



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

We hereby declare that the following CE marked products:

Safety Infusion Administration Sets – *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 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:	551333
Design Examination Certificate: (Class III devices only)	Not Applicable

This Declaration of Conformity covers the [Safety Infusion Administration Sets](#) 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 June 09, 2021


Bryan Stone
Associate Director, Regulatory Affairs



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Annex

Bard Winged Infusion Sets (Non-Safety)

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
0603270	Winged Infusion Set with Injection Site 19G x 0.5in	17701	2 Mar 1998	
0603280	Winged Infusion Set with Injection Site 19G x 1.5in	17701	2 Mar 1998	
0603290	Winged Infusion Set with Injection Site 19G x 2in	17701	2 Mar 1998	
0603300	Winged Infusion Set with Injection Site 20G x 1.5in	17701	2 Mar 1998	
0603310	Winged Infusion Set with Injection Site 22G x 0.5in	17701	2 Mar 1998	
0603320	Winged Infusion Set with Injection Site 22G x 1.5in	17701	2 Mar 1998	
0603340	Winged Infusion Set with Injection Site 25G x .75in	17701	2 Mar 1998	
0604170	Winged Infusion Set 19G x 0.75in	17701	2 Mar 1998	
0604180	Winged Infusion Set 19G x 1 in	17701	2 Mar 1998	
0604190	Winged Infusion Set 20G x 0.75in	17701	2 Mar 1998	
0604200	Winged Infusion Set 20G x 1 in	17701	2 Mar 1998	
0604210	Winged Infusion Set 22G x 0.75in	17701	2 Mar 1998	
0604220	Winged Infusion Set 22G x 1 in	17701	2 Mar 1998	
0604260	Winged Infusion Set with Injection Site 25G x 1.5in	17701	2 Mar 1998	
0604270	Winged Infusion Set with Injection Site 20G x 0.5in	17701	2 Mar 1998	
2205219	Winged Infusion Set with Injection Site 19G x 0.75in	17701	2 Mar 1998	
2205220	Winged Infusion Set with Injection Site 20G x 0.75in	17701	2 Mar 1998	
2205222	Winged Infusion Set with Injection Site 22G x 0.75in	17701	2 Mar 1998	
2206219	Winged Infusion Set with Injection Site 19G x 1in	17701	2 Mar 1998	
2206220	Winged Infusion Set with Injection Site 20G x 1in	17701	2 Mar 1998	
2206222	Winged Infusion Set with Injection Site 22G x 1 in	17701	2 Mar 1998	



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LiftLoc® Safety Winged Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
S01119-75	LiftLoc Safety Infusion Set 19G x 0.75in with Y-Site	17701	19 Feb 2004	
S01120-75	LiftLoc Safety Infusion Set 20G x 0.75in with Y-Site	17701	19 Feb 2004	
S01122-75	LiftLoc Safety Infusion Set 22G x 0.75in with Y-Site	17701	19 Feb 2004	
S01119-10	LiftLoc Safety Infusion Set 19G x 1 in with Y-Site	17701	19 Feb 2004	
S01120-10	LiftLoc Safety Infusion Set 20G x 1 in with Y-Site	17701	19 Feb 2004	
S01122-10	LiftLoc Safety Infusion Set 22G x 1 in with Y-Site	17701	19 Feb 2004	
S01119-15	LiftLoc Safety Infusion Set 19G x 1.5in with Y-Site	17701	19 Feb 2004	
S01120-15	LiftLoc Safety Infusion Set 20G x 1.5in with Y-Site	17701	19 Feb 2004	
S01122-15	LiftLoc Safety Infusion Set 22G x 1.5in with Y-Site	17701	19 Feb 2004	
S01019-75	LiftLoc Safety Infusion Set 19G x 0.75in	17701	19 Feb 2004	
S01020-75	LiftLoc Safety Infusion Set 20G x 0.75in	17701	19 Feb 2004	
S01022-75	LiftLoc Safety Infusion Set 22G x 0.75in	17701	19 Feb 2004	
S01019-10	LiftLoc Safety Infusion Set 19G x 1 in	17701	19 Feb 2004	
S01020-10	LiftLoc Safety Infusion Set 20G x 1 in	17701	19 Feb 2004	
S01022-10	LiftLoc Safety Infusion Set 22G x 1 in	17701	19 Feb 2004	
S01019-15	LiftLoc Safety Infusion Set 19G x 1.5in	17701	19 Feb 2004	
S01020-15	LiftLoc Safety Infusion Set 20G x 1.5in	17701	19 Feb 2004	
S01022-15	LiftLoc Safety Infusion Set 22G x 1.5in	17701	19 Feb 2004	
S01219-75	LiftLoc Safety Infusion Set 19G x 0.75in with Y-Site	17701	7 Dec 2005	D108712 6/2/2011
S01220-75	LiftLoc Safety Infusion Set 20G x 0.75in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D122108 9/15/2011



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S01222-75	LiftLoc Safety Infusion Set 22G x 0.75in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D021026 8/18/2010
S01219-10	LiftLoc Safety Infusion Set 19G x 1 in with Y-Site	17701	7 Dec 2005	D118101 7/29/2011
S01220-10	LiftLoc Safety Infusion Set 20G x 1 in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D108712 5/6/2011
S01222-10	LiftLoc Safety Infusion Set 22G x 1 in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D020822 8/9/2010
S01219-15	LiftLoc Safety Infusion Set 19G x 1.5in with Y-Site	17701	7 Dec 2005	D917626 12/11/2009
S01220-15	LiftLoc Safety Infusion Set 20G x 1.5in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D902605 2/24/2009
S01222-15	LiftLoc Safety Infusion Set 22G x 1.5in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D100502 2/11/2011



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MiniLoc® Safety Winged Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
0631910	MiniLoc Safety Infusion Set 19G x 1 in	17701	27 January 2020	
0631915	MiniLoc Safety Infusion Set 19G x 1.5in	17701	27 January 2020	
0631934	MiniLoc Safety Infusion Set 19G x 0.75in	17701	27 January 2020	
0631950	MiniLoc Safety Infusion Set 19G x 0.5in	17701	27 January 2020	
0632010	MiniLoc Safety Infusion Set 20G x 1 in	17701	27 January 2020	
0632015	MiniLoc Safety Infusion Set 20G x 1.5in	17701	27 January 2020	
0632034	MiniLoc Safety Infusion Set 20G x 0.75in	17701	27 January 2020	
0632050	MiniLoc Safety Infusion Set 20G x 0.5in	17701	27 January 2020	
0632210	MiniLoc Safety Infusion Set 22G x 1 in	17701	27 January 2020	
0632215	MiniLoc Safety Infusion Set 22G x 1.5in	17701	27 January 2020	
0632234	MiniLoc Safety Infusion Set 22G x 0.75in	17701	27 January 2020	
0632250	MiniLoc Safety Infusion Set 22G x 0.5in	17701	27 January 2020	
0681910	MiniLoc Safety Infusion Set 19G x 1 in with Y-site	17701	27 January 2020	
0681915	MiniLoc Safety Infusion Set 19G x 1.5in with Y-site	17701	27 January 2020	
0681934	MiniLoc Safety Infusion Set 19G x 0.75in with Y-site	17701	27 January 2020	
0681950	MiniLoc Safety Infusion Set 19G x 0.5in with Y-site	17701	27 January 2020	
0682010	MiniLoc Safety Infusion Set 20G x 1 in with Y-site	17701	27 January 2020	
0682015	MiniLoc Safety Infusion Set 20G x 1.5in with Y-site	17701	27 January 2020	
0682034	MiniLoc Safety Infusion Set 20G x 0.75in with Y-site	17701	27 January 2020	
0682050	MiniLoc Safety Infusion Set 20G x 0.5in with Y-site	17701	27 January 2020	
0682210	MiniLoc Safety Infusion Set 22G	17701	27 January 2020	



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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
	x 1 7in with Y-site			
0682215	MiniLoc Safety Infusion Set 22G x 1.5in with Y-site	17701	27 January 2020	
0682234	MiniLoc Safety Infusion Set 22G x 0.75in with Y-site	17701	27 January 2020	
0682250	MiniLoc Safety Infusion Set 22G x 0.5in with Y-site	17701	27 January 2020	
S02019-75	MiniLoc Safety Infusion Set 19G x 0.75in	17701	7 Dec 2005	
S02119-75	MiniLoc Safety Infusion Set 19G x 0.75in with Y-Site	17701	7 Dec 2005	
S02219-75	MiniLoc Safety Infusion Set 19G x 0.75in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D900902 1/23/2009
S02020-75	MiniLoc Safety Infusion Set 20G x 0.75in	17701	7 Dec 2005	
S02120-75	MiniLoc Safety Infusion Set 20G x 0.75in with Y-Site	17701	7 Dec 2005	
S02220-75	MiniLoc Safety Infusion Set 20G x 0.75in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D911913 5/18/2009
S02022-75	MiniLoc Safety Infusion Set 22G x 0.75in	17701	7 Dec 2005	
S02122-75	MiniLoc Safety Infusion Set 22G x 0.75in with Y-Site	17701	7 Dec 2005	
S02222-75	MiniLoc Safety Infusion Set 22G x 0.75in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	ASVGS049 7/29/2011
S02019-10	MiniLoc Safety Infusion Set 19G x 1 in	17701	7 Dec 2005	
S02119-10	MiniLoc Safety Infusion Set 19G x 1 in with Y-Site	17701	7 Dec 2005	
S02219-10	MiniLoc Safety Infusion Set 19G x 1 in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D912009 5/18/2009
S02020-10	MiniLoc Safety Infusion Set 20G x 1 in	17701	7 Dec 2005	
S02120-10	MiniLoc Safety Infusion Set 20G x 1 in with Y-Site	17701	7 Dec 2005	
S02220-10	MiniLoc Safety Infusion Set 20G x 1 in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D911902 5/18/2009
S02022-10	MiniLoc Safety Infusion Set 22G x 1 in	17701	7 Dec 2005	
S02122-10	MiniLoc Safety Infusion Set 22G x 1 in with Y-Site	17701	7 Dec 2005	



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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
S02222-10	MiniLoc Safety Infusion Set 22G x 1 in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D901503 2/9/2009
S02019-15	MiniLoc Safety Infusion Set 19G x 1.5in	17701	7 Dec 2005	
S02119-15	MiniLoc Safety Infusion Set 19G x 1.5in with Y-Site	17701	7 Dec 2005	
S02219-15	MiniLoc Safety Infusion Set 19G x 1.5in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D906213 4/14/2009
S02020-15	MiniLoc Safety Infusion Set 20G x 1.5in	17701	7 Dec 2005	
S02120-15	MiniLoc Safety Infusion Set 20G x 1.5in with Y-Site	17701	7 Dec 2005	
S02220-15	MiniLoc Safety Infusion Set 20G x 1.5in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D018716 7/16/2010
S02022-15	MiniLoc Safety Infusion Set 22G x 1.5in	17701	7 Dec 2005	
S02122-15	MiniLoc Safety Infusion Set 22G x 1.5in with Y-Site	17701	7 Dec 2005	
S02222-15	MiniLoc Safety Infusion Set 22G x 1.5in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D906214 3/26/2009
S02019-50	MiniLoc Safety Infusion Set 19G x 0.5in	17701	7 Dec 2005	
S02119-50	MiniLoc Safety Infusion Set 19G x 0.5in with Y-Site	17701	7 Dec 2005	
S02219-50	MiniLoc Safety Infusion Set 19G x 0.5in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D904404 3/26/2009
S02020-50	MiniLoc Safety Infusion Set 20G x 0.5in	17701	7 Dec 2005	
S02120-50	MiniLoc Safety Infusion Set 20G x 0.5in with Y-Site	17701	7 Dec 2005	
S02220-50	MiniLoc Safety Infusion Set 20G x 0.5in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D833715 2/17/2009
S02022-50	MiniLoc Safety Infusion Set 22G x 0.5in	17701	7 Dec 2005	
S02122-50	MiniLoc Safety Infusion Set 22G x 0.5in with Y-Site	17701	7 Dec 2005	
S02222-50	MiniLoc Safety Infusion Set 22G x 0.5in with Y-Site (MicroCLAVE)	17701	7 Dec 2005	D902808 2/27/2009
S02319-75	MiniLoc Safety Infusion Set 19G x 0.75in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	ASYDS096 4/30/2014
S02320-75	MiniLoc Safety Infusion Set 20G x 0.75in with Y-Site (Medegen	17701	25 Jul 2008	ASYES041



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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
	Needleless Injection Cap)			5/14/2014
S02322-75	MiniLoc Safety Infusion Set 22G x 0.75in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	ASVYS023 No transactions on record 13-Aug-2015
S02319-10	MiniLoc Safety Infusion Set 19G x 1 in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	ASYCS064 3/27/2014
S02320-10	MiniLoc Safety Infusion Set 20G x 1 in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	ASYES098 5/28/2014
S02322-10	MiniLoc Safety Infusion Set 22G x 1 in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	ASXIS148 10/14/2013
S02319-15	MiniLoc Safety Infusion Set 19G x 1.5in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	Not produced since acquired 13-Aug-2015
S02320-15	MiniLoc Safety Infusion Set 20G x 1.5in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	ASYBS157 3/06/2014
S02322-15	MiniLoc Shp 22Gx 1.5	17701	25 Jul 2008	Not produced since acquired 13-Aug-2015
S02319-50	MiniLoc Safety Infusion Set 19G x 0.5in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	ASWJS209 11/09/2012
S02320-50	MiniLoc Safety Infusion Set 20G x 0.5in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	ASWIS064 09/24/2012
S02322-50	MiniLoc Safety Infusion Set 22G x 0.5in with Y-Site (Medegen Needleless Injection Cap)	17701	25 Jul 2008	ASWES001 5/18/2012



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Ambix Noncor Safe™ Safety Winged Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
S02019-75FK	Ambix NONCOR Safe 19G x 19mm	17701	26 Jul 2005	D900503 1/22/2009
S02020-75FK	Ambix NONCOR Safe 20G x 19mm	17701	26 Jul 2005	D825218 9/18/2008
S02022-10FK	Ambix NONCOR Safe 22G x 25mm	17701	26 Jul 2005	Never Manufactured 13-Aug-2015
S02022-75FK	Ambix NONCOR Safe 22G x 19mm	17701	26 Jul 2005	D826710 10/10/2008
S02019-10FK	Ambix NONCOR Safe 19G x 25mm	17701	26 Jul 2005	D825216 9/27/2008
S02020-10FK	Ambix NONCOR Safe 20G x 25mm	17701	26 Jul 2005	D027219 10/21/2010
S02019-15FK	Ambix NONCOR Safe 19G x 38mm	17701	26 Jul 2005	D822610 9/12/2008
S02020-15FK	Ambix NONCOR Safe 20G x 38mm	17701	26 Jul 2005	D822613 9/2/2008
S02022-15FK	Ambix NONCOR Safe 22G x 38mm	17701	26 Jul 2005	D826708 10/21/2008
S02019-50FK	Ambix NONCOR Safe 19G x 13mm	17701	26 Jul 2005	D824502 9/18/2008
S02020-50FK	Ambix NONCOR Safe 20G x 13mm	17701	26 Jul 2005	D825313 9/27/2008
S02022-50FK	Ambix NONCOR Safe 22G x 13mm	17701	26 Jul 2005	D815101 6/25/2008



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PowerLoc™ Safety Winged Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
8651910	PowerLoc Safety Infusion Set 19G x 1 in	17701	2 Nov 2007	
8651915	PowerLoc Safety Infusion Set 19G x 1.5in	17701	2 Nov 2007	
8651934	PowerLoc Safety Infusion Set 19G x 0.75in	17701	2 Nov 2007	
8652010	PowerLoc Safety Infusion Set 20G x 1 in	17701	2 Nov 2007	
8652015	PowerLoc Safety Infusion Set 20G x 1.5in	17701	2 Nov 2007	
8652034	PowerLoc Safety Infusion Set 20G x 0.75in	17701	2 Nov 2007	
8652210	PowerLoc Safety Infusion Set 22G x 1 in	17701	2 Nov 2007	
8652215	PowerLoc Safety Infusion Set 22G x 1.5in	17701	2 Nov 2007	
8652234	PowerLoc Safety Infusion Set 22G x 0.75in	17701	2 Nov 2007	
8671910	PowerLoc Safety Infusion Set 19G x 1 in with Y-Site	17701	2 Nov 2007	
8671915	PowerLoc Safety Infusion Set 19G x 1.5in with Y-Site	17701	2 Nov 2007	
8671934	PowerLoc Safety Infusion Set 19G x 0.75in with Y-Site	17701	2 Nov 2007	
8672010	PowerLoc Safety Infusion Set 20G x 1 in with Y-Site	17701	2 Nov 2007	
8672015	PowerLoc Safety Infusion Set 20G x 1.5in with Y-Site	17701	2 Nov 2007	
8672034	PowerLoc Safety Infusion Set 20G x 0.75in with Y-Site	17701	2 Nov 2007	
8672210	PowerLoc Safety Infusion Set 22G x 1 in with Y-Site	17701	2 Nov 2007	
8672215	PowerLoc Safety Infusion Set 22G x 1.5in with Y-Site	17701	2 Nov 2007	
8672234	PowerLoc Safety Infusion Set 22G x 0.75in with Y-Site	17701	2 Nov 2007	



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SafeStep™ Safety Winged Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
LH-0039YN	SafeStep Huber Needle Set 19G x 0.5in with Y-site	17701	4 Dec 2007	
LH-0037YN	SafeStep Huber Needle Set 20G x 0.5in with Y-site	17701	4 Dec 2007	
LH-0035YN	SafeStep Huber Needle Set 22G x 0.5in with Y-site	17701	4 Dec 2007	
LH-0033YN	SafeStep Huber Needle Set 19G x 0.75in with Y-site	17701	4 Dec 2007	
LH-0031YN	SafeStep Huber Needle Set 20G x 0.75in with Y-site	17701	4 Dec 2007	
LH-0029YN	SafeStep Huber Needle Set 22G x 0.75in with Y-site	17701	4 Dec 2007	
LH-0034YN	SafeStep Huber Needle Set 19G x 1 in with Y-site	17701	4 Dec 2007	
LH-0032YN	SafeStep Huber Needle Set 20G x 1 in with Y-site	17701	4 Dec 2007	
LH-0030YN	SafeStep Huber Needle Set 22G x 1 in with Y-site	17701	4 Dec 2007	
LH-0040YN	SafeStep Huber Needle Set 19G x 1.5in with Y-site	17701	4 Dec 2007	
LH-0038YN	SafeStep Huber Needle Set 20G x 1.5in with Y-site	17701	4 Dec 2007	
LH-0036YN	SafeStep Huber Needle Set 22G x 1.5in with Y-site	17701	4 Dec 2007	
LH-0039	SafeStep Huber Needle Set 19G x 0.5in	17701	4 Dec 2007	
LH-0037	SafeStep Huber Needle Set 20G x 0.5in	17701	4 Dec 2007	
LH-0035	SafeStep Huber Needle Set 22G x 0.5in	17701	4 Dec 2007	
LH-0033	SafeStep Huber Needle Set 19G x 0.75in	17701	4 Dec 2007	
LH-0031	SafeStep Huber Needle Set 20G x 0.75in	17701	4 Dec 2007	
LH-0029	SafeStep Huber Needle Set 22G x 0.75in	17701	4 Dec 2007	
LH-0034	SafeStep Huber Needle Set 19G x 1 in	17701	4 Dec 2007	
LH-0032	SafeStep Huber Needle Set 20G x 1 in	17701	4 Dec 2007	



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LH-0030	SafeStep Huber Needle Set 22G x 1 in	17701	4 Dec 2007	
LH-0040	SafeStep Huber Needle Set 19G x 1.5in	17701	4 Dec 2007	
LH-0038	SafeStep Huber Needle Set 20G x 1.5in	17701	4 Dec 2007	
LH-0036	SafeStep Huber Needle Set 22G x 1.5in	17701	4 Dec 2007	
LH-0043YN	SafeStep Huber Needle Set 19G x 2in with Y-Site	17701	4 Dec 2007	D919607 8/4/2009
LH-0042YN	SafeStep Max Power Injectable Infusion Set 20G x 2in with Y-Site	17701	4 Dec 2007	D925106 9/28/2009
LH-0043	SafeStep Huber Needle Set 19G x 2in	17701	4 Dec 2007	D913420 6/24/2009
LH-0042	SafeStep Max Power Injectable Infusion Set 20G x 2in	17701	4 Dec 2007	D925107 9/28/2009



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SureCan SafeStep™ Safety Winged Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
04445012	Surecan Safestep 19G x 12mm (with Y Site)	17701	4 Dec 2007	D021711 9/1/10
04445016	Surecan Safestep 20G x 12mm (with Y Site)	17701	4 Dec 2007	D101016 1/28/11
04445020	Surecan Safestep 22G x 12mm (with Y Site)	17701	4 Dec 2007	D024323 9/28/10
04445013	Surecan Safestep 19G x 19mm (with Y Site)	17701	4 Dec 2007	D102722 3/2/11
04445017	Surecan Safestep 20G x 19mm (with Y Site)	17701	4 Dec 2007	D102725 3/2/11
04445021	Surecan Safestep 22G x 19mm (with Y Site)	17701	4 Dec 2007	D103909 3/8/11
04445014	Surecan Safestep 19G x 25mm (with Y Site)	17701	4 Dec 2007	D024508 9/28/10
04445018	Surecan Safestep 20G x 25mm (with Y Site)	17701	4 Dec 2007	D100714 1/28/11
04445022	Surecan Safestep 22G x 25mm (with Y Site)	17701	4 Dec 2007	D103908 3/8/11
04445015	Surecan Safestep 19G x 38mm (with Y Site)	17701	4 Dec 2007	D024507 9/28/10
04445019	Surecan Safestep 20G x 38mm (with Y Site)	17701	4 Dec 2007	D103910 3/8/11
04445023	Surecan Safestep 22G x 38mm (with Y Site)	17701	4 Dec 2007	D020119 8/3/10
04445000	Surecan Safestep 19G x 12mm	17701	4 Dec 2007	D032244 12/9/10
04445004	Surecan Safestep 20G x 12mm	17701	4 Dec 2007	D102422 2/23/11
04445008	Surecan Safestep 22G x 12mm	17701	4 Dec 2007	D102424 3/2/11
04445001	Surecan Safestep 19G x 19mm	17701	4 Dec 2007	D102105 3/2/11
04445005	Surecan Safestep 20G x 19mm	17701	4 Dec 2007	D102106 2/23/11
04445009	Surecan Safestep 22G x 19mm	17701	4 Dec 2007	D033322 12/27/10
04445002	Surecan Safestep 19G x 25mm	17701	4 Dec 2007	D106617 1/28/11



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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
04445006	Surecan Safestep 20G x 25mm	17701	4 Dec 2007	D102438 3/2/11
04445010	Surecan Safestep 22G x 25mm	17701	4 Dec 2007	D102440 3/2/11
04445003	Surecan Safestep 19G x 38mm	17701	4 Dec 2007	D102421 3/2/11
04445007	Surecan Safestep 20G x 38mm	17701	4 Dec 2007	D024205 9/28/10
04445011	Surecan Safestep 22G x 38mm	17701	4 Dec 2007	D103911 3/8/11

HuberPlus™ Safety Winged Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
011901	Huber Plus 19G x 1in	17701	1 Mar 2006	
011901ny	Huber Plus 19G x 1in Needleless Y Site	17701	1 Mar 2006	
011934	Huber Plus 19G x .75 in	17701	1 Mar 2006	
011934ny	Huber Plus 19G x .75 in Needleless Y Site	17701	1 Mar 2006	
012001	Huber Plus 20G x 1 in	17701	1 Mar 2006	
012001ny	Huber Plus 20G x 1" Needleless Y Site	17701	1 Mar 2006	
012005	Huber Plus 20G x .5"	17701	1 Mar 2006	
012034	Huber Plus 20G x .0.75"	17701	1 Mar 2006	
012034ny	Huber Plus 20G x 0.75" Needleless Y Site	17701	1 Mar 2006	
012201	Huber Plus 22G x 1"	17701	1 Mar 2006	
012201ny	Huber Plus 22G x 1" Needleless Y Site	17701	1 Mar 2006	
012205	Huber Plus 22G x 0.5"	17701	1 Mar 2006	
012234	Huber Plus 22G x 0.75"	17701	1 Mar 2006	
012234ny	Huber Plus 22G x 0.75" Needleless Y Site	17701	1 Mar 2006	
011912	Huber Plus 19G x 1.25 in	17701	1 Mar 2006	
011912ny	Huber Plus 19G x 1.25 in Needleless Y Site	17701	1 Mar 2006	



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011915	Huber Plus 19G x 1.5in	17701	1 Mar 2006	
011915ny	Huber Plus 19G x 1.5in Needleless Y Site	17701	1 Mar 2006	
012012	Huber Plus 20G x 1.25"	17701	1 Mar 2006	
012012ny	Huber Plus 20G x 1.25" Needleless Y Site	17701	1 Mar 2006	
012015	Huber Plus 20G x 1.5"	17701	1 Mar 2006	
012015ny	Huber Plus 20G x 1.5" Needleless Y Site	17701	1 Mar 2006	
012212	Huber Plus 22G x 1.25"	17701	1 Mar 2006	
012212ny	Huber Plus 22G x 1.25" Needleless Y Site	17701	1 Mar 2006	
012215	Huber Plus 22G x 1.5"	17701	1 Mar 2006	
012215ny	Huber Plus 22G x 1.5" Needleless Y Site	17701	1 Mar 2006	



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SafeStep®MAX™ Safety Winged Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
LHP-0037Y	SafeStep Max W/ Y, 20G x ½"	17701	26 Jun 2008	
LHP-0035Y	SafeStep Max W/ Y, 22G x ½"	17701	26 Jun 2008	
LHP-0031Y	SafeStep Max W/ Y, 20G x ¾"	17701	26 Jun 2008	
LHP-0029Y	SafeStep Max W/ Y, 22G x ¾"	17701	26 Jun 2008	D813551 10/1/2008
LHP-0034Y	SafeStep Max W/ Y, 19G x 1"	17701	26 Jun 2008	D813316 8/21/2008
LHP-0032Y	SafeStep Max W/ Y, 20G x 1"	17701	26 Jun 2008	D813506 8/21/2008
LHP-0030Y	SafeStep Max W/ Y, 22G x 1"	17701	26 Jun 2008	D813552 8/21/2008
LHP-0040Y	SafeStep Max W/ Y 19G x 1½"	17701	26 Jun 2008	D901211 3/9/2009
LHP-0038Y	SafeStep Max W/ Y 20G x 1½"	17701	26 Jun 2008	D813550 8/21/2008
LHP-0039	SafeStep Max W/O Y, 19G x ½"	17701	26 Jun 2008	
LHP-0037	SafeStep Max W/O Y, 20G x ½"	17701	26 Jun 2008	D813554 2/18/2009
LHP-0035	SafeStep Max W/O Y, 22G x ½"	17701	26 Jun 2008	D813555 8/21/2008
LHP-0033	SafeStep Max W/O Y, 19G x ¾"	17701	26 Jun 2008	D813553 8/21/2008
LHP-0031	SafeStep Max W/O Y, 20G x ¾"	17701	26 Jun 2008	
LHP-0029	SafeStep Max W/O Y, 22G x ¾"	17701	26 Jun 2008	
LHP-0034	SafeStep Max W/O Y, 19G x 1"	17701	26 Jun 2008	D813314 1/8/2009
LHP-0032	SafeStep Max W/O Y, 20G x 1"	17701	26 Jun 2008	D813507 8/21/2008
LHP-0030	SafeStep Max W/O Y, 22G x 1"	17701	26 Jun 2008	D813312 2/18/2009
LHP-0040	SafeStep Max W/O Y, 19G x 1½"	17701	26 Jun 2008	
LHP-0038	SafeStep Max W/O Y, 20G x 1½"	17701	26 Jun 2008	D813315 8/21/2008
LHP-0036	SafeStep Max W/O Y, 22G x 1½"	17701	26 Jun 2008	



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Surecan® SafeStep®MAX™ Safety Winged Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
04446012	Surecan Safestep Max 19G x 12mm (with Y Site)	17701	26 Jun 2008	
04446016	Surecan Safestep Max 20G x 12mm (with Y Site)	17701	26 Jun 2008	
04446020	Surecan Safestep Max 22G x 12mm (with Y Site)	17701	26 Jun 2008	
04446013	Surecan Safestep Max 19G x 19mm (with Y Site)	17701	26 Jun 2008	
04446017	Surecan Safestep Max 20G x 19mm (with Y Site)	17701	26 Jun 2008	
04446021	Surecan Safestep Max 22G x 19mm (with Y Site)	17701	26 Jun 2008	
04446014	Surecan Safestep Max 19G x 25mm (with Y Site)	17701	26 Jun 2008	
04446018	Surecan Safestep Max 20G x 25mm (with Y Site)	17701	26 Jun 2008	
04446022	Surecan Safestep Max 22G x 25mm (with Y Site)	17701	26 Jun 2008	
04446015	Surecan Safestep Max 19G x 38mm (with Y Site)	17701	26 Jun 2008	
04446019	Surecan Safestep Max 20G x 38mm (with Y Site)	17701	26 Jun 2008	
04446023	Surecan Safestep Max 22G x 38mm (with Y Site)	17701	26 Jun 2008	
04446000	Surecan Safestep Max 19G x 12mm	17701	26 Jun 2008	
04446004	Surecan Safestep Max 20G x 12mm	17701	26 Jun 2008	
04446008	Surecan Safestep Max 22G x 12mm	17701	26 Jun 2008	D912516 8/26/09
04446001	Surecan Safestep Max 19G x 19mm	17701	26 Jun 2008	D912513 5/28/09
04446005	Surecan Safestep Max 20G x 19mm	17701	26 Jun 2008	D412601 5/28/09
04446009	Surecan Safestep Max 22G x 19mm	17701	26 Jun 2008	D024415 9/28/10
04446002	Surecan Safestep Max 19G x 25mm	17701	26 Jun 2008	D912514 5/28/09
04446006	Surecan Safestep Max 20G x 25mm	17701	26 Jun 2008	D024414 9/28/10



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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
04446010	Surecan Safestep Max 22G x 25mm	17701	26 Jun 2008	
04446003	Surecan Safestep Max 19G x 38mm	17701	26 Jun 2008	
04446007	Surecan Safestep Max 20G x 38mm	17701	26 Jun 2008	
04446011	Surecan Safestep Max 22G x 38mm	17701	26 Jun 2008	



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Non-Coring Needle for Use with Implanted Ports (Non-Safety)

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
0602300	Non-Coring Needle for Use with Implantable Ports 19G x 1in	17701	02 March 1998	
0602310	Non-Coring Needle for Use with Implantable Ports 19G x 1.5in	17701	02 March 1998	
0602320	Non-Coring Needle for Use with Implantable Ports 20G x 1in	17701	02 March 1998	
0602330	Non-Coring Needle for Use with Implantable Ports 20G x 1.5in	17701	02 March 1998	
0602340	Non-Coring Needle for Use with Implantable Ports 22G x 1in	17701	02 March 1998	
0602350	Non-Coring Needle for Use with Implantable Ports 22G x 1.5in	17701	02 March 1998	
0602500	Non-Coring Needle for Use with Implantable Ports 19G x 0.75in (Right Angle)	17701	02 March 1998	
0602510	Non-Coring Needle for Use with Implantable Ports 19G x 1in (Right Angle)	17701	02 March 1998	
0602520	Non-Coring Needle for Use with Implantable Ports 19G x 1.5in (Right Angle)	17701	02 March 1998	
0602530	Non-Coring Needle for Use with Implantable Ports 20G x 0.75in (Right Angle)	17701	02 March 1998	
0602540	Non-Coring Needle for Use with Implantable Ports 20G x 1in (Right Angle)	17701	02 March 1998	
0602550	Non-Coring Needle for Use with Implantable Ports 20G x 1.5in (Right Angle)	17701	02 March 1998	
0602560	Non-Coring Needle for Use with Implantable Ports 22G x 0.75in (Right Angle)	17701	02 March 1998	
0602570	Non-Coring Needle for Use with Implantable Ports 22G x 1in (Right Angle)	17701	02 March 1998	
0602590	Non-Coring Needle for Use with Implantable Ports 22G x 0.5in (Right Angle)	17701	02 March 1998	
0602780	Non-Coring Needle for Use with Implantable Ports 19G x 0.5in (Right Angle)	17701	02 March 1998	
0604120	Non-Coring Needle for Use with Implantable Ports 20G x 0.5in (Right Angle)	17701	02 March 1998	
0379180	Needle, Right Angle 1.0 x 22G	17701	07 March 2012	
0355850	Non-Coring Needle, Straight w/guard 22G	17701	07 March 2012	



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EZ Huber* PFM AG

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
SHG19-100	EZ Huber 19 ga x 1 in	17701	12 August 2010	
SHG19-100Y	EZ Huber 19 ga x 1 in w/Y	17701	12 August 2010	
SHG19-150	EZ Huber 19 ga x 1 1/2 inch	17701	12 August 2010	
SHG19-150Y	EZ Huber 19 ga x 1 1/2 in w/Y	17701	12 August 2010	
SHG19-75	EZ Huber 19 ga x 3/4 inch	17701	12 August 2010	
SHG19-75Y	EZ Huber 19 ga x 3/4 in w/Y	17701	12 August 2010	
SHG20-100	EZ Huber 20 ga x 1 inch	17701	12 August 2010	
SHG20-100Y	EZ Huber 20 ga x 1 in w/Y	17701	12 August 2010	
SHG20-150	EZ Huber 20 ga x 1 1/2 inch	17701	12 August 2010	
SHG20-150Y	EZ Huber 20 ga x 1 1/2 in w/Y	17701	12 August 2010	
SHG20-50*	EZ Huber 20 ga x 1/2 inch	17701	12 August 2010	XC67 3/15/2011
SHG20-50Y*	EZ Huber 20 ga x 1/2 in w/Y	17701	12 August 2010	
SHG20-75	EZ Huber 20 ga x 3/4 inch	17701	12 August 2010	
SHG20-75Y	EZ Huber 20 ga x 3/4 in w/Y	17701	12 August 2010	
SHG22-100	EZ Huber 22 ga x 1 inch	17701	12 August 2010	
SHG22-100Y	EZ Huber 22 ga x 1 in w/Y	17701	12 August 2010	
SHG22-150	EZ Huber 22 ga x 1 1/2 inch	17701	12 August 2010	
SHG22-150Y	EZ Huber 22 ga x 1 1/2 in w/Y	17701	12 August 2010	
SHG22-50*	EZ Huber 22 ga x 1/2 inch	17701	12 August 2010	WN33 1/14/2011
SHG22-50Y*	EZ Huber 22 ga x 1/2 in w/Y	17701	12 August 2010	
SHG22-75	EZ Huber 22 ga x 3/4 inch	17701	12 August 2010	
SHG22-75Y	EZ Huber 22 ga x 3/4 in w/Y	17701	12 August 2010	
SHG19-15*	EZ Huber 19 ga x 15 mm	17701	12 August 2010	WH82 9/2/2010
SHG20-15*	EZ Huber 20 ga x 15 mm	17701	12 August 2010	WH83 9/2/2010
SHG22-15*	EZ Huber 22 ga x 15 mm	17701	12 August 2010	WH84 9/2/2010
SHG619-100	EZ Huber 19 ga x 1 inch	17701	12 August 2010	
SHG619-100Y	EZ Huber 19 ga x 1 in w/Y	17701	12 August 2010	
SHG619-150	EZ Huber 19 ga x 1 1/2 inch	17701	12 August 2010	
SHG619-150Y	EZ Huber 19 ga x 1 1/2 in w/Y	17701	12 August 2010	
SHG619-75	EZ Huber 19 ga x 3/4 inch	17701	12 August 2010	



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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
SHG619-75Y	EZ Huber 19 ga x 3/4 in w/Y	17701	12 August 2010	
SHG620-100	EZ Huber 20 ga x 1 inch	17701	12 August 2010	
SHG620-100Y	EZ Huber 20 ga x 1 in w/Y	17701	12 August 2010	
SHG620-150	EZ Huber 20 ga x 1 1/2 inch	17701	12 August 2010	
SHG620-150Y	EZ Huber 20 ga x 1 1/2 in w/Y	17701	12 August 2010	
SHG620-50*	EZ Huber 20 ga x 1/2 inch	17701	12 August 2010	
SHG620-50Y*	EZ Huber 20 ga x 1/2 in w/Y	17701	12 August 2010	
SHG620-75	EZ Huber 20 ga x 3/4 inch	17701	12 August 2010	
SHG620-75Y	EZ Huber 20 ga x 3/4 in w/Y	17701	12 August 2010	
SHG622-100	EZ Huber 22 ga x 1 inch	17701	12 August 2010	
SHG622-100Y	EZ Huber 22 ga x 1 in w/Y	17701	12 August 2010	
SHG622-150*	EZ Huber 22 ga x 1 1/2 inch	17701	12 August 2010	
SHG622-150Y*	EZ Huber 22 ga x 1 1/2 in w/Y	17701	12 August 2010	
SHG622-50	EZ Huber 22 ga x 1/2 inch	17701	12 August 2010	
SHG622-50Y	EZ Huber 22 ga x 1/2 in w/Y	17701	12 August 2010	
SHG622-75	EZ Huber 22 ga x 3/4 inch	17701	12 August 2010	
SHG622-75Y	EZ Huber 22 ga x 3/4 in w/Y	17701	12 August 2010	
SHG19-100YS	EZ Huber 19G x 25mm with Needleless Y-Site	17701	12 August 2010	
SHG19-150YS	EZ Huber 19G x 38mm with Needleless Y-Site	17701	12 August 2010	
SHG19-75YS	EZ Huber 19G x 19mm with Y-Site	17701	12 August 2010	
SHG20-100YS	EZ Huber 20G x 25mm with Needleless Y-Site	17701	12 August 2010	
SHG20-150YS	EZ Huber 20G x 38mm with Needleless Y-Site	17701	12 August 2010	
SHG20-50YS	EZ Huber 20G x 0.5in with Needleless Y-Site	17701	12 August 2010	
SHG20-75YS	EZ Huber 20G x 38mm with Needleless Y-Site	17701	12 August 2010	
SHG22-100YS	EZ Huber 20G x 38mm with Needleless Y-Site	17701	12 August 2010	
SHG22-150YS	EZ Huber 22G x 38mm with Needleless Y-Site	17701	12 August 2010	
SHG22-50YS	EZ Huber 22G x 0.5in with Needleless Y-Site	17701	12 August 2010	
SHG22-75YS	EZ Huber 22G x 19mm with Needleless Y-Site	17701	12 August 2010	
SHN20-50	EZ Huber 20G x .5in,	17701	16 November 2012	
SHN22-50	EZ Huber 22G x .5in,	17701	16 November 2012	
SHN19-60	EZ Huber 19G x .6in,	17701	27 February 2013	



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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
SHN20-60	EZ Huber 20G x .6in,	17701	27 February 2013	
SHN22-60	EZ Huber 22G x .6in,	17701	27 February 2013	
SHNWG19-150	EZ HUBER NW NY 19ga x 1 1/2in	17701	20 May 2019	
SHNWG19-100	EZ HUBER NW NY 19ga x 1in	17701	20 May 2019	
SHNWG19-75	EZ HUBER NW NY 19ga x 3/4in	17701	20 May 2019	
SHNWG19-60	EZ HUBER NW NY 19ga x .6in	17701	20 May 2019	
SHNWG20-100	EZ HUBER NW NY 20ga x 1in	17701	20 May 2019	
SHNWG20-150	EZ HUBER NW NY 20ga x 1 1/2in	17701	20 May 2019	
SHNWG20-75	EZ HUBER NW NY 20ga x 3/4in	17701	20 May 2019	
SHNWG20-60	EZ HUBER NW NY 20ga x .6in	17701	20 May 2019	
SHNWG22-150	EZ HUBER NW NY 22ga x 1 1/2in	17701	20 May 2019	
SHNWG22-100	EZ HUBER NW NY 22ga x 1in	17701	20 May 2019	
SHNWG22-75	EZ HUBER NW NY 22ga x 3/4in	17701	20 May 2019	
SHNWG22-60	EZ HUBER NW NY 22ga x .6in	17701	20 May 2019	

*Product codes have not been sold in the EU or any other geography since BAS acquired the product line

**Codes including "YS" and "SHN" are used to designate non-power injectable device



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PowerLoc®MAX™ Power-Injectable Infusion Set

Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
84446001	PowerLoc Max Power-Injectable Infusion Set 19G x .75 in.	17701	31 August 2012	
84446002	PowerLoc Max Power-Injectable Infusion Set 19G x 1 in.	17701	31 August 2012	
84446003	PowerLoc Max Power-Injectable Infusion Set 19G x 1.5 in.	17701	31 August 2012	
84446005	PowerLoc Max Power-Injectable Infusion Set 20G x .75 in.	17701	31 August 2012	
84446006	PowerLoc Max Power-Injectable Infusion Set 20G x 1 in.	17701	31 August 2012	
84446007	PowerLoc Max Power-Injectable Infusion Set 20G x 1.5 in.	17701	31 August 2012	
84446009	PowerLoc Max Power-Injectable Infusion Set 22G x .75 in.	17701	31 August 2012	
84446010	PowerLoc Max Power-Injectable Infusion Set 22G x 1 in.	17701	31 August 2012	
84446011	PowerLoc Max Power-Injectable Infusion Set 22G x 1.5 in.	17701	31 August 2012	
84446013	PowerLoc Max Power-Injectable Infusion Set 19G x .75 in. with Y-Site	17701	31 August 2012	
84446014	PowerLoc Max Power-Injectable Infusion Set 19G x 1 in. with Y-Site	17701	31 August 2012	
84446015	PowerLoc Max Power-Injectable Infusion Set 19G x 1.5 in. with Y-Site	17701	31 August 2012	
84446017	PowerLoc Max Power-Injectable Infusion Set 20G x .75 in. with Y-Site	17701	31 August 2012	
84446018	PowerLoc Max Power-Injectable Infusion Set 20G x 1 in. with Y-Site	17701	31 August 2012	
84446019	PowerLoc Max Power-Injectable Infusion Set 20G x 1.5 in. with Y-Site	17701	31 August 2012	
84446021	PowerLoc Max Power-Injectable Infusion Set 22G x .75 in. with Y-Site	17701	31 August 2012	
84446022	PowerLoc Max Power-Injectable Infusion Set 22G x 1 in. with Y-Site	17701	31 August 2012	
84446023	PowerLoc Max Power-Injectable Infusion Set 22G x 1.5 in. with Y-Site	17701	31 August 2012	
0131910	PowerLoc Max Power-Injectable Infusion Set 19G x 1.0 in with Y-Site	17701	27 January 2020	
0131915	PowerLoc Max Power-Injectable Infusion Set 19G x 1.5in with Y-Site	17701	27 January 2020	
0131975	PowerLoc Max Power-Injectable Infusion Set 19G x 0.75in with Y-Site	17701	27 January 2020	
0132010	PowerLoc Max Power-Injectable Infusion Set 20G x 1.0 in with Y-Site	17701	27 January 2020	
0132015	PowerLoc Max Power-Injectable Infusion Set 20G x 1.5in with Y-Site	17701	27 January 2020	
0132075	PowerLoc Max Power-Injectable Infusion Set 20G x 0.75in with Y-Site	17701	27 January 2020	
0132210	PowerLoc Max Power-Injectable Infusion Set 22G x 1.0 in with Y-Site	17701	27 January 2020	



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Product Code	Product Description	GMDN Code	Date of first CE-marking	Last Lot Number & Date
0132215	PowerLoc Max Power-Injectable Infusion Set 22G x 1.5in with Y-Site	17701	27 January 2020	
0132275	PowerLoc Max Power-Injectable Infusion Set 22G x 0.75in with Y-Site	17701	27 January 2020	
0141910	PowerLoc Max Power-Injectable Infusion Set 19G x 1.0 in	17701	27 January 2020	
0141915	PowerLoc Max Power-Injectable Infusion Set 19G x 1.5in	17701	27 January 2020	
0141975	PowerLoc Max Power-Injectable Infusion Set 19G x 0.75in	17701	27 January 2020	
0142010	PowerLoc Max Power-Injectable Infusion Set 20G x 1.0 in	17701	27 January 2020	
0142015	PowerLoc Max Power-Injectable Infusion Set 20G x 1.5in	17701	27 January 2020	
0142075	PowerLoc Max Power-Injectable Infusion Set 20G x 0.75in	17701	27 January 2020	
0142210	PowerLoc Max Power-Injectable Infusion Set 22G x 1.0 in	17701	27 January 2020	
0142215	PowerLoc Max Power-Injectable Infusion Set 22G x 1.5in	17701	27 January 2020	
0142275	PowerLoc Max Power-Injectable Infusion Set 22G x 0.75in	17701	27 January 2020	

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Revision History

Revision	Date	Description	Revised by:
0	26 August 2009	Original. Existing products are based on Bard Access Systems' document DCIIa11, Revision 14	M. Nelson
1	02 October 2009	Added Non-Coring Needle for Use with Implanted Ports from KEMA Declaration of Conformity DCIIa11, Revision 17	H. Boland
2	30 October 2009	Added 0604120, Right Angle, 20G x 0.5" Non-Coring Needle for Use with Implanted Ports from KEMA Declaration of Conformity DCIIa11, Revision 17	H. Boland
3	19 March 2010	Added "as amended by 2007/47/EC". Changed "Bsi Product Services" to "British Standards Institution". Updated approver name and title. <u>Annex</u> – Corrected product code 012212 description from 22G x 1.5" to 22G x 1.25". Added product code 012212NY (CE marked per DCIIa11, Revision 14). Removed the following codes (never manufactured): 0602580, LH-0041, LH-0041YN, LH-0039Y, LHP-0033Y, LHP-0036Y. Added last lot numbers to: LH-0042, LH-0042YN, LH-0043, LH-0043YN, LHP-0039, LHP-0029, LHP-0029Y, LHP-0030, LHP-0030Y, LHP-0031, LHP-0031Y, LHP-0032, LHP-0032Y, LHP-0033, LHP-0034, LHP-0034Y, LHP-0036, LHP-0038, LHP-0040, LHP-0040Y.	S. Ly
4	4 November 2011	Added EZ Huber* PFM AG Codes *...is a trademark and/or registered trademark of C.R. Bard, Inc.	M. Nelson
5	7 March 2012	Added 0379180, Needle, Right Angle 1.0 x 22G and 0355850, Needle, Straight w/guard	E. Richey
6	31 Aug 2012	Added PowerLoc Max Power-Injectable Infusion Sets: 84446001, 84446002, 84446003, 84446005, 84446006, 84446007, 84446009, 84446010, 84446011, 84446013, 84446014, 84446015, 84446017, 84446018, 84446019, 84446021, 84446022, 84446023.	D. Thomas
7	16 Nov 2012	Changed "Projected Date of CE-marking" to "Date of first CE-marking" for the following products: <ul style="list-style-type: none"> • Non-Coring Needles for Use with Implanted Ports (Non-Safety) • EZ Huber* PFM AG Added EZ Huber product codes for launch of 0.5 inch configurations in the EU: <ul style="list-style-type: none"> • SHN20-50 • SHN22-50 Added EZ Huber codes that were omitted from PFM codes in Revision 5 of the Declaration of Conformity:	J. Smith

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		<ul style="list-style-type: none"> • SHG 19-100YS • SHG 19-150YS • SHG 19-75YS • SHG 20-100YS • SHG 20-150YS • SHG 20-50YS • SHG 20-75YS • SHG 22-100YS • SHG 22-150YS • SHG 22-50YS • SHG 22-75YS 	
8	February 27, 2013	<p>Added EZ Huber product codes for launch of 0.6inch configurations in the EU:</p> <ul style="list-style-type: none"> • SHN19-60 • SHN20-60 • SHN22-60 	J. Smith
9	August 13, 2015	<p>-Added Last Lot Numbers to MiniLoc codes</p> <ul style="list-style-type: none"> • S02319-75 • S02320-75 • S02322-75 • S02319-10 • S02320-10 • S02322-10 • S02319-15 • S02320-15 • S02322-15 • S02319-50 • S02320-50 • S02322-50 • S02219-75 • S02220-75 • S02222-75 • S02219-10 • S02220-10 • S02222-10 • S02219-15 • S02220-15 • S02222-15 • S02219-50 • S02220-50 • S02222-50 <p>-Added Last Lot Numbers to LiftLoc codes</p> <ul style="list-style-type: none"> • S01219-75 • S01220-75 • S01222-75 • S01219-10 • S01220-10 • S01222-10 • S01219-15 • S01220-15 • S01222-15 <p>-Added Last Lot Numbers to Amix Noncor Safe codes</p> <ul style="list-style-type: none"> • S02019-75FK • S02020-75FK 	K. Plenert for M. Nelson & D. Hull

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		<ul style="list-style-type: none"> • S02022-75FK • S02019-10FK • S02020-10FK • S02019-15FK • S02020-15FK • S02022-15FK • S02019-50KF • S02020-50FK • S02022-50FK <p>-Added Last Lot Numbers to EZ Huber codes</p> <ul style="list-style-type: none"> • SHG20-50 • SHG22-50 • SHG19-15 • SHG20-15 • SHG22-15 <p>Added Last Lot Dates to all codes affected.</p>	
10	February 6, 2017	<p>In order to clarify the device descriptions, updated the following: Bard Winged Infusion Sets (Non-Safety), LiftLoc® Safety Winged Infusion Set, MiniLoc® Safety Winged Infusion Set, Ambix Noncor Safe™ Safety Winged Infusion Set, PowerLoc™ Safety Winged Infusion Set, SafeStep™ Safety Winged Infusion Set, SureCan SafeStep™ Safety Winged Infusion Set, HuberPlus™ Safety Winged Infusion Set, SafeStep®MAX™ Safety Winged Infusion Set, Surecan® SafeStep®MAX™ Safety Winged Infusion Set, Non-Coring Needle for Use with Implanted Ports (Non-Safety).</p>	J. Duke
11	Nov 29, 2018	<p>Added last lot numbers and dates for the following product codes:</p> <ul style="list-style-type: none"> • Each of the product codes in the <u>SureCan SafeStep™ Safety Winged Infusion Set</u> section (page 12 & 13) • Surecan® SafeStep®MAX™ Safety Winged Infusion Set codes, 04446008, 04446001, 04446005, 04446009, 04446002, and 04446006 (page 16) 	J. Duke/J. Lee
12	May 20, 2019	<p>Added new product codes for the following product lines:</p> <ul style="list-style-type: none"> • EZ Huber: SHN WG19-150, SHN WG19-100, SHN WG19-75, SHN WG19-60, SHN WG20-100, SHN WG20-150, SHN WG20-75, SHN WG20-60, SHN WG22-150, SHN WG22-100, SHN WG22-75, SHN WG22-60. 	J. Kuyakana

Declaration of Conformity

13	January 27, 2020	<p>Updated Authorized Representative address from: Bard Limited Forest House, Brighton Road Crawley, West Sussex RH11 9BP UK</p> <p>To BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland</p> <p>Updated Notified Body number from 0086 to 2797.</p> <p>Added new product codes for the following product lines:</p> <ul style="list-style-type: none"> • MiniLoc® Safety Winged Infusion Set: 0631910, 0631915, 0631934, 0631950, 0632010, 0632015, 0632034, 0632050, 0632210, 0632215, 0632234, 0632250, 0681910, 0681915, 0681934, 0681950, 0682010, 0682015, 0682034, 0682050, 0682210, 0682215, 0682234, 0682250. • PowerLoc@MAX™ Power-Injectable Infusion Set: 0131910, 0131915, 0131975, 0132010, 0132015, 0132075, 0132210, 0132215, 0132275, 0141910, 0141915, 0141975, 0142010, 0142015, 0142075, 0142210, 0142215, 0142275. 	D. Schaffer
14	March 1, 2021	Updated DoC to Rev 14 in conjunction with Tech File update	S. Loring
15	June 09, 2021	<p>Updated the following code descriptions for the PowerLoc@MAX™ product line to include “with Y-Site” as a correction to the full product description: 0131910, 0131915, 0131975, 0132010, 0132015, 0132075, 0132210, 0132215, 0132275</p>	A. Ryder