



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:

BD Switzerland Sarl
Route de Crassier 17, Business Park Terre-Bonne,
Batiment A4, 1262 Eysins, Switzerland

We hereby declare that the following CE marked products:

StatLock Stabilization Devices without Extension Set - *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.

Supplementary Information:

Conformity assessment procedure: Annex V and Annex VII
Device classification: Class I sterile in accordance with Annex IX Rule 1
Notified body: British Standards Institution
Notified body number: 2797
Full Quality Assurance Certificate: CE 551349
EC Design Examination Certificate: Not applicable
(Class III devices only)

This Declaration of Conformity covers the Statlock Stabilization Device without Extension Set 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.
on 5 February 2020

Leslie Robinson-Frye
Senior Manager, Regulatory Affairs

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Annex

Arterial

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
VADAC	Arrow Arterial	56631	26 July 2006	
ART0320	Arterial for BD	56631	26 July 2006	
ART0321	Arterial for Vygon	56631	26 July 2006	
ART0422	Arterial Ultra	56631	26 July 2006	
ART0423	Arrow Arterial crescent	56631	26 July 2006	

Central Venous (CV)

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
VCDCE	CV	56631	1 May 2008	
VCDP	CV Plus butterfly	56631	26 July 2006	
VCDPC	CV Plus crescent	56631	26 July 2006	
VCDPP	CV Plus Pediatric	56631	26 July 2006	
VCDPS	CV Plus pigtail	56631	26 July 2006	
CV0321	CV Ultra	56631	26 July 2006	
CV0220CE	CV Plus crescent tricot	56631	1 May 2008	
CV0223	CV Plus crescent tricot fix-post	56631	26 July 2006	
CV0224CE	CV Plus butterfly tricot	56631	1 May 2008	
CV0226CE	CV Plus crescent tricot no pigtail	56631	1 May 2008	
VCDTCE	CP Pediatric	56631	1 May 2008	

Dialysis

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
VHD	Hemodialysis	56631	26 July 2006	
DI0120CE	Dialysis butterfly tricot hydrocolloid clamp	56631	1 May 2008	
VDS2	Dialysis II	56631	26 July 2006	
DI0121	Dialysis butterfly tricot hydrocolloid fixed wing	56631	1 May 2008	
DI0122	Dialysis butterfly tricot hydrocolloid attachable wing	56631	26 July 2006	JUXCF152



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Epidural

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
VEDC	Epidural crescent	34916	26 July 2006	
VEDC2	Continuous Nerve Block (CNB) crescent	34916	26 July 2006	JUYEF460

Intra-Aortic Ballon (IAB)/Percutaneous Sheath Introducers (PSI)

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
0684-00-0472	Datascope IAB	56631	26 July 2006	
IB0200	IBA Stabilization Device	56631	11 Sept 2009	JUWFF165
0684-00-0493	Datascope PSI	56631	26 July 2006	

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Intravenous

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
IV0220	IV Plus no extension set	56631	26 July 2006	
IV0500	IV Ultra Pediatric	56631	26 July 2006	
IV0520CE	IV Ultra	56631	1 May 2008	
IV0501	IV Ultra Neonate blue	56631	26 July 2006	
IV0606CE	IV Elite Delta Terumo Artsana	56631	2 Feb 2009	
IV0607CE	IV Elite Delta Terumo Artsana small	56631	2 Feb 2009	
IV0600CE	IV Elite BD Venflon Venflon Pro & Neoflon	56631	1 Oct 2008	
IV0601CE	IV Elite BD Venflon Venflon Pro & Neoflon Small	56631	1 Oct 2008	
IV0602CE	IV Elite BBraun Vasofix	56631	1 Oct 2008	
IV0603CE	IV Elite BBraun Vasofix Small	56631	1 Oct 2008	
IV0604CE	IV Elite Smiths Optiva 2	56631	1 Oct 2008	JUTCF277
IV0605CE	IV Elite Smiths Optiva 2 Small	56631	1 Oct 2008	JUYDF092
IV0230	IV Baxter T-connector	56631	1 May 2008	JUWEF055
IV0420	IV Kipp Klipp micro	56631	26 July 2006	JUTIF282
IV0421	IV Kipp Klipp macro	56631	26 July 2006	JUVIF178
IV0507	IV Premium Pediatric Baxter micro bore fixed nut retainer	56631	26 July 2006	JUWIF152
IV0508	IV Premium Pediatric Baxter macro bore fixed nut retainer	56631	26 July 2006	JUVIF182
IV0509	IV Premium Pediatric Baxter macro bore Spin-Lock retainer	56631	26 July 2006	
IV0528CE	IV Select no extension set	56631	1 May 2008	Obsolete
IV0568	IV Premium Kipp Micro	56631	26 July 2006	
IV0569	IV Premium Kipp Macro	56631	26 July 2006	
IV0570	IV Premium Abbot OptionLok	56631	26 July 2006	
IV0577	IV Premium Baxter Micro Fixed	56631	26 July 2006	
IV0578	IV Premium Baxter Macro Fixed	56631	26 July 2006	
IV0579	IV Premium Baxter Macro Spin-Lock	56631	26 July 2006	
IV0621CE	For Winged Catheters	56631	1 May 2008	
IV0622	Nexiva	56631	26 July 2006	
IV0624	For Winged Catheters w/ Tegaderm	56631	26 July 2006	JUSJF473
VHFP1CE	Huber Plus	56631	1 May 2008	
VIDMNSCE	IV micro bore tube clip no extension set	56631	1 May 2008	Obsolete
VIFP4	Intima Plus	56631	26 July 2006	
IVNS001/SAIVNS001	StatLock IV Ultra Stabilization Device	56630	9 May 2014	

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Peripherally Inserted Central Catheter (PICC)

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
VCDCCE	PICC II	56631	26 July 2006	
10045415	BSC PICC Plus crescent sliding post	56631	26 July 2006	JUSLF303
10045560	BSC PICC Plus crescent fixed post	56631	26 July 2006	
VPPBFP	PICC Plus butterfly fixed post	56631	26 July 2006	
VPPBSP	PICC Plus butterfly sliding post	56631	1 May 2008	
VPPCSPCE	PICC Plus crescent sliding post	56631	1 May 2008	
VPPDFPCE	PICC Plus crescent fixed post	56631	1 May 2008	
VPPPSPCE	PICC Plus Pediatric sliding post	56631	1 May 2008	
VNN2	Neonate II	56631	1 May 2008	
VCDC2	PICC	56631	1 May 2008	
VFS	First SL	56631	1 May 2008	
NN0200	PICC Neonate	56631	26 July 2006	
NN0201	PICC II Neonate	56631	26 July 2006	
NN0202	PICC Neonate	56631	1 May 2008	
PIC0220CE	PICC Plus crescent tricot sliding post	56631	26 July 2006	
PIC0222	PICC Plus crescent tricot fixed post	56631	26 July 2006	
VCDV	V-Lock	56631	26 July 2006	JUWKF138
SA0743372	StatLock Pediatric Stabilization Device	56631	29 Nov 2017	
0705742	Suture Wing StatLock Securement Device	56630	19 Mar 2008	

Universal

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number
VUPD1012CE	Universal Plus 10-12 FR	56630	26 July 2006	
VUPD1214CE	Universal Plus 12-14 FR	56630	26 July 2006	
VUPD1416CE	Universal Plus 14-16 FR	56630	26 July 2006	
VUPD68CE	Universal Plus 6-8 FR	56630	26 July 2006	
MP0120	Multi-Purpose 5 in.	56630	1 May 2008	
VMPDC	Multi-Purpose 2.5 in crescent	56630	26 July 2006	
IV0636	IV Universal	56630	30 Aug2011	

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Revision History

Revision	Date	Description	Prepared by
0	August 2014	Original - Based on Bard Medical Division Technical File 72. Added last lot numbers to 10045415, DI0122, IV0420, IV0421, IV0507, IV0508, IV0624, IB0200 and VCDV. Included GMDN codes from Australian DoC for consistency. Added date first CE marked. Used date of BMD project beginning.	Darlene Hull
1	May 2015	Update GMDN Codes: - Epidural from 37040 to 34916 - Universal, from 38442 & 15735 to 56630 - IV, PICC, CV, Arterial, Dialysis and IAB PSI from 15735 to 56631	Darlene Hull
2	29 November 2017	Added: - Moved IVNS001/SAIVNS001 StatLock IV Ultra Stabilization Device and 0705742 Suture Wing StatLock Securement Device from DC-EU-ACCS-06 to appropriately represent this line of products - SA0743372 StatLock Pediatric Stabilization Device is the same device design as the VPPSPCE but will be included as a component in Provena PICC trays	P. Holman for B. Stone
3	February 2020	Updated authorized representative address, updated CE number for BSI Netherlands, updated CE certificate number, updated conformity assessment procedure, updated signature block to include Catheter Care Senior Manager, RA.	S.Mohan