



Document Number: DC-029

Version: P

TITLE: Declaration of Conformity for BD Insyte™ Autoguard™ Shielded IV Catheters, BD Insyte™ Autoguard BC Shielded IV Catheters & BD Insyte™ Autoguard™ BC Pro Shielded IV Catheters Page 1 of 6

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson Infusion Therapy Systems, Inc. 9450 South State Street Sandy, Utah 84070, USA
Authorised Representative:	Becton Dickinson Distribution Center NV Laagstraat 57, B-9140 Temse, Belgium
Manufacturing Site(s):	Becton Dickinson Infusion Therapy Systems, Inc. 9450 South State Street Sandy, Utah 84070, USA
Products:	381411 BD Insyte-N™ Autoguard™ Shielded IV Catheter 24 GA 0.56 IN 381412 BD Insyte™ Autoguard™ Shielded IV Catheter 24 GA 0.75 IN 381423 BD Insyte™ Autoguard™ Shielded IV Catheter 22 GA 1.00 IN 381433 BD Insyte™ Autoguard™ Shielded IV Catheter 20 GA 1.00 IN 381434 BD Insyte™ Autoguard™ Shielded IV Catheter 20 GA 1.16 IN 381437 BD Insyte™ Autoguard™ Shielded IV Catheter 20 GA 1.88 IN 381444 BD Insyte™ Autoguard™ Shielded IV Catheter 18 GA 1.16 IN 381447 BD Insyte™ Autoguard™ Shielded IV Catheter 18 GA 1.88 IN 381454 BD Insyte™ Autoguard™ Shielded IV Catheter 16 GA 1.16 IN 381457 BD Insyte™ Autoguard™ Shielded IV Catheter 16 GA 1.77 IN 381467 BD Insyte™ Autoguard™ Shielded IV Catheter 14 GA 1.75 IN 381511 BD Insyte-N™ Autoguard™ Winged Shielded IV Catheter 24 GA 0.56 IN 381512 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 24 GA 0.75 IN 381523 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 22 GA 1.00 IN 381533 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20 GA 1.00 IN 381534 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20 GA 1.16 IN 381537 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20 GA 1.88 IN 381544 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18 GA 1.16 IN 381547 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18 GA 1.88 IN 381554 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16 GA 1.16 IN 381557 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16 GA 1.77 IN 381811 BD Insyte-N™ Autoguard™ Shielded IV Catheter 24 GA 0.56 IN 381812 BD Insyte™ Autoguard™ Shielded IV Catheter 24 GA 0.75 IN 381823 BD Insyte™ Autoguard™ Shielded IV Catheter 22 GA 1.00 IN 381833 BD Insyte™ Autoguard™ Shielded IV Catheter 20 GA 1.00 IN 381834 BD Insyte™ Autoguard™ Shielded IV Catheter 20 GA 1.16 IN 381837 BD Insyte™ Autoguard™ Shielded IV Catheter 20 GA 1.88 IN 381844 BD Insyte™ Autoguard™ Shielded IV Catheter 18 GA 1.16 IN 381847 BD Insyte™ Autoguard™ Shielded IV Catheter 18 GA 1.88 IN 381854 BD Insyte™ Autoguard™ Shielded IV Catheter 16 GA 1.16 IN 381857 BD Insyte™ Autoguard™ Shielded IV Catheter 16 GA 1.77 IN



381867 BD Insyte™ Autoguard™ Shielded IV Catheter 14 GA 1.75 IN
381911 BD Insyte-N™ Autoguard™ Winged Shielded IV Catheter 24 GA 0.56 IN
381912 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 24 GA 0.75 IN
381923 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 22 GA 1.00 IN
381933 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20 GA 1.00IN
381934 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20 GA 1.16 IN
381937 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20 GA 1.88 IN
381944 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18 GA 1.16 IN
381947 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18 GA 1.88 IN
381954 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16 GA 1.16 IN
381957 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16 GA 1.77 IN
381012 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 24 GA 0.75 IN
381023 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 22 GA 1.00 IN
381024 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 22GA 1.25IN
381033 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 20 GA 1.00 IN
381034 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 20 GA 1.16 IN
381037 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 20 GA 1.88 IN
381044 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 18 GA 1.16 IN
381047 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 18 GA 1.88 IN
381054 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 16 GA 1.16 IN
381057 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 16 GA 1.77 IN
382512 BD Insyte™ Autoguard™ BC Shielded IV Catheter 24 GA 0.75 IN
382523 BD Insyte™ Autoguard™ BC Shielded IV Catheter 22 GA 1.00 IN
382533 BD Insyte™ Autoguard™ BC Shielded IV Catheter 20 GA 1.00 IN
382534 BD Insyte™ Autoguard™ BC Shielded IV Catheter 20 GA 1.16 IN
382537 BD Insyte™ Autoguard™ BC Shielded IV Catheter 20 GA 1.88 IN
382544 BD Insyte™ Autoguard™ BC Shielded IV Catheter 18 GA 1.16 IN
382547 BD Insyte™ Autoguard™ BC Shielded IV Catheter 18 GA 1.88 IN
382554 BD Insyte™ Autoguard™ BC Shielded IV Catheter 16 GA 1.16 IN
382557 BD Insyte™ Autoguard™ BC Shielded IV Catheter 16 GA 1.77 IN
382612 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter 24 GA 0.75 IN
382623 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter 22 GA 1.00 IN
382633 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter 20 GA 1.00 IN
382634 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter 20 GA 1.16 IN
382637 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter 20 GA 1.88 IN
382644 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter 18 GA 1.16 IN
382647 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter 18 GA 1.88 IN
382654 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter 16 GA 1.16 IN
382657 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter 16 GA 1.77 IN
382912 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 24 GA 0.75 IN
382923 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 22 GA 1.00 IN

	<p>382924 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 22GA 1.25IN 382933 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 20 GA 1.00 IN 382934 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 20 GA 1.16 IN 382937 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 20 GA 1.88 IN 382944 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 18 GA 1.16 IN 382947 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 18 GA 1.88 IN 382954 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 16 GA 1.16 IN 382957 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 16 GA 1.77 IN 392512 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 24 GA 0.75IN 392523 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 22 GA 1.00IN 392524 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 22 GA 1.25IN 392533 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 20 GA 1.00IN 392534 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 20 GA 1.16IN 392537 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 20 GA 1.88IN 392544 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 18 GA 1.16IN 392547 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 18 GA 1.88IN 392554 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 16 GA 1.16IN 392557 BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 16 GA 1.77IN 392612 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 24GA 0.75IN 392623 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 22GA 1.00IN 392624 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 22 GA 1.25IN 392633 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 20GA 1.00IN 392634 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 20G 1.16IN 392637 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 20G 1.88IN 392644 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 18 GA 1.16IN 392647 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 18 GA 1.88IN 392654 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 16G 1.16IN 392657 BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter 16G 1.77IN</p>
Classification:	Class IIa under Rule 7 of Annex IX of the Council Directive 93/42/EEC, as amended
Conformity Assessment Route:	Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4
GMDN Information:	<p>GMDN Code: 64574</p> <p>GMDN Term: Peripheral intravenous cannula</p> <p>GMDN Definition: A short, thin tube intended to be inserted into a peripheral vein (typically on the hand/arm) to enable short-term (< 30 days) intravenous (IV) access for administration of fluids/medication and blood sampling. Also referred to as a peripheral IV catheter, it is typically assembled with a dedicated introduction needle, and usually includes connectors, injection ports, and wings for fixation. It is not intended to be advanced to the central vasculature. This is a single-use device.</p>

We herewith declare that the above-mentioned products meet the provisions of the Council Directive

93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer.

<p>Harmonised Standards:</p>	<p>EN ISO 14971:2012 (ISO 14971:2007, Corrected version 2007-10-01) EN ISO 13485:2016 (ISO 13485:2016) EN 20594-1:1993 (ISO 594-1:1986) EN ISO 10555-1:2009 (ISO 10555-1:2013) EN ISO 10993-1:2009 (ISO 10993-1:2009) EN ISO 10993-3:2014 (ISO 10993-3:2014) EN ISO 10993-5:2009 (ISO 10993-5:2009) EN ISO 10993-7:2008 (ISO 10993-7:2008) EN ISO 10993-11:2018 (ISO 10993-11:2017) EN ISO 10993-12:2012 (ISO 10993-12:2012) EN ISO 10993-17:2009 (ISO 10993-17:2002) EN ISO 10993-18:2009 (ISO 10993-18:2005) EN ISO 11607-1:2009 (ISO 11607-1:2006) EN ISO 11607-2:2006 (ISO 11607-2:2006) EN ISO 11135-1:2007 (ISO 11135-1:2007) EN 556-1:2001/AC:2006 EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03) EN 1041:2008 EN 62366:2008 (IEC 62366:2007)</p>
<p>Non-Harmonised Standards:</p>	<p>EN 556-1:2001/AC:2006 ISO 594-2:1998 ISO 10555-5:2013 ISO 10993-4:2017 ISO 10993-6:2016 ISO 10993-10:2010 ISO 23908:2011</p>
<p>Notified Body:</p>	<p>BSI Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands Notified Body Number: 2797</p>
<p>EC Certificate Number</p>	<p>CE 01738</p>
<p>Date of issuance of the original CE certificate</p>	<p>03 October 1997</p>



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Obsolete Products

REF	Description	Last Lot Number	Mfg Date
381700	BD Angiocath™ Autoguard™ Shielded IV Catheter 24GA 0.75IN	6235942	2016-09-23
381701	BD Angiocath™ Autoguard™ Shielded IV Catheter 22GA 1.00IN	7151816	2017-06-27
381702	BD Angiocath™ Autoguard™ Shielded IV Catheter 20GA 1.00IN	7146935	2017-06-22
381703	BD Angiocath™ Autoguard™ Shielded IV Catheter 20GA 1.16IN	7163907	2017-07-13
381704	BD Angiocath™ Autoguard™ Shielded IV Catheter 20GA 1.88IN	7132932	2017-06-09
381705	BD Angiocath™ Autoguard™ Shielded IV Catheter 18GA 1.16IN	7157645	2017-07-13
381706	BD Angiocath™ Autoguard™ Shielded IV Catheter 18GA 1.88IN	7121776	2017-06-06
381707	BD Angiocath™ Autoguard™ Shielded IV Catheter 16GA 1.16IN	7129782	2017-06-14
381708	BD Angiocath™ Autoguard™ Shielded IV Catheter 16GA 1.77IN	5216928	2016-08-31
381709	BD Angiocath™ Autoguard™ Shielded IV Catheter 14GA 1.75IN	7037930	2017-03-09
381720	BD Angiocath-N™ Autoguard™ Shielded IV Catheter 24GA 0.56IN	6237952	2016-09-23
382000	BD Angiocath™ Autoguard™ Shielded IV Catheter 24GA 0.75IN	6235942	2016-09-23
382001	BD Angiocath™ Autoguard™ Shielded IV Catheter 22GA 1.0IN	7151816	2017-06-27
382002	BD Angiocath™ Autoguard™ Shielded IV Catheter 20GA 1.0IN	7146935	2017-06-22
382003	BD Angiocath™ Autoguard™ Shielded IV Catheter 20GA 1.16IN	7163907	2017-07-13
382004	BD Angiocath™ Autoguard™ Shielded IV Catheter 20GA 1.88IN	7132932	2017-06-09
382005	BD Angiocath™ Autoguard™ Shielded IV Catheter 18GA 1.16IN	7157645	2017-07-13
382006	BD Angiocath™ Autoguard™ Shielded IV Catheter 18GA 1.88IN	7121776	2017-06-06
382007	BD Angiocath™ Autoguard™ Shielded IV Catheter 16GA 1.16IN	7129782	2017-04-14
382008	BD Angiocath™ Autoguard™ Shielded IV Catheter 16GA 1.77IN	5216928	2016-08-31
382009	BD Angiocath™ Autoguard™ Shielded IV Catheter 14GA 1.75IN	7037930	2017-03-09
382020	BD Angiocath™ Autoguard™ Shielded IV Catheter 24GA 0.56IN	6237952	2016-09-23

Date: 2021-03-05

Roya Borazjani
VP, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems Inc.



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VERSION HISTORY	
Current Version Prepared By: Paul Holman	
Version	Version Description
P	Updated SKU product descriptions from IAG BC to IAG BC Pro for Global launch: 381012, 381023, 381033, 381034, 381037, 381044, 381047, 381054, 381057, 382912, 382923, 382933, 382934, 382937, 382944, 382947, 382954, 382957
O	Added Insyte Autoguard BC Pro SKUs (381024, 382924) to support CE marking and launch. Updated Harmonized Standards List to be in line with current conformity assessments and documents: EN ISO 10993-3:2014 (ISO 10993-3:2014), EN ISO 10993-5:2009 (ISO 10993-5:2009) , EN ISO 10993-11:2018 (ISO 10993-11:2017), EN ISO 10993-12:2012 (ISO 10993-12:2012), EN ISO 10993-17:2009 (ISO 10993-17:2002), EN ISO 10993-18:2009 (ISO 10993-18:2005), EN ISO 11135-1:2007 (ISO 11135-1:2007), EN 556-1:2001/AC:2006 Updated Non-Harmonized Standards List: EN 556-1:2001/AC:2006, ISO 10993-4:2017, ISO 10993-6:2016, ISO 10993-10:2010
N	CE 01738 renewed (expiration date: 26-May-2024). <u>Header</u> : Updated product names to include full trade name.
M	<u>GMDN</u> : Updated GMDN code, term, and definition with replacement GMDN code 64574.
L	Added obsolete products information for BD Angiocath Autoguard.