Ficha Técnica dispositivo médico

FICHA TÉCNICA No. FTDM-155V00	
KIT INJECTOMAT WIFI 20mL	
	
INFORMACIÓN BÁSICA	
Nombre del producto	Kit Injectomat WIFI 20 mL
Referencia	CO0020B
Descripción	Kit perfusor con Jeringa de 20 mL, aguja y extensión para anestesia de 150 cm.
Presentación Comercial	Caja por 1 kit que contiene: - 1 jeringa de 20 mL. - Una aguja hipodérmica 16G. - Una extensión de 150 cm.
Marca	Fresenius Kabi®
Uso o Destino	Para la administración de medicamentos por vía parenteral.
Características Especiales	N/A
Clasificación del Riesgo	IIA
Tipo de Dispositivo	Invasivo

FRESENIUS KABI

Ficha Técnica dispositivo médico

Registro Sanitario INVIMA	- Jeringa Omnifix 20mL INVIMA 2018DM-003767-R2 -Aguja Hipodérmica BD 16G INVIMA 2018DM-0017986 - Linea injectomat PVC 150 cm INVIMA 2016DM-0015114
Permiso de Comercialización	N/A
Tiempo de Vida Útil	-Jeringa Omnifix 20mL: 5 años -Aguja Hipodérmica BD 16G: 5 años -Linea injectomat PVC 150 cm: 5 años
Fecha Resolución	- Jeringa Omnifix 20mL Resolución No. 2019020805 de 27 de mayo de 2019 -Aguja Hipodérmica BD 16G Resolución No. 2018019468 de 09 de mayo de 2018 - Linea injectomat PVC 150 cm Resolución No. 2016032905 de 26 de agosto de 2016
Fecha Vencimiento Registro	- Jeringa Omnifix 20mL 21/05/2028 -Aguja Hipodérmica BD 16G 09/05/2028 - Linea injectomat PVC 150 cm 26/08/2026
Condiciones de Almacenamiento	Almacénese a una temperatura no mayor a 30 °C.
Titular	- Jeringa Omnifix 20mL B. BRAUN MELSUNGEN AG -Aguja Hipodérmica BD 16G BECTON DICKINSON DE COLOMBIA LTDA - Linea injectomat PVC 150 cm FRESENIUS KABI AG
Fabricante	-Jeringa Omnifix 20mL B. BRAUN MEDICAL AG ALMO ERZEUGNISSE ERVIN BUSCH GMBH -Aguja Hipodérmica BD 16G BECTON DICKINSON IDUSTRIAS CIRÚRGICAS LTDA BECTON, DICKINSON & COMPANY BECTON DICKINSON DE MEXICO, S.A. DE CV - Linea injectomat PVC 150 cm

Ficha Técnica dispositivo médico

	FRESENIUS KABI AG CLINICO MEDICAL SP. Z O.O FRESENIUS KABI (NANCHANG) CO., LTD
Importador	- Jeringa Omnifix 20mL B. BRAUN MEDICAL AG BIOSPIFAR S.A. -Aguja Hipodérmica BD 16G BECTON DICKINSON DE COLOMBIA LTDA - Linea injectomat PVC 150 cm FRESENIUS KABI COLOMBIA S.A.S.
Origen	- Jeringa Omnifix 20mL ALEMANIA, SUIZA -Aguja Hipodérmica BD 16G BRASIL, ESTADOS UNIDOS DE AMÉRICA, MÉXICO. - Linea injectomat PVC 150 cm CHINA, POLONIA, ALEMANIA.

DATOS ADICIONALES	
Características	N/A

Elaborado por:	Revisado por:	Aprobado por:
Firmado por: Luis Miguel Bautista Nombre del firmante: Luis Miguel Bautista Motivo de la firma: Tengo la autoría de este documento Hora de firma: 26-jul.-2024 | 12:18 PM PDT 938ED77405FB4BCFB165D2B5815C848D	Signed by: Cindy Hernández Signer Name: Cindy Hernandez Signing Reason: I approve this document Signing Time: 26-Jul-2024 | 4:01 PM EDT BB9DAB38EE5E42D9B9DECED4E7F60AA9	Firmado por: Luis Carlos Garcia Nombre del firmante: Luis Carlos Garcia Motivo de la firma: Apruebo este documento Hora de firma: 29-jul.-2024 | 7:25 AM PDT 9469B1FDA59F44B8887FA1C7ECF16CFE
Luis Miguel Bautista Angarita **Analista Junior de Asuntos Regulatorios**	Cindy Hernández **Gerente De Marketing MedTech**	Luis Carlos García Melo **Coordinador de Asuntos Regulatorios**

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luismiguel.bautista@fresenius-kabi.com
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Luis Carlos Garcia luis.garcia-melo@fresenius-kabi.com Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 9469B1FD-A59F-44B8-887F-A1C7ECF16CFE Using IP Address: 201.234.176.27 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): Apruebo este documento	Sent: 7/26/2024 1:01:51 PM Viewed: 7/29/2024 7:23:37 AM Signed: 7/29/2024 7:26:10 AM

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