

Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 USA
Phone: +1-801-522-5000
Fax: +1-801-522-4948



Declaration of Conformity

Manufacturer's Name and Address:

Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, Utah 84116 USA

European Authorized Representative's Name & Address:

Becton Dickinson Ireland Limited
Donore Road
Drogheda
Co. Louth
A92 YW26
Ireland

We hereby declare that the following CE marked products:

Provena Midline, PowerMidline, PowerGlide, PowerGlide Pro Midline Catheter Kits - *Refer to attached Annex*

Comply with:

European Community Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) as amended by Directive 2007/47/EC.

Supplementary Information:

Conformity assessment procedure: [Annex II](#)
Device classification: [Class IIa in accordance with Annex IX Rule 7](#)
Notified body: [British Standards Institution](#)
Notified body number: [2797](#)
Full Quality Assurance Certificate: [CE 551333](#)
EC Design Examination Certificate: [Not applicable](#)
(Class III devices only)

This Declaration of Conformity covers the [Provena Midline, PowerMidline, PowerGlide, and PowerGlide Pro Midline Catheter Kits](#) as specified above, and is valid for all products concerned bearing the CE marking.

Issued at, and under the sole responsibility of,
Bard Access Systems, Inc.
Salt Lake City, Utah on [September 09, 2022](#).

DocuSigned by:

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Christopher Rogers
Vice President, Regulatory Affairs

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Annex

Provena Midline Catheters

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
S64153118	3Fr SL Provena Midline CE Basic Kit	32151	27 March 2019	
S64244118	4Fr DL Provena Midline CE Basic Kit	32151	27 March 2019	
S64153208	3Fr SL Provena Midline CE Bedside Kit	32151	27 March 2019	
S64244208	4Fr DL Provena Midline CE Bedside Kit	32151	27 March 2019	

PowerMidline Catheters

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
P6153118	3Fr SL PowerMidline Basic Kit, CE Region	32151	27 July 2017	
P6154118	4Fr SL PowerMidline Basic Kit, CE Region	32151	27 July 2017	
P6254118	4Fr DL PowerMidline Basic Kit, CE Region	32151	27 July 2017	
P6255118	5Fr DL PowerMidline Basic Kit, CE Region	32151	27 July 2017	
P6153208	3Fr SL PowerMidline Bedside Kit, CE Region	32151	22 January 2018	
P6154208	4Fr SL PowerMidline Bedside Kit, CE Region	32151	22 January 2018	
P6254208	4Fr DL PowerMidline Bedside Kit, CE Region	32151	22 January 2018	
P6255208	5Fr DL PowerMidline Bedside Kit, CE Region	32151	22 January 2018	

PowerGlide Midline Catheters

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
6022080	22 Gauge PowerGlide Midline Catheter, 8cm, Basic Kit	32151	24 February 2015	REBU1408
6020080	20 Gauge PowerGlide Midline Catheter, 8cm, Basic Kit	32151	16 June 2014	RECX3168
6020100	20 Gauge PowerGlide Midline Catheter, 10cm, Basic Kit	32151	16 June 2014	RECN1694
6018080	18 Gauge PowerGlide Midline Catheter, 8cm, Basic Kit	32151	16 June 2014	RECX3167

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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
6018100	18 Gauge PowerGlide Midline Catheter, 10cm, Basic Kit	32151	16 June 2014	RECZ3168
6018081	18 Gauge PowerGlide Midline Catheter, 8cm, Intermediate Kit	32151	3 June 2015	REBY2144
6018101	18 Gauge PowerGlide Midline Catheter, 10cm, Intermediate Kit	32151	3 June 2015	REBZ0485
6020081	20 Gauge PowerGlide Midline Catheter, 8cm, Intermediate Kit	32151	3 June 2015	REBU1773
6020101	20 Gauge PowerGlide Midline Catheter, 10cm, Intermediate Kit	32151	3 June 2015	RECQ2106
6022081	22 Gauge PowerGlide Midline Catheter, 8cm, Intermediate Kit	32151	3 June 2015	REBT1644

PowerGlide Pro Midline Catheters

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
6F122080	22 Gauge PowerGlide Pro Midline Catheter, 8cm, Basic Kit	32151	12 May 2017	
6F120100	20 Gauge PowerGlide Pro Midline Catheter, 10cm, Basic Kit	32151	12 May 2017	
6F120080	20 Gauge PowerGlide Pro Midline Catheter, 8cm, Basic Kit	32151	12 May 2017	
6F118100	18 Gauge PowerGlide Pro Midline Catheter, 10cm, Basic Kit	32151	12 May 2017	
6F118080	18 Gauge PowerGlide Pro Midline Catheter, 8cm, Basic Kit	32151	12 May 2017	
6F118081	18 Gauge PowerGlide Pro Midline Catheter, 8cm, Intermediate Kit	32151	12 May 2017	
6F118101	18 Gauge PowerGlide Pro Midline Catheter, 10cm, Intermediate Kit	32151	12 May 2017	
6F120081	20 Gauge PowerGlide Pro Midline Catheter, 8cm, Intermediate Kit	32151	12 May 2017	
6F120101	20 Gauge PowerGlide Pro Midline Catheter, 10cm, Intermediate Kit	32151	12 May 2017	
6F122081	22 Gauge PowerGlide Pro Midline Catheter, 8cm, Intermediate Kit	32151	12 May 2017	
6F122080TX	22 Gauge PowerGlide Pro Midline Catheter, 8cm, Basic Kit with Cue Needle Tracking System	32151	29 Oct 2020	
6F120080TX	20 Gauge PowerGlide Pro Midline Catheter, 8cm, Basic Kit with Cue Needle Tracking System	32151	29 Oct 2020	
6F120100TX	20 Gauge PowerGlide Pro Midline Catheter, 10cm, Basic Kit with Cue Needle Tracking System	32151	29 Oct 2020	

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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
6F118080TX	18 Gauge PowerGlide Pro Midline Catheter 8cm, Basic Kit with Cue Needle Tracking System	32151	29 Oct 2020	
6F188100TX	18 Gauge PowerGlide Pro Midline Catheter 10cm, Basic Kit with Cue Needle Tracking System	32151	29 Oct 2020	

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Revision History

Revision	Date	Description	Prepared by				
0	16-June-2014	Original - Based on Bard Access Systems' document DC0003 Rev. 4.	C. Coombs				
1	22-August-2014	Separated the Declarations of Conformity for Per-Q-Cath and Groshong Midline Catheters from the PowerGlide Midline Catheters into separate documents.	E. Peterson				
2	24 February 2015	Added the following product code: 6022080	Z. Borla				
3	3 June 2015	Added the following product codes: 6018081, 6018101, 6020081, 6020101, 6022081	C. Coombs				
4	30 July 2015	Recombined the Declaration of Conformity for Per-Q-Cath and Groshong Midline Catheters with the PowerGlide Midline Catheters. Updated all products' GMDN codes to 40601	Z. Borla				
5	19 December 2016	Page 1 – Added “by Directive 2007/47/EC” under the section titled Comply With.	C. Coombs				
6	12 May 2017	Updated the DoC to include PowerGlide Pro Midline Catheters and added a table to the annex with following product codes: 6F122080, 6F120100, 6F120080, 6F118100, 6F118080, 6F118081, 6F118101, 6F120081, 6F120101, 6F122081.	J. Kuyakana				
7	27 July 2017	Updated the DoC to include PowerMidline Catheters and added a table to the annex with the following product codes: P6153118, P6154118, P6254118, P6255118.	J. Kuyakana				
8	22 January 2018	Added to PowerMidline Catheters' table the following product codes: P6153208, P6154208, P6254208, and P6255208.	J. Kuyakana				
9	27 March 2019	Updated the DoC to include Provena Midline Catheters and added a table to the annex with the following product codes: S64153118, S64244118, S64153208, and S64244208.	J. Kuyakana				
10	30 January 2020	<div>Updated Authorized Representative address from:<table><tr><td>From</td><td>To:</td></tr><tr><td>Bard Limited Forest House, Brighton Road Crawley, West Sussex RH11 9BP UK</td><td>BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland</td></tr></table></div> <div>Updated Notified Body number from 0086 to 2797</div>	From	To:	Bard Limited Forest House, Brighton Road Crawley, West Sussex RH11 9BP UK	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland	L. Solon
From	To:						
Bard Limited Forest House, Brighton Road Crawley, West Sussex RH11 9BP UK	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland						
11	February 12, 2020	<div>The Provena Midline, PowerMidline, PowerGlide and PowerGlide Pro devices were reclassified from IIb to IIa per Annex IX rule 7. This DoC has been renamed DC-EU-MIDL-01a.</div> <div>The GMDN code was updated from 40601 (Peripheral Vascular Catheter) to 32151 (Peripheral Vascular Infusion Catheter) because the previous GMDN code was obsolesced.</div>	S. Loring				

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Revision	Date	Description	Prepared by
12	October 29, 2020	Added in product codes for PowerGlide Pro Midline Catheters with Cue Needle Tracking System Obsolesced PowerGlide Midline product codes; this product has been discontinued.	S. Loring
13	August 31, 2022	Updated Authorized Representative address from: BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland To Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland Replaced Signatory from Roya Borazjani To Christopher Rogers Updated letterhead to include BD logo and company contact information.	Kiran M