FICHA TÉCNICA DE DISPOSITIVO MÉDICO

FICHA TÉCNICA No. FTDM-289V00	
Bomba de infusión volumétrica, accesorios y repuestos /Bomba de infusión para líquidos parenterales	
	
INFORMACIÓN BÁSICA	
Nombre del producto	Set Injectomat MC Agilia 50 mL Fotoprotección
Referencia	CO0050FPCO
Descripción	Kit Injectomat para perfusión. Contiene una jeringa Injectomat opaca de 50 mL, más una línea de 150cm.
Presentación Comercial	Caja plegadiza que contiene 1 kit.
Marca	No Aplica
Uso o Destino	Para administración por vía parenteral de medicamentos sensibles a la luz.
Características Especiales	Caja (Kit con Jeringa opaca + Extensión).
Clasificación del Riesgo	IIb
Tipo de Dispositivo	Equipo biomédico para tratamiento.
Registro Sanitario INVIMA	***No Aplica.***
Permiso de Comercialización	INVIMA 2021EBC-0006194-R1
Tiempo de Vida Útil	***No Aplica.***

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Fecha Resolución	23 de Abril de 2021.
Fecha Vencimiento Registro	23/04/2031.
Condiciones de Almacenamiento	Almacénese a una temperatura inferior a 30 °C.
Titular	Fresenius Kabi AG, con domicilio en Alemania.
Fabricante	• Fresenius Kabi AG - Alemania • Fresenius Kabi (Nanchang) Co. Ltd - China • Clinico Medical SP z.o.o - Polonia • Fresenius Vial S.A.S - Francia
Importador	Fresenius Kabi Colombia S.A.S. Bogotá D.C., Colombia.
Origen	• Alemania • China • Polonia • Francia

DATOS ADICIONALES	
Características	Jeringa: Jeringa con cánula libre de PVC, con capacidad de 50 mL color característico opaca con protección de luz. Resiste hasta 2 Bar de presión. Tope de pistón notable, pistón con doble sellado, escalado negro, lleno de contrastes. Línea: Línea en polietileno de color amarilla, con protección de luz. 150 cm.

Elaborado por:	Revisado por:	Aprobado por:
DocuSigned by: nestor castiblanco-rodriguez Signer Name: nestor castiblanco-rodriguez Signing Reason: I am the author of this document Signing Time: 02-Jan-2024 | 2:13 PM EST 2E2FC47B066F4BB29F2DF608B27294CE	DocuSigned by: Cindy Hernández Signer Name: Cindy Hernández Signing Reason: I approve this document Signing Time: 03-Jan-2024 | 8:03 AM EST BB9DAB38EE5E42D9B9DECED4E7F60AA9	DocuSigned by: Luis Carlos García Nombre del firmante: Luis Carlos García Motivo de la firma: Apruebo este documento Hora de firma: 04-ene.-2024 | 5:58 AM PST 9469B1FDA59F44B8887FA1C7ECF16CFE
Nestor Castiblanco **Analista de Asuntos Regulatorios**	Cindy Hernández **Gerente de Marketing MedTech**	Luis Carlos García Melo **Coordinador de Asuntos Regulatorios**

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nestor.castiblanco-rodriguez@fresenius-kabi.com
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Envelope Sent	Hashed/Encrypted	1/2/2024 11:10:38 AM
Certified Delivered	Security Checked	1/4/2024 5:24:51 AM
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