose of clearing mucus, blood, meconium and other secretions from the nasal passages, mouth, trachea, and vocal chords.  
The specimen traps are used for the purpose of collecting a specimen (mucus) sample of suctionate for diagnostic purposes.

Sterility: Yes *Refer to Attached Table*

Measuring Function: No

Directive Classification: I (measuring/sterile) and IIa

In Accordance with Annex: V, VII and II

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principals, the classification rules at each stage, from the design of the device until its final inspection before being supplied, in accordance with clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

If this Declaration of Conformity contains Class I, non-sterile, non-measurement devices, it is noted that they are not regulated by TÜV SÜD P.S. and follow conformity assessment procedures set out in Annex VII, in accordance with clause 6.6 of Schedule 3 Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Date CE Marking Approved: *Refer to Attached Table* Current Standards to which Conformity is declared: *Refer to Attached Table*

Reorder codes/GMDN Codes: *Refer to Attached Table*

EC Certificate(s): *Refer to Attached Table*

Notified Body Name: TÜV SÜD Product Service GmbH Identification Number: 0123  
Ridlerst 65  
D-80339 München, Germany

Signature: *Alexis Erazo*  
Alexis Erazo, Sr. Regulatory Affairs Specialist

*10-Oct-2016*  
Date

**Products Covered By This Certificate**

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
<b>EC Certificate:</b> G1 14 11 74735 015 expires 23-Feb-2020					
<b>Class IIa</b>					
<b>Annex II</b>					
1180250001	Argyle™ Aero Flow Suction Catheter, Funnel End with Undulated Tip, 10 Fr/Ch (3.33 mm) x 20-7/8" (53 cm)	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250019	Argyle™ Aero Flow Suction Catheter, Funnel End with Undulated Tip, 12 Fr/Ch (4.0 mm) x 53 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250027	Argyle™ Aero Flow Suction Catheter, Funnel End with Undulated Tip, 14 Fr/Ch (4.67 mm) x 53 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250068	Argyle™ Aero Jet Suction Catheter, Funnel End with Undulated Tip, 12 Fr/Ch (4.0 mm) x 51 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250076	Argyle™ Aero Jet Suction Catheter, Funnel End with Undulated Tip, 14 Fr/Ch (4.67 mm) x 51 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250159	Argyle™ Aero Flow Suction Catheter, Vacuum Control, 16 Fr/Ch (5.33 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250415	Argyle™ Aero Flow Suction Catheter, Funnel End, 8 Fr/Ch (2.67 mm) x 48 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011

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1180250423	Argyle™ Aero Flow Suction Catheter, Funnel End, 10 Fr/Ch (3.33 mm) x 48 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250431	Argyle™ Aero Flow Suction Catheter, Funnel End, 12 Fr/Ch (4.0 mm) x 48 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250449	Argyle™ Aero Flow Suction Catheter, Funnel End, 14 Fr/Ch (4.67 mm) x 48 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250456	Argyle™ Aero Flow Suction Catheter, Funnel End, 14 Fr/Ch (4.67 mm) x 63 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250464	Argyle™ Aero Flow Suction Catheter, Funnel End, 16 Fr/Ch (5.33 mm) x 48 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250472	Argyle™ Aero Flow Suction Catheter, Funnel End, 16 Fr/Ch (5.33 mm) x 63 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250514	Argyle™ Aero Flow Suction Catheter, Vacuum Control with Undulated Tip, 12 Fr/Ch (4.0 mm) x 53 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011

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1180250522	Argyle™ Aero Flow Suction Catheter, Vacuum Control with Undulated Tip, 14 Fr/Ch (4.67 mm) x 53 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250563	Argyle™ Aero Jet Suction Catheter, Vacuum Control with Undulated Tip, 12 Fr/Ch (4.0 mm) x 49 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250571	Argyle™ Aero Jet Suction Catheter, Vacuum Control with Undulated Tip, 14 Fr/Ch (4.67 mm) x 47 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250605	Argyle™ Aero Flow Suction Catheter, Control Valve, 14 Fr/Ch (4.67 mm) x 30 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250738	Argyle™ Aero Jet Suction Catheter, Vacuum Control, 12 Fr/Ch (4.0 mm) x 47 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250746	Argyle™ Aero Jet Suction Catheter, Vacuum Control, 14 Fr/Ch (4.67 mm) x 47 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250753	Argyle™ Aero Jet Suction Catheter, Vacuum Control, 16 Fr/Ch (5.33 mm) x 47 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011

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1180250811	Argyle™ Aero Flow Suction Catheter, Coudé Tip, 8 Fr/Ch (2.67 mm) x 40 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250829	Argyle™ Aero Flow Suction Catheter, Coudé Tip, 10 Fr/Ch (3.33 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250837	Argyle™ Aero Flow Suction Catheter, Coudé Tip, 12 Fr/Ch (4.0 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250845	Argyle™ Aero Flow Suction Catheter, Coudé Tip, 14 Fr/Ch (4.67 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250852	Argyle™ Aero Flow Suction Catheter, Coudé Tip, 16 Fr/Ch (5.33 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250860	Argyle™ Aero Flow Suction Catheter, Coudé Tip, 14 Fr/Ch (4.67 mm) x 65 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250928	Argyle™ Aero Jet Suction Catheter, Funnel End, 10 Fr/Ch (3.33 mm) x 47 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011

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1180250936	Argyle™ Aero Jet Suction Catheter, Funnel End, 12 Fr/Ch (4.0 mm) x 47 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250944	Argyle™ Aero Jet Suction Catheter, Funnel End, 14 Fr/Ch (4.67 mm) x 47 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180250951	Argyle™ Aero Jet Suction Catheter, Funnel End, 16 Fr/Ch (5.33 mm) x 47 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180251158	Argyle™ Aero Flow Suction Catheter, Tapered End, 16 Fr/Ch (5.33 mm) x 19 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180251736	Argyle™ Aero Flow Suction Catheter, Vacuum Control with Coudé Tip, 10 Fr/Ch (3.33 mm) x 51 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180251744	Argyle™ Aero Flow Suction Catheter, Vacuum Control with Coudé Tip, 12 Fr/Ch (4.0 mm) x 52 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180251751	Argyle™ Aero Flow Suction Catheter, Vacuum Control with Coudé Tip, 14 Fr/Ch (4.67 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011

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1180251769	Argyle™ Aero Flow Suction Catheter, Vacuum Control with Coudé Tip, 16 Fr/Ch (5.33 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180251801	Argyle™ Paediatric Suction Catheter, Vacuum Control, 5 Fr/Ch (1.7 mm) x 24 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180251819	Argyle™ Paediatric Suction Catheter, Vacuum Control, 6 Fr/Ch (2.0 mm) x 24 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180251827	Argyle™ Paediatric Suction Catheter, Vacuum Control, 8 Fr/Ch (2.67 mm) x 29 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180256420	Argyle™ Paediatric Suction Catheter, Tapered End, 8 Fr/Ch (2.67 mm) x 32 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180256438	Argyle™ Paediatric Suction Catheter, Tapered End, 10 Fr/Ch (3.33 mm) x 32 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180830067	Argyle™ Suction Catheter, Tapered End, 6 Fr/Ch (2.0 mm) x 39 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011

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1180830083	Argyle™ Suction Catheter, Tapered End, 8 Fr/Ch (2.67 mm) x 39 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180830109	Argyle™ Suction Catheter, Tapered End, 10 Fr/Ch (3.33 mm) x 44 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180830125	Argyle™ Suction Catheter, Tapered End, 12 Fr/Ch (4.0 mm) x 44 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180830141	Argyle™ Suction Catheter, Tapered End, 14 Fr/Ch (4.67 mm) x 44 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180830166	Argyle™ Suction Catheter, Tapered End, 16 Fr/Ch (5.33 mm) x 44 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180830182	Argyle™ Suction Catheter, Tapered End, 18 Fr/Ch (6.0 mm) x 44 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180832089	Argyle™ Suction Catheter, Tapered End, 8 Fr/Ch (2.67 mm) x 39 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011



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1180832121	Argyle™ Suction Catheter, Tapered End, 12 Fr/Ch (4.0 mm) x 44 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180832147	Argyle™ Suction Catheter, Tapered End, 14 Fr/Ch (4.67 mm) x 44 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180833723	Argyle™ Suction Catheter, Mercy Metras, 12 Fr/Ch (4.0 mm) x 51 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180833756	Argyle™ Suction Catheter, Mercy Metras, 15 Fr/Ch (5.0 mm) x 51 cm (Obsolete per C*73420 6/16/2014)	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180851055	Argyle™ Paediatric Suction Catheter, Vacuum Control, 5 Fr/Ch (1.67 mm) x 30 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180851063	Argyle™ Suction Catheter, Vacuum Control, 6 Fr/Ch (2.0 mm) x 44 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180851071	Argyle™ Paediatric Suction Catheter, Vacuum Control, 6 Fr/Ch (2.0 mm) x 30 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011

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<b>Class IIa</b> <span style="float: right;"><b>Annex II</b></span>					
1180851089	Argyle™ Suction Catheter, Vacuum Control, 8 Fr/Ch (2.67 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180851097	Argyle™ Paediatric Suction Catheter, Vacuum Control, 8 Fr/Ch (2.67 mm) x 30 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
1180851105	Argyle™ Suction Catheter, Vacuum Control, 10 Fr/Ch (3.33 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180851121	Argyle™ Suction Catheter, Vacuum Control, 12 Fr/Ch (4.0 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180851147	Argyle™ Suction Catheter, Vacuum Control, 14 Fr/Ch (4.67 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180851162	Argyle™ Suction Catheter, Vacuum Control, 16 Fr/Ch (5.33 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180851188	Argyle™ Suction Catheter, Vacuum Control, 18 Fr/Ch (6.0 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011

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1180853069	Argyle™ Suction Catheter, Moulded Funnel, 6 Fr/Ch (2.0 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180853085	Argyle™ Suction Catheter, Moulded Funnel, 8 Fr/Ch (2.67 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180853101	Argyle™ Suction Catheter, Moulded Funnel, 10 Fr/Ch (3.33 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180853127	Argyle™ Suction Catheter, Moulded Funnel, 12 Fr/Ch (4.0 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180853143	Argyle™ Suction Catheter, Moulded Funnel, 14 Fr/Ch (4.67 mm), 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180853168	Argyle™ Suction Catheter, Moulded Funnel, 16 Fr/Ch (5.33 mm), 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
1180853184	Argyle™ Suction Catheter, Moulded Funnel, 18 Fr/Ch (6.0 mm), 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011

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2051	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, 5 Fr/Ch (1.67 mm) x 39 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2058	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, 5 Fr/Ch (1.67 mm) x 39 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2061	Argyle™ Catheter Gentle Flow Suction, Vacuum Control, 6 Fr/Ch (2.0 mm) x 39 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2068	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, 6 Fr/Ch (2.0 mm) x 39 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2081	Argyle™ Suction Catheter, Vacuum Control, 8 Fr/Ch (2.67 mm) x 39 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2088	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, 8 Fr/Ch (2.67 mm) x 39 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2101L	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, Long, 10 Fr/Ch (3.33 mm) x 61 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011

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2108	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, 10 Fr/Ch (3.33 mm) x 50 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2108L	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, Long, 10 Fr/Ch (3.33 mm) x 61 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2121	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, 12 Fr/Ch (4.0 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2121L	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, Long, 12 Fr/Ch (4.0 mm) x 61 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2128	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, 12 Fr/Ch (4.0 mm) x 50 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2128L	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, Long, 12 Fr/Ch (4.0 mm) x 61 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2141	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, 14 Fr/Ch (4.67 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011

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2141L	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, Long, 14 Fr/Ch (4.67 mm) x 61 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2148	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, 14 Fr/Ch (4.67 mm) x 50 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2148L	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, Long, 14 Fr/Ch (4.67 mm) x 61 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2161	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, 16 Fr/Ch (5.33 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2161L	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, Long, 16 Fr/Ch (5.33 mm) x 61 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2168	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, 16 Fr/Ch (5.33 mm) x 50 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2168L	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, Long, 16 Fr/Ch (5.33 mm) x 61 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011

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2181	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, 18 Fr/Ch (6.0 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2181L	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, Long, 18 Fr/Ch (6.0 mm) x 61 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
2188	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, 18 Fr/Ch (6.0 mm) x 50 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
2188L	Argyle™ Gentle Flow Suction Catheter, Moulded Funnel, Long, 18 Fr/Ch (6.0 mm) x 61 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888250092	Argyle™ Aero Flow Suction Catheter, Vacuum Control, 5 Fr/Ch (1.67 mm) x 35 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888250118	Argyle™ Aero Flow Suction Catheter, Vacuum Control, 8 Fr/Ch (2.67 mm) x 40 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888250126	Argyle™ Aero Flow Suction Catheter, Vacuum Control, 10 Fr/Ch (3.33 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011

**Products Covered By This Certificate**

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
<b>EC Certificate:</b> G1 14 11 74735 015 expires 23-Feb-2020					
<b>Class IIa</b>					
<b>Annex II</b>					
8888250134	Argyle™ Aero Flow Suction Catheter, Vacuum Control, 12 Fr/Ch (4.0 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888250142	Argyle™ Aero Flow Suction Catheter, Vacuum Control, 14 Fr/Ch (4.67 mm) x 52 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888250217	Argyle™ Suction Catheter, Vacuum Control, 10 Fr/Ch (3.33 mm) x 54 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888250233	Argyle™ Suction Catheter, Vacuum Control, 18 Fr/Ch (6.0 mm) x 54 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888251058	Argyle™ Aero Flow Suction Catheter, Tapered End, 14 Fr/Ch (4.67 mm) x 49 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888251215	Argyle™ Suction Catheter, Tapered End, 10 Fr/Ch (3.33 mm) x 54 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888256016	Argyle™ Paediatric Suction Catheter, Cuffed Vacuum Control, 5 Fr/Ch (1.67 mm) x 32 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011



**Products Covered By This Certificate**

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
<b>EC Certificate:</b> G1 14 11 74735 015 expires 23-Feb-2020					
<b>Class IIa</b>					
<b>Annex II</b>					
8888256024	Argyle™ Paediatric Suction Catheter, Cuffed Vacuum Control, 8 Fr/Ch (1.67 mm) x 32 cm	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888256503	Argyle™ Replogle Suction Catheter, 10 Fr/Ch (3.3 mm) x 24" (61 cm)	EO	Catheter, suction, general-purpose [34923]	5	7/11/2011
8888257360	Argyle™ Mucus Trap with Vacuum Breaker, 10 Fr/Ch (3.33 mm), Catheter, 20 ml	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	2/25/1999
8888257378	Argyle™ Mucus Trap with Vacuum Breaker, 8 Fr/Ch (2.67 mm), Catheter, 20 mL	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	2/25/1999
8888257386	Argyle™ Mucus Trap with Vacuum Breaker, 6.5 Fr/Ch (2.2 mm), Catheter, 20 mL	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	2/25/1999
8888257469	Argyle™ Mucus Trap with Vacuum Breaker and Filter, 10 Fr/Ch (3.33 mm), Catheter, 20 mL	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	2/25/1999
8888257477	Argyle™ Mucus Trap with Vacuum Breaker and Filter, 8 Fr/Ch (2.67 mm), Catheter, 20 mL	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	2/25/1999

**Products Covered By This Certificate**

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
<b>EC Certificate:</b> G1 14 11 74735 015 expires 23-Feb-2020					
<b>Class IIa</b>					
<b>Annex II</b>					
8888257485	Argyle™ Mucus Trap with Vacuum Breaker and Filter, 6.5 Fr/Ch (2.2 mm), Catheter, 20 mL	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	2/25/1999
8888257527	Argyle™ Suction Catheter with Mucus Trap, 20 mL, 10 Fr/Ch (3.33 mm)	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	2/25/1999
8888257535	Argyle™ Suction Catheter with Mucus Trap, 20 mL, 8 Fr/Ch (2.67 mm)	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	2/25/1999
8888257550	Argyle™ Suction Catheter with Mucus Trap, 20 mL 6.5 Fr/Ch (2.2 mm),	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	2/25/1999
STC0520	Argyle™ Suction Control Tube, 5 Fr/Ch (1.67 mm) x 19-5/8" (50 cm)	Gamma	Catheter, suction/insufflation, tracheobronchial [31249]	5	1/8/2010
STC0620	Argyle™ Suction Control Tube, 6 Fr/Ch (2.0 mm) x 19-5/8" (50 cm)	Gamma	Catheter, suction/insufflation, tracheobronchial [31249]	5	1/8/2010
STC0820	Argyle™ Suction Control Tube, 8 Fr/Ch (2.67 mm) x 19-5/8" (50 cm)	Gamma	Catheter, suction/insufflation, tracheobronchial [31249]	5	1/8/2010

**Products Covered By This Certificate**

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
<b>EC Certificate:</b> G1 14 11 74735 015 expires 23-Feb-2020					
<b>Class IIa Annex II</b>					
STC1020	Argyle™ Suction Control Tube, 10 Fr/Ch (3.33 mm) x 19-5/8" (50 cm)	Gamma	Catheter, suction/insufflation, tracheobronchial [31249]	5	1/8/2010
STC1220	Argyle™ Suction Control Tube, 12 Fr/Ch (4.0 mm) x 19-5/8" (50 cm)	Gamma	Catheter, suction/insufflation, tracheobronchial [31249]	5	1/8/2010
STC1420	Argyle™ Suction Control Tube, 14 Fr/Ch (4.67 mm) x 19-5/8" (50 cm)	Gamma	Catheter, suction/insufflation, tracheobronchial [31249]	5	1/8/2010
STC1620	Argyle™ Suction Control Tube, 16 Fr/Ch (5.33 mm) x 19-5/8" (50 cm)	Gamma	Catheter, suction/insufflation, tracheobronchial [31249]	5	1/8/2010
STC1820	Argyle™ Suction Control Tube, 18 Fr/Ch (6.0 mm) x 19-5/8" (50 cm)	Gamma	Catheter, suction/insufflation, tracheobronchial [31249]	5	1/8/2010
STC2020	Argyle™ Suction Control Tube, 20 Fr/Ch (6.7 mm) x 19-5/8" (50 cm)	Gamma	Catheter, suction/insufflation, tracheobronchial [31249]	5	1/8/2010

**EC Certificate:** G1 16 07 74735 037 expires 20-Sep-2021

**Products Covered By This Certificate**

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
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**EC Certificate:** G1 16 07 74735 037 expires 20-Sep-2021

<b>Class IIa</b>	<b>Annex II</b>
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2101	Argyle™ Gentle Flow Suction Catheter, Vacuum Control, 10 Fr/Ch (3.33 mm) x 50 cm	EO	Catheter, suction/insufflation, tracheobronchial [31249]	5	4/25/2011
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**EC Certificate:** G2S 15 02 74735 025 expires 23-Feb-2020

<b>Class I (measuring/sterile)</b>	<b>Annex V and VII</b>
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8884724500	Argyle™ Specimen Trap, 40 mL	EO	Collector, mucus [38472]	1	2/25/1999
8884724504	Argyle™ Specimen Trap, 70 mL	EO	Collector, mucus [38472]	1	2/25/1999
8888258608	Argyle™ Lukens Specimen Container, 14 Fr/Ch (4.67 mm), 20 mL	EO	Collector, mucus [38472]	1	12/8/2008

**EC Certificate:** Self Certified

*Products Covered By This Certificate*

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
<b>EC Certificate:</b> <i>Self Certified</i>					
<b>Class I (non-sterile)</b> <b>Annex VII</b>					
8888310367	Argyle™ Specimen Adapter	Non	Unclassified [38442]	1	7/11/2011

## Standards to Which Conformity is Declared:

Standard Name:	Standard Title:	Version:
EN 556-1:2001/AC:2006	Sterilization Of Medical Devices - Requirements For Medical Devices To Be Designated "Sterile" - Part 1: Requirements For Terminally Sterilized Medical Devices	2001 COR 1 2006
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice	2011
ISO 11135-1:2007	Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices	1 ED 2007
EN ISO 11137-1:2006/A1:2013	Sterilization of Health Care Products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2006/A1:2013
EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices	2008
ISO 10993-1:2009	ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009
BS EN ISO 8836:2009	Suction Catheters for Use in the Respiratory Tract	2009
ISO 10993-7	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	2008 COR 1 2009
EN ISO 13485:2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes	2012/AC:2012

Unless otherwise indicated, full conformance to listed standards is assumed.

Standard Name:	Standard Title:	Version:
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices	2012
EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	2006
EN ISO 15223-1:2012	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements	2012

Unless otherwise indicated, full conformance to listed standards is assumed.