



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by *Capt. Sean M. Boyd, MPH, USPHS*

3. acting in the capacity of *Deputy Director for Regulatory Affairs*

4. bears the seal/stamp of *U.S. Department of Health and Human Services*

Certified

5. at Washington, D.C.

6. the *sixth* of December, 2018

7. by *Assistant Authentication Officer, United States Department of State*

8. No. *19010433-9*

9. Seal/Stamp:

10. Signature:

Leo J Muldoon

Certificate No. 2027-11-2018

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Three Pages)

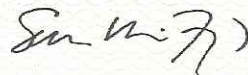
Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.



CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from November 29, 2018 to November 28, 2020.



Certificate No. 2027-11-2018

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

BECTON DICKINSON INFUSION THERAPY SYSTEMS INC.
S.A. de C.V.
PERIFERICO LUIS DONALDO
COLOSIO No. 579
NOGALES, Sonora MEXICO 84048

Becton, Dickinson and Company
ROUTE 7 AND GRACE WAY
CANAAAN, CT USA 06018

BECTON DICKINSON AND COMPANY
2153 12th Ave
COLUMBUS, NE USA 68601

BECTON DICKINSON MEDICAL (SINGAPORE)
30 TUAS AVENUE 2
SINGAPORE, South West SINGAPORE 639461

BD Caribe LTD.
RD 31, KM 24.3
Juncos, PR USA 00777

---END OF MANUFACTURER/DISTRIBUTOR LIST---



Certificate No. 2027-11-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

Becton, Dickinson and Company
ROUTE 7 AND GRACE WAY
CANAAAN, CT USA 06018

Name of Product(s)

309659 BD Syringe Oral 1ml LS 200 S/C
309646 BD Syringe Oral 5ml LL SP125
305851 BD Syringe Oral 1ml clear Sterile
305853 BD Syringe Oral 3ml clear Sterile
305855 BD Syringe Oral 5ml clear Sterile
305857 BD Syringe Oral 10ml clear Sterile
305863 BD Syringe Oral 60ml clear Sterile
309658 BD Syringe Oral 3ml LL EURO 200S/C
309649 BD Syringe 5ml clear LL Euro 125 S/C
309628 BD Syringe 1ml LL W/O DN
309606 BD Syringe Safety -lok 3ml

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

BECTON DICKINSON AND COMPANY
2153 12th Ave
COLUMBUS, NE USA 68601

Name of Product(s)

309653 Syringe 60mL LL TIP 1mL 2 oz IN 1/4 oz
309654 Syringe 60 MI S/T
309620 Syringe catheter Tip 2oz
305106 BD Precision Glide Needle 30G 1/2 (0.3mmx13mm)
305180 BD Blunt fill needle 18Gx1-1/2in
305181 BD Blunt fill needle 18Gx1in
305211 BD Blunt fill filter needle 18Gx1-1/2in
305236 BD Blunt fill needle filter NS 18Gx1-1/2in
305200 BD Nokor filter needle 19Gx1-1/2in
305201 BD Nokor filter needle 18Gx1-1/2in thin Wall
305214 BD Nokor filter needle 18Gxin thin Wall
305215 BD Admix Nokor needle 18Gx 1-1/2in thin Wall

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

BD Caribe LTD.
RD 31, KM 24.3
Juncos, PR USA 00777

Name of Product(s)



Certificate No. 2027-11-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 3

305225 BD Syringe Filling Conector
400273 BD Perisafe kit 18G
400286 BD 19G Durasafe minikit
400287 BD 20G Durasafe minikit
405018 BD Epidural Needle 18Gx3 1/2in Touhy Type Point
405028 Needle epid S/SU 20GA TW3-1/2in tuohy
405092 BD Epidural Needle 17Gx3 1/2in Touhy Type Point
405160 Spinal needle 20Gx1-1/4in introducer
405185 BD Epidural Needle 20Gx2in Weiss type point TW
405188 BD Epidural Needle 18Gx3-1/2in Weiss type point TW
405191 BD Epidural Needle 17Gx3-1/2in Weiss type point TW
408262 BD Westcott Needle 20Gx3-1/2in
408263 BD Westcott Needle 20Gx5-1/2in
408264 BD Westcott Needle 20Gx7in
408265 BD Westcott Needle 22Gx3-1/2in
408267 BD Westcott Needle 22G 7in
408268 BD Chiba Needle 22Gxin TW
408269 BD Chiba Needle 22Gx8in TW
408270 BD Angiography needle 18Gx2-3/64in
408273 BD Angiography needle 18Gx2-7/8in
408300 BD Angiography needle 18Gx2-3/4in
408348 BD NEEDLE REGIONAL BLOCK S/SU 22G 1-1/2IN
409442 BD Whitacre Spinal Needle 25GA 4-11/16in
409443 BD Whitacre Spinal Needle 27GA 4-11/16in
405234 BD QUINCKE Spinal Needle 25GA 4-11/16in
405081 BD Quincke Spinal Needle 27GA x 3-1/2in
405138 BD Whitacre Spinal Needle 25GA 3-1/2in TW
405292 BD EPILOX SYRINGE

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

BECTON DICKINSON MEDICAL (SINGAPORE)
30 TUAS AVENUE 2
SINGAPORE, South West SINGAPORE 639461

Name of Product(s)

305761 BD ECLIPSE Needle 25Gx1in
305762 BD ECLIPSE Needle 23Gx1in
305763 BD ECLIPSE Needle 22Gx1 1/2in
305764 BD ECLIPSE Needle 21Gx1in
305765 BD ECLIPSE Needle 21Gx1 1/2in
305766 BD ECLIPSE Needle 18Gx1 1/2in
305767 BD ECLIPSE Needle 25Gx1 1/2in
305768 BD ECLIPSE Needle 22Gx1in
305769 BD ECLIPSE Needle 23Gx1 1/4in

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

BECTON DICKINSON INFUSION THERAPY SYSTEMS INC. S.A. de C.V.
PERIFERICO LUIS DONALDO



Certificate No. 2027-11-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 3

COLOSIO No. 579

NOGALES, Sonora MEXICO 84048

Name of Product(s)

305224 BD Disposable CORNWALL Syringe System

-----END OF PRODUCT LIST-----





REPÚBLICA FEDERATIVA DO BRASIL
MINISTÉRIO DA SAÚDE
AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA
GERÊNCIA GERAL DE TECNOLOGIA DE PRODUTOS PARA SAÚDE

CERTIDÃO PARA GOVERNO ESTRANGEIRO

A Agência Nacional de Vigilância Sanitária, vinculada ao Ministério da Saúde, CERTIFICA que o produto abaixo indicado, é fabricado de acordo com as leis vigentes no Brasil, com a sua venda autorizada em todo o Território Brasileiro.

Esta CERTIDÃO está sendo concedida específica e exclusivamente para EXPORTAÇÃO com as suas características a seguir discriminadas, não sendo válida a sua utilização para outros fins que não os aqui previstos.

RAZAO SOCIAL: BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA.

CNPJ: 21.551.379/0001-06

ENDEREÇO: RUA CYRO CORREIA PEREIRA, 550 - CIDADE INDUSTRIAL - CURITIBA - PR CEP: 81170-230

NOME TÉCNICO	Seringas Descartáveis
NOME COMERCIAL	BD PLASTIPAK SÉRINGA HIPODÉRMICA COM AGULHA
CLASSE DE RISCO	II - MEDIO RISCO
LOCAL DE FABRICAÇÃO	BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA. - BRASIL - Fabricar
REGISTRO Nº	10033430024
DATA DO REGISTRO	24/05/1994
VÁLIDO ATÉ	VIGENTE

Documento emitido eletronicamente às: 17:18:31 do dia 03/01/2018 (Hora e data de Brasília - DF)
Código de controle do comprovante: 9F6E.DF14.98B8.21F2.19A3.B1BE.2CC7.07FD.444C.8FB0

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MODELO COMERCIAL:

Embalagem contendo: 1, 10, 50, 100, 150, 400, 450, 600, 700, 1000 e 1400 unidades. Volumes das seringas: 1ml; 2ml; 3ml; 5ml; 10ml; 20ml. Tipos de bico: Luer Lok (BD Luer Lok Tip) ou Luer Slip. 0.30 X 13 / 30G 1/2"0.38 X 13 / 27.5G 1/2"0.40 X 13 / 27G 1/2"0.45 X 10 / 26G 3/8"0.45 X 13 / 26G 1/2"0.50 X 25 / 25G 1"0.50 X 20 / 25G 3/4"0.50 X 15 / 25G 5/8"0.55 X 25 / 24G 1"0.55 X 20 / 24G 3/4"0.60 X 40 / 23G 1 1/2"0.60 X 30 / 23G 1 1/4"0.60 X 25 / 23G 1"0.70 X 40 / 22G 1 1/2"0.70 X 30 / 22G 1 1/4"0.70 X 25 / 22G 1"0.80 X 40 / 21G 1 1/2"0.80 X 30 / 21G 1 1/4"0.80 X 25 / 21G 1"0.90 X 40 / 20G 1 1/2"0.90 X 30 / 20G 1 1/4"0.90 X 25 / 20G 1"1.00 X 40 / 19G 1 1/2"1.00 X 30 / 19G 1 1/4"1.00 X 25 / 19G 1"1.20 X 40 / 18G 1 1/2"1.20 X 30 / 18G 1 1/4"1.20 X 25 / 18G 1"1.60 X 40 / 16G 1 1/2"1.60 X 30 / 16G 1 1/4"1.60 X 25 / 16G 1"

Documento emitido eletronicamente às: 17:18:31 do dia 03/01/2018 (Hora e data de Brasília - DF)

Código de controle do comprovante: 9F6E.DF14.98B8.21F2.19A3.B1BE.2CC7.07FD.444C.8FB0

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1. País: (Country / Pays):		REPÚBLICA FEDERATIVA DO BRASIL	
Este documento público (This public document / Le présent acte public)			
2. Foi assinado por: (Has been signed by / A été signé par)		Agência Nacional de Vigilância Sanitária	
3. Na qualidade de: (Acting in the capacity of / Agissant en qualité de)		Orgão Público	
4. Tem o selo / carimbo de: (Bears the seal / stamp of / Est revêtu du sceau / timbre de)		Certidão Expedida Via Internet	
Certificado (Certified / Attesté)			
5. Em: (At / À)	Brasília	6. No dia: (The / Le)	04/01/2018
7. Por: (By / Par):	RAMILO SIMÕES CORREA		
8. Nº: (Nº / Sous n°)	3502470		
9. Selo / Carimbo: (Seal / Stamp / Sceau / Timbre)		10. Firma: (Signature)	
		 Assinatura Eletrônica Electronic Signature Signature Électronique	

Tipo de documento:
(Type of document / Type d'acte)

Certidão para Governo Estrangeiro

Nome do titular:
(Name of holder of document / Nom du titulaire)

Becton Dickinson Indústrias Cirúrgicas Ltda

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A presente Apostila foi firmada com assinatura eletrônica, conforme a Lei nº 11.419/2006.

This Apostille was electronically signed in accordance with Law nº 11.419/2006.

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Any questions about this Apostille may be directed to the Ombudsman of the CNJ:

Veuillez contacter l'Ombudsman de la CNJ pour toute question relative à cette Apostille:

☎ 55 61 2326-4607

@ ouvidoria@cnj.jus.br

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Código (Code):

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CRC:

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A 2067268



Petição Eletrônica



Faltam 14 minutos e 36 segundos para expirar a sessão

Validação de Certidão	
01	<p>Código de Controle da Certidão:</p> <p>Informe o código de controle do comprovante</p> <input type="text" value="9F6E.DF14.98B8.21F2.19A3.B1BE.2CC7.07FD.444C.8FB0"/>
<div>Sair</div> <div>Validar</div>	
Resultado da Validação da Certidão	
<div></div> <p>O Número de Certidão (9F6E.DF14.98B8.21F2.19A3.B1BE.2CC7.07FD.444C.8FB0), é uma Certidão Válida!</p> <p>Nº Certidão: 9F6E.DF14.98B8.21F2.19A3.B1BE.2CC7.07FD.444C.8FB0</p> <p>Data de Emissão: 03/01/2018 17:18:31</p> <p>Nº Registro: 10033430024</p> <p>Situação do registro do produto: VIGENTE</p> <p>Emitir Certidão</p>	

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**REPÚBLICA FEDERATIVA DO BRASIL
MINISTÉRIO DA SAÚDE
AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA
GERÊNCIA GERAL DE TECNOLOGIA DE PRODUTOS PARA SAÚDE**

CERTIDÃO PARA GOVERNO ESTRANGEIRO

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RAZAO SOCIAL: BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA.

CNPJ: 21.551.379/0001-06

ENDEREÇO: RUA CYRO CORREIA PEREIRA, 550 - CIDADE INDUSTRIAL - CURITIBA - PR CEP: 81170-230

NOME TÉCNICO	Seringas Descartaveis
NOME COMERCIAL	BD Emerald Seringa com Agulha
CLASSE DE RISCO	II - MEDIO RISCO
FABRICANTE LEGAL	BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA. - BRASIL - Fabricar
REGISTRO Nº	10033430572
DATA DO REGISTRO	31/05/2010
VÁLIDO ATÉ	VIGENTE

Documento emitido eletronicamente às: 12:37:54 do dia 27/02/2019 (Hora e data de Brasília - DF)

Código de controle do comprovante: B4B0.D34E.B561.12FD.8CBA.2A02.35DE.3969.B102.A6A6

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MODELO COMERCIAL:

3,0mL 0,30 X 13 mm (30G 1/2"); 3,0mL 0,38 X 13 mm (27,5G 1/2"); 3,0mL 0,40 X 13 mm (27G 1/2"); 3,0mL 0,45 X 10 mm (26G 3/8"); 3,0mL 0,45 X 13 mm (26G 1/2"); 3,0mL 0,50 X 25 mm (25G 1"); 3,0mL 0,50 X 20 mm (25G 3/4"); 3,0mL 0,50 X 15 mm (25G 5/8"); 3,0mL 0,55 X 25 mm (24G 1"); 3,0mL 0,55 X 20 mm (24G 3/4"); 3,0mL 0,60 X 40 mm (23G 1 1/2"); 3,0mL 0,60 X 30 mm (23G 1 1/4"); 3,0mL 0,60 X 25 mm (23G 1"); 3,0mL 0,70 X 40 mm (22G 1 1/2"); 3,0mL 0,70 X 30 mm (22G 1 1/4"); 3,0mL 0,70 X 25 mm (22G 1"); 3,0mL 0,80 X 40 mm (21G 1 1/2"); 3,0mL 0,80 X 30 mm (21G 1 1/4"); 3,0mL 0,80 X 25 mm (21G 1"); 3,0mL 0,90 X 40 mm (20G 1 1/2"); 3,0mL 0,90 X 30 mm (20G 1 1/4"); 3,0mL 0,90 X 25 mm (20G 1"); 3,0mL 1,00 X 40 mm (19G 1 1/2"); 3,0mL 1,00 X 30 mm (19G 1 1/4"); 3,0mL 1,00 X 25 mm (19G 1"); 3,0mL 1,20 X 40 mm (18G 1 1/2"); 3,0mL 1,20 X 30 mm (18G 1 1/4"); 3,0mL 1,20 X 25 mm (18G 1"); 3,0mL 1,60 X 40 mm (16G 1 1/2"); 3,0mL 1,60 X 30 mm (16G 1 1/4"); 3,0mL 1,60 X 25 mm (16G 1"); 5,0mL 0,30 X 13 mm (30G 1/2"); 5,0mL 0,38 X 13 mm (27,5G 1/2"); 5,0mL 0,40 X 13 mm (27G 1/2"); 5,0mL 0,45 X 10 mm (26G 3/8"); 5,0mL 0,45 X 13 mm (26G 1/2"); 5,0mL 0,50 X 25 mm (25G 1"); 5,0mL 0,50 X 20 mm (25G 3/4"); 5,0mL 0,50 X 15 mm (25G 5/8"); 5,0mL 0,55 X 25 mm (24G 1"); 5,0mL 0,55 X 20 mm (24G 3/4"); 5,0mL 0,60 X 40 mm (23G 1 1/2"); 5,0mL 0,60 X 30 mm (23G 1 1/4"); 5,0mL 0,60 X 25 mm (23G 1"); 5,0mL 0,70 X 40 mm (22G 1 1/2"); 5,0mL 0,70 X 30 mm (22G 1 1/4"); 5,0mL 0,70 X 25 mm (22G 1"); 5,0mL 0,80 X 40 mm (21G 1 1/2"); 5,0mL 0,80 X 30 mm (21G 1 1/4"); 5,0mL 0,80 X 25 mm (21G 1"); 5,0mL 0,90 X 40 mm (20G 1 1/2"); 5,0mL 0,90 X 30 mm (20G 1 1/4"); 5,0mL 0,90 X 25 mm (20G 1"); 5,0mL 1,00 X 40 mm (19G 1 1/2"); 5,0mL 1,00 X 30 mm (19G 1 1/4"); 5,0mL 1,00 X 25 mm (19G 1"); 5,0mL 1,20 X 40 mm (18G 1 1/2"); 5,0mL 1,20 X 30 mm (18G 1 1/4"); 5,0mL 1,20 X 25 mm (18G 1"); 5,0mL 1,60 X 40 mm (16G 1 1/2"); 5,0mL 1,60 X 30 mm (16G 1 1/4"); 5,0mL 1,60 X 25 mm (16G 1"); 10,0mL 0,30 X 13 mm (30G 1/2"); 10,0mL 0,38 X 13 mm (27,5G 1/2"); 10,0mL 0,40 X 13 mm (27G 1/2"); 10,0mL 0,45 X 10 mm (26G 3/8"); 10,0mL 0,45 X 13 mm (26G 1/2"); 10,0mL 0,50 X 25 mm (25G 1"); 10,0mL 0,50 X 20 mm (25G 3/4"); 10,0mL 0,50 X 15 mm (25G 5/8"); 10,0mL 0,55 X 25 mm (24G 1"); 10,0mL 0,55 X 20 mm (24G 3/4"); 10,0mL 0,60 X 40 mm (23G 1 1/2"); 10,0mL 0,60 X 30 mm (23G 1 1/4"); 10,0mL 0,60 X 25 mm (23G 1"); 10,0mL 0,70 X 40 mm (22G 1 1/2"); 10,0mL 0,70 X 30 mm (22G 1 1/4"); 10,0mL 0,70 X 25 mm (22G 1"); 10,0mL 0,80 X 40 mm (21G 1 1/2"); 10,0mL 0,80 X 30 mm (21G 1 1/4"); 10,0mL 0,80 X 25 mm (21G 1"); 10,0mL 0,90 X 40 mm (20G 1 1/2"); 10,0mL 0,90 X 30 mm (20G 1 1/4"); 10,0mL 0,90 X 25 mm (20G 1"); 10,0mL 1,00 X 40 mm (19G 1 1/2"); 10,0mL 1,00 X 30 mm (19G 1 1/4"); 10,0mL 1,00 X 25 mm (19G 1"); 10,0mL 1,20 X 40 mm (18G 1 1/2"); 10,0mL 1,20 X 30 mm (18G 1 1/4"); 10,0mL 1,20 X 25 mm (18G 1"); 10,0mL 1,60 X 40 mm (16G 1 1/2"); 10,0mL 1,60 X 30 mm (16G 1 1/4"); 10,0mL 1,60 X 25 mm (16G 1").

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12:37:54 do dia 27/02/2019 (Hora e data de Brasília - DF)

Código de controle do comprovante:

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 CONSELHO NACIONAL DE JUSTIÇA		BRASIL APOSTILLE (Convention de La Haye du 5 octobre 1961)	
1. País: (Country / Pays):		REPÚBLICA FEDERATIVA DO BRASIL	
Este documento público (This public document / Le présent acte public)			
2. Foi assinado por: (Has been signed by / A été signé par)		Agência Nacional de Vigilância Sanitária	
3. Na qualidade de: (Acting in the capacity of / Agissant en qualité de)		Órgão Público	
4. Tem o selo / carimbo de: (Bears the seal / stamp of / Est revêtu du sceau / timbre de)		Certidão Expedida Via Internet	
Certificado (Certified / Attesté)			
5. Em: (At / À)	Brasília	6. No dia: (The / Le)	07/03/2019
7. Por: (By / Par):	RAMILO SIMÕES CORREA		
8. Nº: (Nº / Sous nº)	8086881		
9. Selo / Carimbo: (Seal / Stamp / Sceau / Timbre)			10. Firma: (Signature)
		Assinatura Eletrônica Electronic Signature Signature Électronique	

Tipo de documento:
 (Type of document / Type d'acte)

Certidão para Governo Estrangeiro

Nome do titular:
 (Name of holder of document / Nom du titulaire)

Becton Dickinson Indústrias Cirúrgicas Ltda

Esta Apostila certifica apenas a assinatura, a capacidade do signatário e, quando apropriado, o selo ou carimbo constantes no documento público. Ela não certifica o conteúdo do documento para o qual foi emitida.

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A presente Apostila foi firmada com assinatura eletrônica, conforme a Lei nº 11.419/2006.

This Apostille was electronically signed in accordance with Law nº 11.419/2006.

Cette Apostille a été signée par une signature électronique, d'après la Loi nº 11.419/2006.

Dúvidas a respeito desta Apostila entrar em contato com a Ouvidoria do CNJ.

Any questions about this Apostille may be directed to the Ombudsman of the CNJ.

Veuillez contacter l'Ombudsman de la CNJ pour toute question relative à cette Apostille.

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Código (Code):

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CRC

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www.cnj.jus.br/apostila/conferencia

55 61 2326-4607

@ ouvidoria@cnj.jus.br

19.0.00327264-0

A 4132552

Validação de Certidão

01

Código de Controle da Certidão:

Informe o código de controle do comprovante

B4B0.D34E.B561.12FD.8CBA.2A02.35DE.3969.B102.A6A6

Sair

Validar

Resultado da Validação da Certidão

O Número de Certidão (B4B0.D34E.B561.12FD.8CBA.2A02.35DE.3969.B102.A6A6), é uma **Certidão Válida!**

Nº Certidão: B4B0.D34E.B561.12FD.8CBA.2A02.35DE.3969.B102.A6A6

Data de Emissão: 27/02/2019 12:37:54

Nº Registro: 10033430572

Situação do registro do produto: VIGENTE[Emitir Certidão](#)

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by CAPT Sean M. Boyd, MPH, USPHS

3. acting in the capacity of Deputy Director for Regulatory Affairs

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the twenty-eighth of December, 2018

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 19013652-15

9. Seal/Stamp:

10. Signature:



Chana M Turner

Certificate No. 2905-12-2018

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

Name of Manufacturer/Distributor, Address

See Attached List

See Attached List

(Eight Pages)

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.



CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from December 17, 2018 to December 16, 2020.



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 2905-12-2018

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Legal Manufacturer

Manufacturing Facility

BECTON DICKINSON INFUSION THERAPY SYSTEMS INC.
9450 South State Street
SANDY, UT USA 84070

Manufacturing Facility

BECTON DICKINSON INFUSION THERAPY SYSTEMS INC.
S.A. de C.V.
PERIFERICO LUIS DONALDO
COLOSIO No. 579
NOGALES, Sonora MEXICO 84048

Manufacturing Facility

BECTON DICKINSON INDUSTRIAS CIRURGICAS, LTDA.
Avenida Presidente Juscelino Kubitschek
273 Francisco Bernardino
JUIZ DE FORA, Minas Gerais BRAZIL 36081-000

Manufacturing Facility

BECTON DICKINSON AND COMPANY
2153 12th Ave
COLUMBUS, NE USA 68601

Manufacturing Facility

BECTON DICKINSON MEDICAL (SINGAPORE)
30 TUAS AVENUE 2
SINGAPORE, South West SINGAPORE 639461

Manufacturing Facility

Becton, Dickinson and Company
ROUTE 7 AND GRACE WAY
CANAAAN, CT USA 06018

---END OF MANUFACTURER/DISTRIBUTOR LIST---



Certificate No. 2905-12-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 8

Name of Manufacturer

Manufacturing Facility

Becton, Dickinson and Company
ROUTE 7 AND GRACE WAY
CANAAAN, CT USA 06018

Name of Product(s)

303369 BD Threaded Lock Cannula
303340 BD Cannula (Interlink) 17 G BD blunt plastic cannula (BNS)
303347 BD 10ml Syringe with Luer-Lok™ Tip with Blunt Plastic Cannula
303348 BD 10ml Syringe with Luer-Lok™ Tip with Blunt Plastic Cannula
303370 BD Lever Lock Cannula
303379 BD Threaded Lock Cannula
303392 BD 5ml Syringe with BD Twinpak™
303397 BD Cannula (Interlink) 15 G BD Interlink threaded lock cannula (BNS)
303401 BD 3ml Syringe with Luer-Lok™ Tip with Vial Access Cannula
303403 BD 5ml Syringe with Luer-Lok™ Tip with Vial Access Cannula
303405 BD 10ml Syringe with Luer-Lok™ Tip with Vial Access Cannula

Name of Manufacturer

Manufacturing Facility

BECTON DICKINSON AND COMPANY
2153 12th Ave
COLUMBUS, NE USA 68601

Manufacturing Facility

Becton, Dickinson and Company
ROUTE 7 AND GRACE WAY
CANAAAN, CT USA 06018

Name of Product(s)

303391 BD 3ml Syringe with BD Twinpak™
303393 BD 10ml Syringe with BD Twinpak™

Name of Manufacturer

Manufacturing Facility

BECTON DICKINSON AND COMPANY
2153 12th Ave
COLUMBUS, NE USA 68601

Name of Product(s)

303345 BD Blunt Plastic Cannula
303346 BD 3ml Syringe with Luer-Lok™ Tip with Blunt Plastic Cannula
303366 BD Syringe Cannula
303367 BD Vial Access Cannula
303376 BD Bare Cannula
303377 BD Vial Access Cannula
303390 BD Twinpak™

Name of Manufacturer

Manufacturing Facility

BECTON DICKINSON INDUSTRIAS CIRURGICAS, LTDA.
Avenida Presidente Juscelino Kubitschek
273 Francisco Bernardino
JUIZ DE FORA, Minas Gerais BRAZIL 36081-000

Name of Product(s)

381112 BD Angiocath™ IV Catheter 24GA 0.75IN (0.7 x 19 mm)



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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 8

381123 BD Angiocath™ IV Catheter 22GA 1.00IN (0.9 x 25 mm)
381134 BD Angiocath™ IV Catheter 20GA 1.16IN (1.1 x 30 mm)
381137 BD Angiocath™ IV Catheter 20GA 1.88IN (1.1 x 48 mm)
381144 BD Angiocath™ IV Catheter 18GA 1.16IN (1.3 x 30 mm)
381147 BD Angiocath™ IV Catheter 18GA 1.88IN (1.3 x 48 mm)

Name of Manufacturer

Manufacturing Facility

BECTON DICKINSON INFUSION THERAPY SYSTEMS INC. S.A. de C.V.

PERIFERICO LUIS DONALDO

COLOSIO No. 579

NOGALES, Sonora MEXICO 84048

Name of Product(s)

380408 Insyte Introducer FN OEM BNS
381154 BD Angiocath™ IV Catheter 16GA 1.16IN (1.7 x 30 mm)
381157 BD Angiocath™ IV Catheter 16GA 1.88IN (1.7 x 48 mm)
381164 BD Angiocath™ IV Catheter 14GA 1.16IN (2.1 x 30 mm)
381167 BD Angiocath™ IV Catheter 14GA 1.88IN (2.1 x 48 mm)
382258 BD Angiocath™ IV Catheter for Special Placement 16GA x 3.25IN (1.7 x 83 mm)
382259 BD Angiocath™ IV Catheter for Special Placement 16GA x 5.25IN (1.7 x 133 mm)
382268 BD Angiocath™ IV Catheter for Special Placement 14GA x 3.25IN (2.1 x 83 mm)
382269 BD Angiocath™ IV Catheter for Special Placement 14GA x 5.25IN (2.1 x 133 mm)
382277 BD Angiocath™ IV Catheter for Special Placement 12GA x 3.00IN (2.8 x 76 mm)
382287 BD Angiocath™ IV Catheter for Special Placement 10GA x 3.00IN (3.4 x 76 mm)
383312 BD Saf-T-Intima™ Safety System with Removable PRN 24GA 0.75IN (0.7 x 19 mm)
383313 BD Saf-T-Intima™ Safety System with Y Adapter 24GA 0.75IN (0.7 x 19 mm)
383322 BD Saf-T-Intima™ Safety System with Removable PRN 22GA 0.75IN (0.9 x 19 mm)
383323 BD Saf-T-Intima™ Safety System with Y Adapter 22GA 0.75IN (0.9 x 19 mm)
383335 BD Saf-T-Intima™ Safety System with Removable PRN 20GA 1.00IN (1.1 x 25 mm)
383336 BD Saf-T-Intima™ Safety System with Y Adapter 20GA 1.00IN (1.1 x 25 mm)
383346 BD Saf-T-Intima™ Safety System with Y Adapter 18GA 1.00IN (1.3 x 25 mm)
383550 BD Nexiva™ Closed IV Catheter System – Single Port with MaxZero™ Needleless Connector 24GA 0.56IN (0.7 x 14 mm)
383551 BD Nexiva™ Closed IV Catheter System – Single Port with MaxZero™ Needleless Connector 24GA 0.75IN (0.7 x 19 mm)
383552 BD Nexiva™ Closed IV Catheter System – Single Port with MaxZero™ Needleless Connector 22GA 1.00IN (0.9 x 25 mm)
383556 BD Nexiva™ Closed IV Catheter System – Single Port with MaxZero™ Needleless Connector 20GA 1.00IN (1.1 x 25 mm)
383557 BD Nexiva™ Closed IV Catheter System – Single Port with MaxZero™ Needleless Connector 20GA 1.25IN (1.1 x 32 mm)
383558 BD Nexiva™ Closed IV Catheter System – Single Port with MaxZero™ Needleless Connector 20GA 1.75IN (1.1 x 45 mm)
383559 BD Nexiva™ Closed IV Catheter System – Single Port with MaxZero™ Needleless Connector 18GA 1.25IN (1.3 x 32 mm)
383560 BD Nexiva™ Closed IV Catheter System – Single Port with MaxZero™ Needleless Connector 18GA 1.75IN (1.3 x 45 mm)
383590 BD Nexiva Diffusics™ Closed IV Catheter System 24GA 0.75IN (0.7 x 19 mm)
383591 BD Nexiva Diffusics™ Closed IV Catheter System 22GA 1.00IN (0.9 x 25 mm)
383592 BD Nexiva Diffusics™ Closed IV Catheter System 20GA 1.00IN (1.1 x 25 mm)
383593 BD Nexiva Diffusics™ Closed IV Catheter System 20GA 1.25IN (1.1 x 32 mm)
383594 BD Nexiva Diffusics™ Closed IV Catheter System 18GA 1.25IN (1.3 x 32 mm)
383691 BD Nexiva™ Diffusics™ Closed IV Catheter System 24GA 0.75IN (0.7 x 19 mm)
383692 BD Nexiva™ Diffusics™ Closed IV Catheter System 22GA 1.00IN (0.9 x 25 mm)
383693 BD Nexiva™ Diffusics™ Closed IV Catheter System 20GA 1.00IN (1.1 x 25 mm)
383694 BD Nexiva™ Diffusics™ Closed IV Catheter System 20GA 1.25IN (1.1 x 32 mm)
383695 BD Nexiva™ Diffusics™ Closed IV Catheter System 18GA 1.25IN (1.3 x 32 mm)



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385100 BD Q-Syte™ Luer Access Split Septum
385101 BD Q-Syte™ Extension Set 15 cm (6 IN) 1.14 ml Std Bore
385102 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.34 ml Micro Bore
385103 BD Q-Syte™ Luer Access Split Septum
385104 BD Q-Syte™ Extension Set 15 cm (6 IN) 1.14 ml Std Bore
385105 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.34 ml Micro Bore
385106 Q-Syte Vial Access Adapter BD Q-Syte™ Vial Access Adapter
385108 BD Q-Syte™ Vial Access Adapter
385120 BD I.V. Loop
385121 BD J-Loop
385150 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.60 ml
385151 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.25 ml
385152 BD Q-Syte™ Extension Set 15 cm (6 IN) 1.00 ml
385153 BD Q-Syte™ Extension Set 36 cm (14 IN) 0.55 ml
385154 BD Q-Syte™ Power Injectable Extension Set 15 cm
385155 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 1.60 ml
385156 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 2.25 ml
385157 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 0.45 ml
385158 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 0.80 ml
385161 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 1.60 ml
385162 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 2.25 ml
385163 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.45 ml
385164 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 0.80 ml
385165 BD Q-Syte™ Y Extension Set 20 8m (8 IN) 1.40 ml
385166 BD Q-Syte™ Dual Y Extension Set 50 cm (20 IN) 3.20 ml
386120 IV Start Pak BD IV Start Pak™
386140 IV Start Pak BD IV Start Pak™ IV Site Prep Kit
386142 IV Start Pak BD IV Start Pak™ IV Site Prep Kit
386150 IV Start Pak BD IV Start Pak™ IV Site Prep Kit
386159 IV Start Pak BD IV Start Pak™ IV Site Prep Kit
386162 IV Start Pak BD IV Start Pak™ IV Site Prep Kit
386170 BD IV Start Pak™ IV Site Prep Kit
386172 BD IV Start Pak™ IV Site Prep Kit
386175 IV Start Pak BD IV Start Pak™ IV Site Prep Kit
386179 IV Start Pak BD IV Start Pak™ IV Site Prep Kit
386180 IV Start Pak BD IV Start Pak™ IV Site Prep Kit
386190 IV Start Pak BD IV Start Pak™ IV Site Prep Kit
386718 BD IV Start Pak™ IV Site Prep Kit
386719 BD IV Start Pak™ IV Site Prep Kit
386720 BD IV Start Pak™ IV Site Prep Kit
394600 BD Connecta™ Stopcock (White 360Deg "ON" Directed Tap)
394601 BD Connecta™ Stopcock (with Colored Plugs) (White 360Deg "ON" Directed Tap)
394602 BD Connecta™ Stopcock (Blue 360Deg "ON" Directed Tap)
394605 BD Connecta™ Stopcock (Red 360Deg "ON" Directed Tap)
394908 BD Connecta™ Stopcock (White 360Deg "OFF" Directed Tap)
394910 BD Connecta™ Stopcock (White 360Deg "OFF" Directed Tap)
394911 BD Connecta™ Stopcock (Blue 360Deg "OFF" Directed Tap)
394912 BD Connecta™ Stopcock (Red 360Deg "OFF" Directed Tap)
395156 BD Connecta™ Stopcock without cap (White 180Deg "OFF" directed Tap)
395157 BD Connecta™ Stopcock without cap (Red 180Deg "OFF" directed Tap)
395159 BD Connecta™ Stopcock without cap (Blue 180Deg "OFF" directed Tap)
395162 BD Connecta™ Stopcock without cap (Yellow 180Deg "OFF" directed Tap)
395163 BD Connecta™ Stopcock without cap (Red 360Deg "OFF" directed Tap)
395165 BD Connecta™ Stopcock without cap (White 360Deg "OFF" directed Tap)
395167 BD Connecta™ Stopcock without cap (Blue 360Deg "OFF" directed Tap)
395168 BD Connecta™ Stopcock without cap (Yellow 360Deg "OFF" directed Tap)
395169 BD Connecta™ Stopcock without cap (White 90Deg "OFF" directed Tap)
395174 BD Connecta™ Stopcock without cap (White 360 "ON" directed Tap)



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395175 BD Connecta™ Stopcock without cap (Red 360Deg "ON" directed Tap)
395176 BD Connecta™ Stopcock without cap (Blue 360Deg "ON" directed Tap)
395177 BD Connecta™ Stopcock without cap (Yellow 360Deg "ON" directed Tap)
395179 BD Connecta™ Stopcock (White 180Deg "OFF" directed Tap)
395180 BD Connecta™ Stopcock without nut (White 360Deg "ON" directed Tap)
395197 BD Connecta™ Stopcock without plug (Blue 360Deg "ON" directed Tap)
395214 BD Connecta™ Stopcock (White 360Deg "ON" directed Tap)
395215 BD Connecta™ Stopcock (Blue 360Deg "ON" directed Tap)
395217 BD Connecta™ Stopcock without nut
395220 BD Connecta™ Stopcock (Blue 180Deg "OFF" directed Tap)
395222 BD Connecta™ Stopcock (Red 180Deg "OFF" directed Tap)
395224 BD Connecta™ Stopcock (Yellow 180Deg "OFF" directed Tap)
395225 BD Connecta™ Stopcock (White 360Deg "OFF" directed Tap)
395250 BD Connecta™ Stopcock without nut cap (Red 360Deg "ON" directed Tap)
395251 BD Connecta™ Stopcock with .50 cm extension tube (White 360Deg "ON" directed Tap)

Name of Manufacturer

Legal Manufacturer

Manufacturing Facility

BECTON DICKINSON INFUSION THERAPY SYSTEMS INC.

9450 South State Street

SANDY, UT USA 84070

Name of Product(s)

380510 BD Q-Syte™ Luer Access Split Septum
381012 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 24GA 0.75IN (0.7 x 19 mm)
381023 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 22GA 1.00IN (0.9 x 25 mm)
381033 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 20GA 1.00IN (1.1 x 25 mm)
381034 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 20GA 1.16IN (1.1 x 30 mm)
381037 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 20GA 1.88IN (1.1 x 48 mm)
381044 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 18GA 1.16IN (1.3 x 30 mm)
381047 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 18GA 1.88IN (1.3 x 48 mm)
381054 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 16GA 1.16IN (1.7 x 30 mm)
381057 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 16GA 1.77IN (1.7 x 45 mm)
381411 BD Insyte-N™ Autoguard™ Shielded IV Catheter 24GA 0.56IN (0.7 x 14 mm)
381412 BD Insyte™ Autoguard™ Shielded IV Catheter 24GA 0.75IN (0.7 x 19 mm)
381423 BD Insyte™ Autoguard™ Shielded IV Catheter 22GA 1.00IN (0.9 x 25 mm)
381433 BD Insyte™ Autoguard™ Shielded IV Catheter 20GA 1.00IN (1.1 x 25 mm)
381434 BD Insyte™ Autoguard™ Shielded IV Catheter 20GA 1.16IN (1.1 x 30 mm)
381437 BD Insyte™ Autoguard™ Shielded IV Catheter 20GA 1.88IN (1.1 x 48 mm)
381444 BD Insyte™ Autoguard™ Shielded IV Catheter 18GA 1.16IN (1.3 x 30 mm)
381447 BD Insyte™ Autoguard™ Shielded IV Catheter 18GA 1.88IN (1.3 x 48 mm)
381454 BD Insyte™ Autoguard™ Shielded IV Catheter 16GA 1.16IN (1.7 x 30 mm)
381457 BD Insyte™ Autoguard™ Shielded IV Catheter 16GA 1.77IN (1.7 x 45 mm) no pres
381467 BD Insyte™ Autoguard™ Shielded IV Catheter 14GA 1.75IN (2.1 x 45 mm)
381511 BD Insyte-N™ Autoguard™ Winged Shielded IV Catheter 24GA 0.56IN (0.7 x 14 mm)
381512 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 24GA 0.75IN (0.7 x 19 mm)
381523 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 22GA 1.00IN (0.9 x 25 mm)
381533 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20GA 1.00IN (1.1 x 25 mm)



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Certificate to Foreign Government - Name of Product(s) Attachment Page 5 of 8

381534 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20GA 1.16IN (1.1 x 30 mm)
381537 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20GA 1.88IN (1.1 x 48 mm)
381544 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18GA 1.16IN (1.3 x 30 mm)
381547 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18GA 1.88IN (1.3 x 48 mm)
381554 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16GA 1.16IN (1.7 x 30 mm)
381557 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16GA 1.77IN (1.7 x 45 mm)
381700 BD Angiocath™ Autoguard™ Shielded IV Catheter 24GA 0.75IN (0.7 x 19 mm)
381701 BD Angiocath™ Autoguard™ Shielded IV Catheter 22GA 1.00IN (0.9 x 25 mm)
381702 BD Angiocath™ Autoguard™ Shielded IV Catheter 20GA 1.00IN (1.1 x 25 mm)
381703 BD Angiocath™ Autoguard™ Shielded IV Catheter 20GA 1.16IN (1.1 x 30 mm)
381704 BD Angiocath™ Autoguard™ Shielded IV Catheter 20GA 1.88IN (1.1 x 48 mm)
381705 BD Angiocath™ Autoguard™ Shielded IV Catheter 18GA 1.16IN (1.3 x 30 mm)
381706 BD Angiocath™ Autoguard™ Shielded IV Catheter 18GA 1.88IN (1.3 x 48 mm)
381707 BD Angiocath™ Autoguard™ Shielded IV Catheter 16GA 1.16IN (1.7 x 30 mm)
381708 BD Angiocath™ Autoguard™ Shielded IV Catheter 16GA 1.77IN (1.7 x 45 mm)
381709 BD Angiocath™ Autoguard™ Shielded IV Catheter 14GA 1.75IN (2.1 x 45 mm)
381720 BD Angiocath-N™ Autoguard™ Shielded IV Catheter 24GA 0.56IN (0.7 x 14 mm)
381811 BD Insyte-N™ Autoguard™ Shielded IV Catheter 24GA 0.56IN (0.7 x 14 mm)
381812 BD Insyte™ Autoguard™ Shielded IV Catheter 24GA 0.75IN (0.7 x 19 mm)
381823 BD Insyte™ Autoguard™ Shielded IV Catheter 22GA 1.00IN (0.9 x 25 mm)
381833 BD Insyte™ Autoguard™ Shielded IV Catheter 20GA 1.00IN (1.1 x 25 mm)
381834 BD Insyte™ Autoguard™ Shielded IV Catheter 20GA 1.16IN (1.1 x 30 mm)
381837 BD Insyte™ Autoguard™ Shielded IV Catheter 20GA 1.88IN (1.1 x 48 mm)
381844 BD Insyte™ Autoguard™ Shielded IV Catheter 18GA 1.16IN (1.3 x 30 mm)
381847 BD Insyte™ Autoguard™ Shielded IV Catheter 18GA 1.88IN (1.3 x 48 mm)
381854 BD Insyte™ Autoguard™ Shielded IV Catheter 16GA 1.16IN (1.7 x 30 mm)
381857 BD Insyte™ Autoguard™ Shielded IV Catheter 16GA 1.77IN (1.7 x 45 mm)
381867 BD Insyte™ Autoguard™ 14GA 1.75IN (2.1 x 45 mm)
381911 BD Insyte-N™ Autoguard™ Winged Shielded IV Catheter 24GA 0.56IN (0.7 x 14 mm)
381912 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 24GA 0.75IN (0.7 x 19 mm)
381923 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 22GA 1.00IN (0.9 x 25 mm)
381933 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20GA 1.00IN (1.1 x 25 mm)
381934 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20GA 1.16IN (1.1 x 30 mm)
381937 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 20GA 1.88IN (1.1 x 48 mm)
381944 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18GA 1.16IN (1.3 x 30 mm)
381947 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 18GA 1.88IN (1.3 x 48 mm)
381954 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16GA 1.16IN (1.7 x 30 mm)
381957 BD Insyte™ Autoguard™ Winged Shielded IV Catheter 16GA 1.77IN (1.7 x 45 mm)
382512 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 24GA 0.75IN (0.7 x 19 mm)
382523 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 22GA 1.00IN (0.9 x 25 mm)
382533 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 20GA 1.00IN (1.1 x 25 mm)
382534 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 20GA 1.16IN (1.1 x 30 mm)
382537 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 20GA 1.88IN (1.1 x 48 mm)
382544 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 18GA 1.16IN (1.3 x 30 mm)
382547 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 18GA 1.88IN (1.3 x 48 mm)
382554 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 16GA 1.16IN (1.7 x 30 mm)
382557 BD Insyte™ Autoguard™ BC Shielded IV Catheter Blood Control Technology 16GA 1.77IN (1.7 x 45 mm)
382612 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 24GA 0.75IN (0.7 x 19 mm)



Certificate No. 2905-12-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 6 of 8

- 382623 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 22GA 1.00IN (0.9 x 25 mm)
- 382633 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 20GA 1.00IN (1.1 x 25 mm)
- 382634 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 20GA 1.16IN (1.1 x 30 mm)
- 382637 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 20GA 1.88IN (1.1 x 48 mm)
- 382644 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 18GA 1.16IN (1.3 x 30 mm)
- 382647 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 18GA 1.88IN (1.3 x 48 mm)
- 382654 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 16GA 1.16IN (1.7 x 30 mm)
- 382657 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 16GA 1.77IN (1.7 x 45 mm)
- 382912 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 24GA 0.75IN (0.7 x 19 mm)
- 382923 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 22GA 1.00IN (0.9 x 25 mm)
- 382933 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 20GA 1.00IN (1.1 x 25 mm)
- 382934 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 20GA 1.16IN (1.1 x 30 mm)
- 382937 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 20GA 1.88IN (1.1 x 48 mm)
- 382944 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 18GA 1.16IN (1.3 x 30 mm)
- 382947 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 18GA 1.88IN (1.3 x 48 mm)
- 382954 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 16GA 1.16IN (1.7 x 30 mm)
- 382957 BD Insyte™ Autoguard™ BC Winged Shielded IV Catheter Blood Control Technology 16GA 1.77IN (1.7 x 45 mm)
- 383510 BD Nexiva™ Closed IV Catheter System – Single Port 24GA 0.56IN (0.7 x 14 mm)
- 383511 BD Nexiva™ Closed IV Catheter System – Single Port 24GA 0.75IN (0.7 x 19 mm)
- 383512 BD Nexiva™ Closed IV Catheter System – Single Port 22GA 1.00IN (0.9 x 25 mm)
- 383513 BD Nexiva™ Closed IV Catheter System – Single Port 22GA 1.75IN (0.9 x 45 mm)
- 383516 BD Nexiva™ Closed IV Catheter System – Single Port 20GA 1.00IN (1.1 x 25 mm)
- 383517 BD Nexiva™ Closed IV Catheter System – Single Port 20GA 1.25IN (1.1 x 32 mm)
- 383518 BD Nexiva™ Closed IV Catheter System – Single Port 20GA 1.75IN (1.1 x 45 mm)
- 383519 BD Nexiva™ Closed IV Catheter System – Single Port 18GA 1.25IN (1.3 x 32 mm)
- 383520 BD Nexiva™ Closed IV Catheter System – Single Port 18GA 1.75IN (1.3 x 45 mm)
- 383530 BD Nexiva™ Closed IV Catheter System – Dual Port 24GA 0.56IN (0.7 x 14 mm)
- 383531 BD Nexiva™ Closed IV Catheter System – Dual Port 24GA 0.75IN (0.7 x 19 mm)
- 383532 BD Nexiva™ Closed IV Catheter System – Dual Port 22GA 1.00IN (0.9 x 25 mm)
- 383536 BD Nexiva™ Closed IV Catheter System – Dual Port 20GA 1.00IN (1.1 x 25 mm)
- 383537 BD Nexiva™ Closed IV Catheter System – Dual Port 20GA 1.25IN (1.1 x 32 mm)
- 383538 BD Nexiva™ Closed IV Catheter System – Dual Port 20GA 1.75IN (1.1 x 45 mm)
- 383539 BD Nexiva™ Closed IV Catheter System – Dual Port 18GA 1.25IN (1.3 x 32 mm)
- 383540 BD Nexiva™ Closed IV Catheter System – Dual Port 18GA 1.75IN (1.3 x 45 mm)
- 383541 BD Nexiva™ Closed IV Catheter System – Dual Port 24 GA 0.75 IN (0.7 x 19 mm)
- 383542 BD Nexiva™ Closed IV Catheter System – Dual Port 22 GA 1.00 IN (0.9 x 25 mm)
- 383543 BD Nexiva™ Closed IV Catheter System – Dual Port 20 GA 1.00 IN (1.1 x 25 mm)
- 383544 BD Nexiva™ Closed IV Catheter System – Dual Port 22 GA 1.25 IN (1.1 x 32 mm)
- 383545 BD Nexiva™ Closed IV Catheter System – Dual Port 18 GA 1.25 IN (1.3 x 32 mm)
- 383640 BD Nexiva™ Closed IV Catheter System 24GA 0.56IN (0.7 x 14 mm)
- 383641 BD Nexiva™ Closed IV Catheter System 24GA 0.75IN (0.7 x 19 mm)



Certificate No. 2905-12-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 7 of 8

383642 BD Nexiva™ Closed IV Catheter System 22GA 1.00IN (0.9 x 25 mm)
383646 BD Nexiva™ Closed IV Catheter System 20GA 1.00IN (1.1 x 25 mm)
383647 BD Nexiva™ Closed IV Catheter System 20GA 1.25IN (1.1 x 32 mm)
383648 BD Nexiva™ Closed IV Catheter System 20GA 1.75IN (1.1 x 45 mm)
383649 BD Nexiva™ Closed IV Catheter System 18GA 1.25IN (1.3 x 32 mm)
383650 BD Nexiva™ Closed IV Catheter System 18GA 1.75IN (1.3 x 45 mm)
384008 BD Introsyte-N™ Autoguard™ Shielded Introducer 26 GA 19 mm
384010 BD Introsyte™ Autoguard™ Shielded Introducer 20 GA 32 mm
384011 BD Introsyte™ Autoguard™ Shielded Introducer 18 GA 32 mm
384012 BD Introsyte™ Autoguard™ Shielded Introducer 16 GA 32 mm
384021 BD Introsyte-N™ 26 GA (1.9F) 19 mm
384030 BD Introsyte™ 20 GA (3F) 32 mm
384031 BD Introsyte-N™ 22 GA (2.8F) 25 mm
384040 BD Introsyte™ 18 GA (2.8F) 32 mm
384050 BD Introsyte™ 16GA (5F) 32 mm

Name of Manufacturer

Manufacturing Facility

BECTON DICKINSON MEDICAL (SINGAPORE)
30 TUAS AVENUE 2
SINGAPORE, South West SINGAPORE 639461

Name of Product(s)

381211 BD Insyte-N™ IV Catheter 24GA 0.56IN (0.7 x 14 mm)
381237 BD Insyte™ IV Catheter 20GA 1.88IN (1.1 x 48 mm)
381244 BD Insyte™ IV Catheter 18GA 1.16IN (1.3 x 30 mm)
381247 BD Insyte™ IV Catheter 18GA 1.88IN (1.3 x 48 mm)
381254 BD Insyte™ IV Catheter 16GA 1.16IN (1.7 x 30 mm)
381257 BD Insyte™ IV Catheter 16GA 1.77IN (1.7 x 45 mm)
381311 BD Insyte-N™ IV Catheter with Wings 24GA 0.56IN (0.7 x 14 mm)
381312 BD Insyte-W™ IV Catheter with Wings 24GA 0.75IN (0.7 x 19 mm)
381323 BD Insyte-W™ IV Catheter with Wings 22GA 1.00IN (0.9 x 25 mm)
381333 BD Insyte-W™ IV Catheter with Wings 20GA 1.00IN (1.1 x 25 mm)
381334 BD Insyte-W™ IV Catheter with Wings 20GA 1.16IN (1.1 x 30 mm)
381337 BD Insyte-W™ IV Catheter with Wings 20GA 1.88IN (1.1 x 48 mm)
381344 BD Insyte-W™ IV Catheter with Wings 18GA 1.16IN (1.3 x 30 mm)
381347 BD Insyte-W™ IV Catheter with Wings 18GA 1.88IN (1.3 x 48 mm)
381354 BD Insyte-W™ IV Catheter with Wings 16GA 1.16IN (1.7 x 30 mm)
381357 BD Insyte-W™ IV Catheter with Wings 16GA 1.77IN (1.7 x 45 mm)
386801 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 18 GA 1.25 IN (1.3 x 32 mm)
386802 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 18 GA 2.00 IN (1.3 x 51 mm)
386803 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 20 GA 1.00 IN (1.1 x 25 mm)
386804 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 20 GA 1.25 IN (1.1 x 32 mm)
386805 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 20 GA 2.00 IN (1.1 x 51 mm)
386806 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 22 GA 1.00 IN (0.9 x 25 mm)
386807 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 24 GA 0.75 IN (0.7 x 19 mm)
386808 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 18 GA 1.25 IN (1.3 x 32 mm)
386809 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 18 GA 2.00 IN (1.3 x 51 mm)
386810 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 20 GA 1.00 IN (1.1 x 25 mm)
386811 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 20 GA 1.25 IN (1.1 x 32 mm)
386812 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 20 GA 2.00 IN (1.1 x 51 mm)
386813 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 22 GA 1.00 IN (0.9 x 25 mm)
386814 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 22 GA 2.00 IN (0.9 x 51 mm)
386815 BD Cathena™ Safety IV Catheter BD Multiguard™ Technology 24 GA 0.75 IN (0.7 x 19 mm)
386816 BD Cathena™ Safety IV Catheter 16 GA 1.25 IN (1.7 x 32 mm)
386817 BD Cathena™ Safety IV Catheter 16 GA 2.00 IN (1.7 x 51 mm)
386818 BD Cathena™ Safety IV Catheter 24 GA 0.75 IN (0.7 x 19 mm)
386819 BD Cathena™ Safety IV Catheter 16 GA 1.25 IN (1.7 x 32 mm)



Certificate No. 2905-12-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 8 of 8

386820 BD Cathena™ Safety IV Catheter 16 GA 2.00 IN (1.7 x 51 mm)
386821 BD Cathena™ Safety IV Catheter 24 GA 0.75 IN (0.7 x 19 mm)
391660 BD Neoflon™ Pro Safety Safety IV Catheter 24 GA 0.75 IN (0.7 x 19 mm)
391661 BD Neoflon™ Pro Safety Safety IV Catheter BD Multiguard™ Technology 24 GA 0.75 IN (0.7 x 19 mm)
391662 BD Neoflon™ Pro Safety Safety IV Catheter with Wings 24 GA 0.75 IN (0.7 x 19 mm)
391663 Neoflon Pro Safety BD Neoflon™ Pro Safety IV Catheter with Wings BD Multiguard™ Technology 24
GA 0.75 IN (0.7 x 19 mm)

Name of Manufacturer

Manufacturing Facility

BECTON DICKINSON INDUSTRIAS CIRURGICAS, LTDA.
Avenida Presidente Juscelino Kubitschek
273 Francisco Bernardino
JUIZ DE FORA, Minas Gerais BRAZIL 36081-000

Manufacturing Facility

BECTON DICKINSON MEDICAL (SINGAPORE)
30 TUAS AVENUE 2
SINGAPORE, South West SINGAPORE 639461

Name of Product(s)

381212 BD Insyte™ IV Catheter 24GA 0.75IN (0.7 x 19 mm)
381223 BD Insyte™ IV Catheter 22GA 1.00IN (0.9 x 25 mm)
381233 BD Insyte™ IV Catheter 20GA 1.00IN (1.1 x 25 mm)
381234 BD Insyte™ IV Catheter 20GA 1.16IN (1.1 x 30 mm)
381267 BD Insyte™ IV Catheter 14GA 1.75IN (2.1 x 45 mm)

END OF PRODUCT LIST





REPÚBLICA FEDERATIVA DO BRASIL
MINISTÉRIO DA SAÚDE
AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA
GERÊNCIA GERAL DE TECNOLOGIA DE PRODUTOS PARA SAÚDE
CERTIDÃO PARA GOVERNO ESTRANGEIRO

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CNPJ: 21.551.379/0001-06

ENDEREÇO: RUA CYRO CORREIA PEREIRA, 550 - CIDADE INDUSTRIAL - CURITIBA - PR CEP: 81170-230

NOME TÉCNICO	Seringas Descartaveis
NOME COMERCIAL	BD PLASTIPAK SERINGA HIPODERMICA SEM AGULHA
CLASSE DE RISCO	II - MEDIO RISCO
FABRICANTE LEGAL	BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA. - BRASIL - Fabricar,BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA. - BRASIL - Unidade Fabril
REGISTRO Nº	10033430030
DATA DO REGISTRO	27/05/1994
VÁLIDO ATÉ	VIGENTE

Documento emitido eletronicamente às: 13:36:25 do dia 16/10/2018 (Hora e data de Brasília - DF)

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1. País: (Country / Pays):		REPÚBLICA FEDERATIVA DO BRASIL	
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3. Na qualidade de: (Acting in the capacity of / Agissant en qualité de)		Órgão Público	
4. Tem o selo / carimbo de: (Bears the seal / stamp of / Est revêtu du sceau/ timbre de)		Certidão Expedida Via Internet	
Certificado (Certified / Attesté)			
5. Em: (At / À)	Brasília	6. No dia: (The / Le)	17/10/2018
7. Por: (By / Par):	RAMILO SIMÕES CORREA		
8. Nº: (Nº/ Sous nº)	6665910		
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Becton Dickinson Indústrias Cirúrgicas Ltda

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Any questions about this Apostille may be directed to the Ombudsman of the CNJ:

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@ ouvidoria@cnj.jus.br

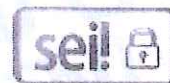
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Verifique a autenticidade deste documento no endereço: <http://www.anvisa.gov.br/validacertidaogtpps>

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America

This public document

2. has been signed by CDR Cesar A. Perez

3. acting in the capacity of Director, DRP2 Division of Establishment Support Office of Regulatory Programs

4. bears the seal/stamp of U.S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the thirty-first of May, 2019

7. by Assistant Authentication Officer, United States Department of State

8. No. 19039368-3

9. Seal/Stamp:

10. Signature:

Z M Daley
Zelda Daley

Certificate No. 8807-4-2019

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,



CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from May 17, 2019 to May 16, 2021.



Certificate No. 8807-4-2019

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Owner Operator

BECTON, DICKINSON & CO.

One Becton Drive

Franklin Lakes, NJ USA 07417

Name of Manufacturer

Manufacturing Facility

BD MEDICAL - DIABETES CARE

1329 West Highway 6

HOLDREGE, NE USA 68949

Name of Product(s)

328468 - BD Insulin Syringe 0.5mL 31G x 8mm

928853 - Insulin Syringe 1mL 30G x 8mm

328504 - BD Insulin Syringe 1mL 29G x 12.7mm

328512 - BD Insulin Syringe 0.3mL 31G x 8mm

328466 - BD Insulin Syringe 0.5mL 30G x 12.7mm

928855 - Insulin Syringe 0.3mL 30G x 8mm

928854 - Insulin Syringe 0.5mL 30G x 8mm

928856 - Insulin Syringe 1mL 30G x 8mm

324912 - BD Insulin Syringe 1mL 31G x 6mm

-----END OF PRODUCT LIST-----





Certificate No. 8807-4-2019

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

Manufacturing Facility

BD MEDICAL - DIABETES CARE
1329 West Highway 6
HOLDREGE, NE USA 68949

----END OF MANUFACTURER/DISTRIBUTOR LIST----



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by *CDR Cesar A. Perez, PhD*

3. acting in the capacity of *Director, Division of International Compliance Operations*

4. bears the seal/stamp of *U.S. Department of Health and Human Services*

Certified

5. at Washington, D.C.

6. the *ninth* of April, 2019

7. by *Assistant Authentication Officer, United States Department of State*

8. No. *19029355-9*

9. Seal/Stamp.

10. Signature:



Leo J Muldoon



Certificate No. 7163-3-2019

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

371603- BD E-Z Scrub 160, Surgical Scrub
Brush/Sponge With Nail Cleaner

Name of Manufacturer/Distributor, Address

Name of Manufacturer

Legal Manufacturer/Manufacturer

BECTON DICKINSON INFUSION THERAPY SYSTEMS INC.
9450 South State Street
SANDY, UT USA 84070

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

CDR Cesar A. Perez, PhD, Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from March 26, 2019 to March 25, 2021.



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America

This public document

2. has been signed by CAPT Sean M. Boyd, MPH, USPHS

3. acting in the capacity of Deputy Director for Regulatory Affairs

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the fifth of November, 2018

7. by Assistant Authentication Officer, United States Department of State

8. No. 19005490-15

9. Seal/Stamp:

10. Signature:

Chana M Turner

Certificate No. 511-10-2018

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.



CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from October 26, 2018 to October 25, 2020.



No. 511-10-2018

Attachment to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

Manufacturing Facility
BD MEDICAL - DIABETES CARE
1329 West Highway 6
HOLDREGE, NE USA 68949

---END OF MANUFACTURER/DISTRIBUTOR LIST---



Application No. 511-10-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

Manufacturing Facility

BD MEDICAL - DIABETES CARE
1329 West Highway 6
HOLDREGE, NE USA 68949

Name of Product(s)

328322 - BD Ultra-Fine™ II Syringe 30G x 8mm, 0.3 mL
324916 - BD Ultra-Fine™ Syringe 31G x 6mm, 0.3 mL
328325 - BD Ultra-Fine™ II Syringe 30G x 8mm, 0.5 mL
324917 - BD Ultra-Fine™ Syringe 31G x 6mm, 0.5 mL
326713 - BD Ultra-Fine™ Syringe 31G x 8mm, 0.5 mL
328328 - BD Ultra-Fine™ II Syringe 30G x 8mm, 1.0 mL
326732 - BD Ultra-Fine™ Syringe 30G x 8mm, 1.0 mL
305930 - BD SafetyGlide Insulin Syringe 1ml 29G x 1/2 (0.33mm x 13mm)
305934 - BD SafetyGlide Insulin Syringe 1/2ml 30G x 5/16 (0.3mm x 8mm)
305937 - BD SafetyGlide Insulin Syringe 3/10ml 31G x 5/16 (0.25mm x 8mm)

-----END OF PRODUCT LIST-----





APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by Capt. Sean M. Boyd, MPH, USPHS

3. acting in the capacity of Deputy Director for Regulatory Affairs

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the ninth of October, 2018

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 19001143-7

9. Seal/Stamp:

10. Signature:

Leo J Muldoon

Certificate No. 15710-9-2018

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)


Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.



CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 27, 2018 to September 26, 2020.



Certificate No. 15710-9-2018

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

Manufacturing Facility

BD MEDICAL - DIABETES CARE
1329 West Highway 6
HOLDREGE, NE USA 68949

-----END OF MANUFACTURER/DISTRIBUTOR LIST-----



Certificate No. 15710-9-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Owner Operator

BECTON, DICKINSON & CO.

One Becton Drive

Franklin Lakes, NJ USA 07417

Name of Manufacturer

Manufacturing Facility

BD MEDICAL - DIABETES CARE

1329 West Highway 6

HOLDREGE, NE USA 68949

Name of Product(s)

326678 - BD Ultra-Fine™ Insulin Syringe 1mL 31G x 6mm

326679 - BD Ultra-Fine™ Insulin Syringe 0.5mL 31G x 6mm

326680 - BD Ultra-Fine™ Insulin Syringe 0.3mL 31G x 6mm

-----END OF PRODUCT LIST-----

