

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:	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 22 GA 1.25 IN 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

**TITLE: Declaration of Conformity for BD Insyte™ Autoguard™ Shielded IV Catheters
& BD Insyte™ Autoguard™ BC Pro Shielded IV Catheters**

	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 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
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:	GMDN Code: 64574 GMDN Term: Peripheral intravenous cannula 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.

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.

**TITLE: Declaration of Conformity for BD Insyte™ Autoguard™ Shielded IV Catheters
& BD Insyte™ Autoguard™ BC Pro Shielded IV Catheters**

Harmonised Standards:	EN ISO 14971:2019 (ISO 14971:2019) 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 11607-1:2020 (ISO 11607-1:2019) EN ISO 11607-2:2020 (ISO 11607-2:2019) 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)
Non-Harmonised Standards:	EN 556-1:2001/AC:2006 ISO 594-2:1998 ISO 80369-7:2021 (applicable to 381012, 381023, 381024, 381033, 381044, 381047, 381054, and 381057 only) ISO 10555-5:2013 ISO 10993-4:2017 ISO 10993-6:2016 ISO 10993-10:2010 ISO 23908:2011
Notified Body:	BSI Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands Notified Body Number: 2797
EC Certificate Number	CE 01738
Date of issuance of the original CE certificate	03 October 1997



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Obsolete Products

REF	Description	Last Lot Number	Mfg Date	Exp Date
381411 [†]	BD Insyte-N™ Autoguard™ Shielded IV Catheter 24 GA 0.56 IN	1293284	10/1/2021	9/30/2021
381412 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 24 GA 0.75 IN	1336774	12/1/2021	11/30/2024
381423 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 22 GA 1.00 IN	1347816	12/1/2021	11/30/2024
381433 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 20 GA 1.00 IN	1328518	12/1/2021	11/30/2024
381434 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 20 GA 1.16 IN	1342776	12/1/2021	11/30/2024
381437 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 20 GA 1.88 IN	1300906	11/1/2021	10/31/2024
381444 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 18 GA 1.16 IN	1343890	12/1/2021	11/30/2024
381447 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 18 GA 1.88 IN	1322434	11/1/2021	10/31/2024
381454 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 16 GA 1.16 IN	1137802	5/1/2021	4/30/2024
381457 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 16 GA 1.77 IN	1322435	TBD	TBD
381467 [†]	BD Insyte™ Autoguard™ Shielded IV Catheter 14 GA 1.75 IN	1307623	11/1/2021	10/31/2024
381511 [†]	BD Insyte-N™ Autoguard™ Winged Shielded IV Catheter 24 G 0.56 IN	1294850	10/1/2021	9/30/2024
381512 [†]	BD Insyte™ Autoguard™ Winged Shielded IV Catheter 24 GA 0.75 IN	1293263	10/1/2021	9/30/2024
381523 [†]	BD Insyte™ Autoguard™ Winged Shielded IV Catheter 22 GA 1.00 IN	1327746	11/1/2021	10/31/2024
381533 [†]	BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20 GA 1.00 IN	1294896	10/1/2021	9/30/2024
381534 [†]	BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20 GA 1.16 IN	1294848	10/1/2021	9/30/2024
381537 [†]	BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20 GA 1.88 IN	1300894	11/1/2021	10/31/2024
381544 [†]	BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18 GA 1.16 IN	1321663	11/1/2021	10/31/2024
381547 [†]	BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18 Ga 1.88 IN	1116198	4/1/2021	3/31/2024
381554 [†]	BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16 GA 1.16 IN	1137800	5/1/2021	4/30/2024
381557 [†]	BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16 GA 1.77 IN	1116198	5/1/2021	4/30/2024
382512 [†]	BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 24 GA 0.75 IN	1137800	5/1/2021	4/30/2024
382523 [†]	BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 22 GA 1.00 IN	1134899	5/1/2021	4/30/2024
382533 [†]	BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 20 GA 1.00 IN	1341216	12/1/2021	11/30/2024
382534 [†]	BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 20 GA 1.16 IN	1322351	12/1/2021	11/30/2024
382537 [†]	BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 20 GA 1.88 IN	1328530	12/1/2021	11/30/2024
382544 [†]	BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 18 GA 1.16 IN	1321694	11/1/2021	10/31/2024
382547 [†]	BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 18 GA 1.88 IN	1130382	5/1/2021	4/30/2024



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& BD Insyte™ Autoguard™ BC Pro Shielded IV Catheters**

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REF	Description	Last Lot Number	Mfg Date	Exp Date
382554 [†]	BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 16 GA 1.16 IN	1144877	6/1/2021	5/31/2024
382557 [†]	BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 16 GA 1.77 IN	1144366	6/1/2021	5/31/2024
382612 [†]	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 24 GA 0.75 IN	1322455	11/1/2021	10/31/2024
382623 [†]	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 22 GA 1.00 IN	1307626	11/1/2021	10/31/2024
382633 [†]	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 20 GA 1.00 IN	1320607	11/1/2021	10/31/2024
382634 [†]	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 20 GA 1.16 IN	1336520	12/1/2021	11/30/2024
382637 [†]	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 20 GA 1.88 IN	0169585	6/1/2020	5/31/2023
382644 [†]	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 18 GA 1.16 IN	1328522	12/1/2021	11/30/2024
382647 [†]	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 18 GA 1.88 IN	1076261	3/1/2021	2/29/2024
382654 [†]	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 16 GA 1.16 IN	1152563	6/1/2021	5/31/2024
382657 [†]	BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 16 GA 1.77 IN	0275048	10/1/2020	9/30/2023
392512 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 24 GA 0.75 IN	1089073	4/1/2021	3/31/2024
392523 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 22 GA 1.00 IN	1328318	11/1/2021	10/31/2024
392524 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 22 GA 1.25 IN	9248015	9/1/2019	8/31/2022
392533 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 20 GA 1.00 IN	1322199	11/1/2021	10/31/2024
392534 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 20 GA 1.16 IN	9228982	TBD	TBD
392537 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 20 GA 1.88 IN	1056707	3/1/2021	2/29/2024
392544 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 18 GA 1.16 IN	1095338	4/1/2021	3/31/2024
392547 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 18 GA 1.88 IN	0247831	9/1/2020	8/31/2023
392554 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 16 GA 1.16 IN	0265148	10/1/2020	9/30/2023
392557 [†]	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter Blood Control Technology 16 GA 1.77 IN	9267608	9/1/2019	8/31/2022
392612 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 24 GA 0.75 IN	1123636	5/1/2021	4/30/2024

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REF	Description	Last Lot Number	Mfg Date	Exp Date
392623 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 22 GA 1.00 IN	1280532	10/1/2021	9/30/2024
392624 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 22 GA 1.25 IN	9326705	11/1/2019	10/31/2022
392633 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 20 GA 1.00 IN	1182420	7/1/2021	6/30/2024
392634 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 20 GA 1.16 IN	0259036	9/1/2020	8/31/2023
392637 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 20 GA 1.88 IN	9347630	12/1/2019	11/30/2022
392644 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 18 GA 1.16 IN	1103755	4/1/2021	3/31/2024
392647 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 18 GA 1.88 IN	9347632	12/1/2019	11/30/2022
392654 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 16 GA 1.16 IN	1068446	3/1/2021	2/29/2024
392657 [†]	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter Blood Control Technology 16 GA 1.77 IN	9345323	12/1/2019	11/30/2022

[†] No longer manufactured with the CE mark. The existing inventory will continue to be sold until depletion; at which time the product will be sold without the CE mark to territories where product is registered.

Date: 2023-12-13

DocuSigned by:




Signer Name: Christopher Rogers
Signing Reason: I approve this document
Signing Time: 13-Dec-2023 | 9:56:37 AM PST

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Christopher Rogers
VP, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems Inc.

VERSION HISTORY	
Current Version Prepared By: Paul Holman	
Version	Version Description
T	Added ISO 80369-7:2021 to Non-Harmonized Standards to reflect current standard adherence and qualification of associated luer and thread/lug changes for specific SKUs.
S	Updated Harmonized Standard EN ISO 11607-1:2020 (ISO 11607-1:2019) and EN ISO 11607-2:2020 (ISO 11607-2:2019) to reflect current standard adherence and qualification documentation of packaging materials. Updated Obsolete Product dates, last lot and expiry information
R	Replaced Harmonized Standard EN ISO 14971:2012 with ISO 14971:2019 to reflect risk management documentation and procedures. Removed CE mark on Insyte Autoguard, Insyte Autoguard BC, Insyte Autoguard BC Pro product SKUs in global distribution. These products were added to the Obsolete Table with available last lot information. Removed AngioCath Autoguard products from the Obsolete Table after last batch expiry was surpassed. Removed AngioCath Autoguard products from the Obsolete Table after last batch expiry was surpassed.

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