

Technical File: **SDG-49**

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: **Urological Catheters**

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

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



Intended Use: Foley catheters are retention catheters to drain the urine from the urine bladder. Urethral Catheters are intermittent catheters to drain the urine from the urine bladder. These catheters are used in a variety of clinical conditions such as post-surgical following urethral surgery or in conditions resulting in incontinence.

Sterility: Yes *Refer to Attached Table*

Measuring Function: No

Directive Classification: I (sterile/non-measuring), IIa and IIb

In Accordance with Annex: VII, V and II

The manufacturer has exclusive responsibility for this Declaration of Conformity.

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

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

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

Signature:   
Keith Gattozzi, Regulatory Affairs Specialist

*16-Mar-2020*  
Date

*Products Covered By This Certificate*

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
<b>EC Certificate:</b> G1 074735 0083						
<b>Class</b>	<b>Ila</b>	<b>Annex II excluding (4)</b>				
1180835124	Dover™ Intermittent PVC Urethral Catheter, Female, 12 Fr/Ch (4.0 mm) x 7-7/8" (20 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
1180835140	Dover™ Intermittent PVC Urethral Catheter, Female, 14 Fr/Ch (4.7 mm) x 7-7/8" (20 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
1180835165	Dover™ Intermittent PVC Urethral Catheter, Female, 16 Fr/Ch (5.3 mm) x 7-7/8" (20 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
1180836080	Dover™ Intermittent PVC Urethral Catheter, 8 Fr/Ch (2.7 mm) x 15-3/4" (40 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
1180836106	Dover™ Intermittent PVC Urethral Catheter, 10 Fr/Ch (3.3 mm) x 15-3/4" (40 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
1180836114	Dover™ Intermittent PVC Urethral Catheter, 10 Fr/Ch (3.3 mm) x 60 cm	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
1180836122	Dover™ Intermittent PVC Urethral Catheter, 12 Fr/Ch (4.0 mm) x 15-3/4" (40 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011

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<b>Class</b>	<b>Ila</b>	<b>Annex II excluding (4)</b>				
1180836148	Dover™ Intermittent PVC Urethral Catheter, 14 Fr/Ch (4.7 mm) x 15-3/4" (40 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
1180836163	Dover™ Intermittent PVC Urethral Catheter, 16 Fr/Ch (5.3 mm) x 15-3/4" (40 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
1180836189	Dover™ Intermittent PVC Urethral Catheter, 18 Fr/Ch (6.0 mm) x 15-3/4" (40 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
1180836205	Dover™ Intermittent PVC Urethral Catheter, 20 Fr/Ch (6.7 mm) x 15-3/4" (40 cm)	No	EO	Single-administration urethral drainage catheter [45603]	5	8/29/2011
6006	Dover™ Hydrogel Coated Urethral Catheter, 6 Fr/Ch (2.0 mm)	No	EO	Single-administration urethral drainage catheter [45603]	5	5/17/2007
NT0620	Dover™ Nelaton Urinary Catheter, Two Side Eyes, 6 Fr/Ch (2.0 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008
NT0620P	Dover™ Nelaton Urinary Catheter, Two Side Eyes, 6 Fr/Ch (2.0 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008

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<b>Class</b>	<b>Ila</b>	<b>Annex II excluding (4)</b>				
NT0820	Dover™ Nelaton Urinary Catheter Two Side Eyes, 8 Fr/Ch (2.7 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008
NT1020	Dover™ Nelaton Urinary Catheter Two Side Eyes, 10 Fr/Ch (3.3 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008
NT1220	Dover™ Nelaton Urinary Catheter Two Side Eyes, 12 Fr/Ch (4.0 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008
NT1220P	Dover™ Nelaton Urinary Catheter, Two Side Eyes, 12 Fr/Ch (4.0 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008
NT1420	Dover™ Nelaton Urinary Catheter, Two Side Eyes, 14 Fr/Ch (4.7 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008
NT1420P	Dover™ Nelaton Urinary Catheter, Two Side Eyes, 14 Fr/Ch (4.7 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008
NT1620	Dover™ Nelaton Urinary Catheter, Two Side Eyes, 16 Fr/Ch (5.3 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008

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Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
<b>EC Certificate:</b> G1 074735 0083						

Class	IIa	Annex II excluding (4)				
NT1620P	Dover™ Nelaton Urinary Catheter, Two Side Eyes, 16 Fr/Ch (5.3 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008
NT1820	Dover™ Nelaton Urinary Catheter, Two Side Eyes, 18 Fr/Ch (6.0 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008
NT2020	Dover™ Nelaton Urinary Catheter, Two Side Eyes, 20 Fr/Ch (6.7 mm) x 15-3/4" (40 cm)	No	Gamma	Single-administration urethral drainage catheter [45603]	5	8/6/2008

Class	IIb	Annex II excluding (4)				
20512C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 5 mL, 2-Way, 12 Fr/Ch (4.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
20514C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 5 mL, 2-Way, 14 Fr/Ch (4.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
20516C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 5 mL, 2-Way, 16 Fr/Ch (5.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
20518C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 5 mL, 2-Way, 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004

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<b>Class</b>	<b>IIb</b>	<b>Annex II excluding (4)</b>				
20520C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 5 mL, 2-Way, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
20522C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 5 mL, 2-Way, 22 Fr/Ch (7.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
20524C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 5 mL, 2-Way, 24 Fr/Ch (8.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
23014C	Silicone 14FR 30CC 2way Coude'	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
23018C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 30 mL, 2-Way, 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
23020C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 30 mL, 2-Way, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
23022C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 30 mL, 2-Way, 22 Fr/Ch (7.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004

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<b>Class</b>	<b>IIb</b>	<b>Annex II excluding (4)</b>				
23024C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 30 mL, 2-Way, 24 Fr/Ch (8.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
23026C	Dover™ 100% Silicone Foley Catheter, Coudé Tip, 30 mL, 2-Way, 26 Fr/Ch (8.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	11/1/2004
40516L	Dover™ 100% Silicone Foley Catheter, Council Tip, 5 mL, 2-Way, 16 Fr/Ch (5.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006
40518L	Dover™ 100% Silicone Foley Catheter, Council Tip, 5 mL, 2-Way, 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006
40520L	Dover™ 100% Silicone Foley Catheter, Council Tip, 5 mL, 2-Way, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006
40522L	Dover™ 100% Silicone Foley Catheter, Council Tip, 5 mL, 2-Way, 22 Fr/Ch (7.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006
40524L	Dover™ 100% Silicone Foley Catheter, Council Tip, 5 mL, 2-Way, 24 Fr/Ch (8.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006

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6108	Dover™ 100% Silicone Foley Catheter, 3 mL, 2-Way, Luer-Lock Adapter, 8 Fr/Ch (2.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/1/2002
8887103084	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 8 Fr/Ch (2.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887103102	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 10 Fr/Ch (3.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887105123	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 12 Fr/Ch (4.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887105149	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887105164	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887105180	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011



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8887105206	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-way, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887115122	Dover™ 100% Silicone Female Foley Catheter, 12 Fr/Ch (4.0 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887115148	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887115163	Dover™ 100% Silicone Female Foley Catheter, 5 mL, 2-Way, 16 Fr/Ch (5.3 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887205121	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 5-10 mL, 12 Fr/Ch (4.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887205147	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 5-10 mL, 14 Fr/Ch (4.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887205162	Dover™ 100% Silicone Foley Catheter Tiemann Tip, 5-10 mL, 16 Fr/Ch (5.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011

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<b>Class</b>	<b>IIb</b>	<b>Annex II excluding (4)</b>				
8887205188	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 5-10 mL, 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887205204	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 5-10 mL, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887205220	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 5-10 mL, 22 Fr/Ch (7.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887205246	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 5-10 mL, 24 Fr/Ch (8.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887230186	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 30 mL, 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887230202	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 30 mL, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887230228	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 30 mL, 22 Fr/Ch (7.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011

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Class	IIb	<i>Annex II excluding (4)</i>				
8887230244	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 30 mL, 24 Fr/Ch (8.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887230269	Dover™ 100% Silicone Foley Catheter, Tiemann Tip, 30 mL, 26 Fr/Ch (8.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887403080	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 8 Fr/Ch (2.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887403106	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 10 Fr/Ch (3.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887405127	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 12 Fr/Ch (4.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887405143	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887405168	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011

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8887405184	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887405200	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887405226	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 22 Fr/Ch (7.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887405242	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 24 Fr/Ch (8.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887415126	Dover™ 100% Silicone Foley Catheter, 5 mL, 2-Way, Female, 12 Fr/Ch (4.0 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887415142	Dover™ 100% Silicone Foley Catheter, 5 mL, 2-Way, Female, 14 Fr/Ch (4.7 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887415167	Dover™ 100% Silicone Female Foley Catheter, 5 mL, 2-Way, 16 Fr/Ch (5.3 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011

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<b>Class</b>	<b>IIb</b>	<b>Annex II excluding (4)</b>				
8887603069	Dover™ Paediatric 100% Silicone Foley Catheter, 1.5 mL, 2-Way, 6 Fr/Ch (2.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887603085	Dover™ Paediatric 100% Silicone Foley Catheter, 3 mL, 2-Way, 8 Fr/Ch (2.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887603101	Dover™ Paediatric 100% Silicone Foley Catheter, 3 mL, 2-Way, 10 Fr/Ch (3.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887605122	Dover™ 100% Silicone Foley Catheter, 5 mL, 2-Way, Retention, 12 Fr/Ch (4.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887605148	Dover™ 100% Silicone Foley Catheter, 5 mL, 2-Way, Retention, 14 Fr/Ch (4.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887605163	Dover™ 100% Silicone Foley Catheter, 5 mL, 2-Way, Retention, 16 Fr/Ch (5.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887605189	Dover™ 100% Silicone Foley Catheter, 5 mL, 2-Way, Retention, 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011

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8887605205	Dover™ 100% Silicone Foley Catheter, 5-10 mL 2-Way, Retention, 20 Fr/Ch (6.7 mm), 5 mL	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887605221	Dover™ 100% Silicone Foley Catheter, 5 mL 2-Way, Retention 22 Fr/Ch (7.3 mm), 5 mL	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887605247	Dover™ 100% Silicone Foley Catheter, 5-10 mL 2-Way, 24 Fr/Ch (8.0 mm),	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887605262	Dover™ 100% Silicone Foley Catheter, 5-10 mL 2-Way, Retention 26 Fr/Ch (8.7 mm),	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887605303	Dover™ 100% Silicone Foley Catheter, 5 mL, 2-Way, 30 Fr/Ch (10.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	10/16/2006
8887615121	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 12 Fr/Ch (4.0 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/29/2011
8887615147	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/24/2011

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<b>Class</b>	<b>IIb</b>	<b>Annex II excluding (4)</b>				
8887615162	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/24/2011
8887615188	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 18 Fr/Ch (6.0 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887630161	Dover™ 100% Silicone Foley Catheter, 20 mL 2-Way, 16 Fr/Ch (5.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887630187	Dover™ 100% Silicone Foley Catheter, 30 mL 2-Way, 18 Fr/Ch (6.0 mm),	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887630203	Dover™ 100% Silicone Foley Catheter, 30 mL 2-Way, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887630229	Dover™ 100% Silicone Foley Catheter, 30 mL 2-Way, 22 Fr/Ch (7.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011
8887630245	Dover™ 100% Silicone Foley Catheter, 30 mL 2-Way, 24 Fr/Ch (8.0 mm),	No	EO	Indwelling urethral drainage catheter [34917]	5	4/22/2011

*Products Covered By This Certificate*

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
<b>EC Certificate:</b> G1 074735 0083						
<b>Class</b>	<b>IIb</b>	<b>Annex II excluding (4)</b>				
8887664161	Dover™ 100% Silicone Foley Catheter, 5 mL 3-Way, 16 Fr/Ch (5.3 mm).	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006
8887664182	Dover™ 100% Silicone Foley Catheter, 5 mL 3-Way 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006
8887664203	Dover™ 100% Silicone Foley Catheter, 5 mL, 3-Way, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006
8887664224	Dover™ 100% Silicone Foley Catheter, 5 mL 3-Way, 22 Fr/Ch (7.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006
8887664245	Dover™ 100% Silicone Foley Catheter, 5 mL 3-Way, 24 Fr/Ch (8.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	3/17/2006
8887664266	Dover™ 100% Silicone Foley Catheter, 5 mL, 3-Way, 26 Fr/Ch (8.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	10/16/2006
8887664287	Dover™ 100% Silicone Foley Catheter, 5 mL, 3-Way, 28 Fr/Ch (9.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	10/16/2006



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<i>Class</i>	<i>IIb</i>	<i>Annex II excluding (4)</i>				
8887665183	Dover™ 100% Silicone Foley Catheter, 3-Way 18 Fr/Ch (6.0 mm), 30 mL	No	EO	Indwelling urethral drainage catheter [34917]	5	5/7/1999
8887665209	Dover™ 100% Silicone Foley Catheter, 3-Way 20 Fr/Ch (6.7 mm), 30 mL	No	EO	Indwelling urethral drainage catheter [34917]	5	5/7/1999
8887665225	Dover™ 100% Silicone Foley Catheter, 3-Way 22 Fr/Ch (7.3 mm), 30 mL	No	EO	Indwelling urethral drainage catheter [34917]	5	5/7/1999
8887665241	Dover™ 100% Silicone Foley Catheter, 3-Way 24 Fr/Ch (8.0 mm), 30 mL	No	EO	Indwelling urethral drainage catheter [34917]	5	5/7/1999
8887703083	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 8 Fr/Ch (2.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887703109	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 10 Fr/Ch (3.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887705120	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 12 Fr/Ch (4.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011

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<b>EC Certificate:</b> G1 074735 0083						
<i>Class</i>	<i>IIb</i>	<i>Annex II excluding (4)</i>				
8887705146	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887705161	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887705187	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 18 Fr/Ch (6.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887705203	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 20 Fr/Ch (6.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887715129	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 12 Fr/Ch (4.0 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887715145	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887715160	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011

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<b>Class</b>	<b>IIb</b>	<b>Annex II excluding (4)</b>				
8887715186	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 18 Fr/Ch (6.0 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887803081	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 8 Fr/Ch (2.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887803107	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 10 Fr/Ch (3.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887805128	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 12 Fr/Ch (4.0 mm) x 43 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887805144	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm) x 43 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887805169	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm) x 43 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887805185	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 18 Fr/Ch (6.0 mm) x 43 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011

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<b>Class</b>	<b>IIb</b>	<b>Annex II excluding (4)</b>				
8887805201	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 20 Fr/Ch (6.7 mm) x 43 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887805227	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 22 Fr/Ch (7.3 mm) x 43 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887815127	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 12 Fr/Ch (4.0 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887815143	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887815168	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
8887815184	Dover™ 100% Silicone Female Foley Catheter, 5-10 mL, 2-Way, 18 Fr/Ch (6.0 mm) x 25 cm	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
A887603069	Dover™ Paediatric 100% Silicone Foley Catheter, 1.5 mL, 2-Way, 6 Fr/Ch (2.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011

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<b>EC Certificate:</b> G1 074735 0083						
<b>Class</b>	<b>IIb</b>	<b>Annex II excluding (4)</b>				
A887603085	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 8 Fr/Ch (2.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/11/2011
A887603101	Dover™ Paediatric 100% Silicone Foley Catheter, 3-5 mL, 2-Way, 10 Fr/Ch (3.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/29/2011
A887605122	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 12 Fr/Ch (4.0 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/24/2011
A887605148	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/24/2011
A887605163	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm)	No	EO	Indwelling urethral drainage catheter [34917]	5	8/24/2011
NT0820P	Dover™ Foley Catheter, 8 Fr/Ch (2.7 mm)	No	Gamma	Indwelling urethral drainage catheter [34917]	5	8/6/2008
NT1020P	Dover™ Foley Catheter, 10 Fr/Ch (3.3 mm)	No	Gamma	Indwelling urethral drainage catheter [34917]	5	8/6/2008

**Products Covered By This Certificate**

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
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**EC Certificate:** G1 074735 0083

Class	IIb	Annex II excluding (4)				
NT1820P	Dover™ Foley Catheter, 18 Fr/Ch (6.0 mm)	No	Gamma	Indwelling urethral drainage catheter [34917]	5	8/6/2008
NT2020P	Dover™ Foley Catheter, 20 Fr/Ch (6.7 mm)	No	Gamma	Indwelling urethral drainage catheter [34917]	5	8/6/2008

**EC Certificate:** G2S 074735 0084

Class	I (sterile/non-measuring)	Annex VII and V				
1180342352	Dover™ Vaginal Irrigation Set with Applicator, 130 cm Tube	No	EO	Vaginal douche, reusable [32616]	5	8/29/2011