



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

CERTIFICADO DE AUTORIZACIÓN DE MODIFICACIÓN

N° rev: 1991-56#0004

El Instituto Nacional de Productos Médicos de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por MTG GROUP S.R.L. , se autoriza la modificación en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM), del PM 1991-56 aprobado según:

Disposición autorizante N° Disposición 5683/09 de fecha 09 noviembre 2009
Disposiciones modificatorias y reválidas N°: Disposición Modificatoria 6746/11
Disposición cambio titularidad 4235/12
Disposición Modificatoria 1991-56#0001
Reválida 1991-56#0002
Disposición Modificatoria 1991-56#0003

Del siguiente/s dato/s característico/s:

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACION/RECTIFICACION AUTORIZADA
Modelos	SISTEMA DE STENT VASCULAR LIFESTENT SOLO: EX060201L LifeStent Solo 6x20 / 1000mm EX060203L LifeStent Solo 6x20 / 1350mm EX060301L LifeStent Solo 6x30 / 1000mm EX060303L LifeStent Solo 6x30 / 1350mm EX060401L LifeStent Solo 6x40 / 1000mm EX060403L LifeStent Solo 6x40 / 1350mm EX060601L LifeStent Solo 6x60 /	SISTEMA DE STENT VASCULAR LIFESTENT SOLO EX062003L Sistema de stent vascular Lifestent Solo STENT VASCULAR LIFESTENT 5F 5F050201C LifeStent 5F 5/20/800 vas. 5F050301C LifeStent 5F 5/30/800 vas. 5F050401C LifeStent 5F 5/40/800 vas. 5F050601C LifeStent 5F 5/60/800 vas. 5F050801C LifeStent 5F 5/80/800 vas. 5F051001C LifeStent 5F 5/100/800 vas. 5F051201C LifeStent 5F 5/120/800 vas.

1000mm	5F051501C LifeStent 5F 5/150/800
EX060603L LifeStent Solo 6x60 /	vas.
1350mm	5F051701C LifeStent 5F 5/170/800
EX060801L LifeStent Solo 6x80 /	vas.
1000mm	5F060201C LifeStent 5F 6/20/800 vas.
EX060803L LifeStent Solo 6x80 /	5F060301C LifeStent 5F 6/30/800 vas.
1350mm	5F060401C LifeStent 5F 6/40/800 vas.
EX061001L LifeStent Solo 6x100	5F060601C LifeStent 5F 6/60/800 vas.
/1000mm	5F060801C LifeStent 5F 6/80/800 vas.
EX061003L LifeStent Solo 6x100	5F061001C LifeStent 5F 6/100/800
/1350mm	vas.
EX061201L LifeStent Solo 6x120	5F061201C LifeStent 5F 6/120/800
/1000mm	vas.
EX061203L LifeStent Solo 6x120	5F061501C LifeStent 5F 6/150/800
/1350mm	vas.
EX061501L LifeStent Solo 6x150	5F070201C LifeStent 5F 7/20/800 vas.
/1000mm	5F070301C LifeStent 5F 7/30/800 vas.
EX061503L LifeStent Solo 6x150	5F070401C LifeStent 5F 7/40/800 vas.
/1350mm	5F070601C LifeStent 5F 7/60/800 vas.
EX061701L LifeStent Solo 6x170	5F070801C LifeStent 5F 7/80/800 vas.
/1000mm	5F071001C LifeStent 5F 7/100/800
EX061703L LifeStent Solo 6x170	vas.
/1350mm	5F071201C LifeStent 5F 7/120/800
EX062001L LifeStent Solo 6x200	vas.
/1000mm	5F050203C LifeStent 5F 5/20/1350
EX062003L LifeStent Solo 6x200	vas.
/1350mm	5F050303C LifeStent 5F 5/30/1350
EX062502L LifeStent Solo 6x250	vas.
/1000mm	5F050403C LifeStent 5F 5/40/1350
EX062503L LifeStent Solo 6x250	vas.
/1350mm	5F050603C LifeStent 5F 5/60/1350
EX070201L LifeStent Solo 7x20 /	vas.
1000mm	5F050803C LifeStent 5F 5/80/1350
EX070203L LifeStent Solo 7x20 /	vas.
1350mm	5F051003C LifeStent 5F 5/100/1350
EX070301L LifeStent Solo 7x30 /	vas.
1000mm	5F051203C LifeStent 5F 5/120/1350
EX070303L LifeStent Solo 7x30 /	vas.
1350mm	5F051503C LifeStent 5F 5/150/1350
EX070401L LifeStent Solo 7x40 /	vas.
1000mm	5F051703C LifeStent 5F 5/170/1350
EX070403L LifeStent Solo 7x40 /	vas.
1350mm	5F060203C LifeStent 5F 6/20/1350
EX070601L LifeStent Solo 7x60 /	vas.
1000mm	5F060303C LifeStent 5F 6/30/1350
EX070603L LifeStent Solo 7x60 /	vas.
1350mm	5F060403C LifeStent 5F 6/40/1350
EX070801L LifeStent Solo 7x80 /	vas.
1000mm	5F060603C LifeStent 5F 6/60/1350
EX070803L LifeStent Solo 7x80 /	vas.

1350mm EX071001L LifeStent Solo 7x100 /1000mm EX071003L LifeStent Solo 7x100 /1350mm EX071201L LifeStent Solo 7x120 /1000mm EX071203L LifeStent Solo 7x120 /1350mm EX071501L LifeStent Solo 7x150 /1000mm EX071503L LifeStent Solo 7x150 /1350mm EX071701L LifeStent Solo 7x170 /1000mm EX071703L LifeStent Solo 7x170 /1350mm EX072001L LifeStent Solo 7x200 /1000mm EX072003L LifeStent Solo 7x200 /1350mm EX072502L LifeStent Solo 7x250 /1000mm EX072503L LifeStent Solo 7x250 /1350mm STENT VASCULAR BARD LIFESTENT EX050201C LifeStent 5x20 CATH 80 CM EX050301C LifeStent 5x30 CATH 80 CM EX050401C LifeStent 5x40 CATH 80 CM EX050601C LifeStent 5x60 CATH 80 CM EX050801C LifeStent 5x80 CATH 80 CM EX050203C LifeStent 5x20 CATH 130 CM EX050303C LifeStent 5x30 CATH 130 CM EX050403C LifeStent 5x40 CATH 130 CM EX050603C LifeStent 5x60 CATH 130 CM EX050803C LifeStent 5x80 CATH130 CM EX060201C LifeStent 6x20 CATH 80 CM	5F060803C LifeStent 5F 6/80/1350 vas. 5F061003C LifeStent 5F 6/100/1350 vas. 5F061203C LifeStent 5F 6/120/1350 vas. 5F061503C LifeStent 5F 6/150/1350 vas. 5F070203C LifeStent 5F 7/20/1350 vas. 5F070303C LifeStent 5F 7/30/1350 vas. 5F070403C LifeStent 5F 7/40/1350 vas. 5F070603C LifeStent 5F 7/60/1350 vas. 5F070803C LifeStent 5F 7/80/1350 vas. 5F071003C LifeStent 5F 7/100/1350 vas. 5F071203C LifeStent 5F 7/120/1350 vas.
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	EX060301C LifeStent 6x30 CATH 80 CM	
	EX060401C LifeStent 6x40 CATH 80 CM	
	EX060601C LifeStent 6x60 CATH 80 CM	
	EX060801C LifeStent 6x80 CATH 80 CM	
	EX060203C LifeStent 6x20 CATH 130 CM	
	EX060303C LifeStent 6x30 CATH 130 CM	
	EX060403C LifeStent 6x40 CATH 130 CM	
	EX060603C LifeStent 6x60 CATH 130 CM	
	EX060803C LifeStent 6x80 CATH 130 CM	
	EX070201C LifeStent 7x20 CATH 80 CM	
	EX070301C LifeStent 7x30 CATH 80 CM	
	EX070401C LifeStent 7x40 CATH 80 CM	
	EX070601C LifeStent 7x60 CATH 80 CM	
	EX070801C LifeStent 7x80 CATH 80 CM	
	EX070203C LifeStent 7x20 CATH 130 CM	
	EX070303C LifeStent 7x30 CATH 130 CM	
	EX070403C LifeStent 7x40 CATH 130 CM	
	EX070603C LifeStent 7x60 CATH 130 CM	
	EX070803C LifeStent 7x80 CATH 130 CM	
	EX080201C LifeStent 8x20 CATH 80 CM	
	EX080301C LifeStent 8x30 CATH 80 CM	
	EX080401C LifeStent 8x40 CATH 80 CM	
	EX080601C LifeStent 8x60 CATH 80 CM	
	EX080801C LifeStent 8x80 CATH 80 CM	
	EX080203C LifeStent 8x20 CATH 130 CM	

	EX080303C LifeStent 8x30 CATH 130 CM EX080403C LifeStent 8x40 CATH 130 CM EX080603C LifeStent 8x60 CATH 130 CM EX080803C LifeStent 8x80 CATH 130 CM EX090201C LifeStent 9x20 CATH 80 CM EX090301C LifeStent 9x30 CATH 80 CM EX090401C LifeStent 9x40 CATH 80 CM EX090601C LifeStent 9x60 CATH 80 CM EX090801C LifeStent 9x80 CATH 80 CM EX090203C LifeStent 9x20 CATH 130 CM EX090303C LifeStent 9x30 CATH 130 CM EX090403C LifeStent 9x40 CATH 130 CM EX090603C LifeStent 9x60 CATH 130 CM EX090803C LifeStent 9x80 CATH 130 CM EX100201C LifeStent 10x20 CATH 80 CM EX100301C LifeStent 10x30 CATH 80 CM EX100401C LifeStent 10x40 CATH 80 CM EX100601C LifeStent 10x60 CATH 80 CM EX100801C LifeStent 10x80 CATH 80 CM EX100203C LifeStent 10x20 CATH 130 CM EX100303C LifeStent 10x30 CATH 130 CM EX100403C LifeStent 10x40 CATH 130 CM EX100603C LifeStent 10x60 CATH 130 CM EX100803C LifeStent 10x80 CATH 130 CM STENT VASCULAR BARD	
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	LIFESTENT XL EX051001C LifeStent XL 5x100 CATH 80 CM EX051201C LifeStent XL 5x120 CATH 80 CM EX051501C LifeStent XL 5x150 CATH 80 CM EX051701C LifeStent XL 5x170 CATH 80 CM EX051003C LifeStent XL 5x100 CATH 130 CM EX051203C LifeStent XL 5x120 CATH 130 CM EX051503C LifeStent XL 5x150 CATH 130 CM EX051703C LifeStent XL 5x170 CATH 130 CM EX061001C LifeStent XL 6x100 CATH 80 CM EX061201C LifeStent XL 6x120 CATH 80 CM EX061501C LifeStent XL 6x150 CATH 80 CM EX061701C LifeStent XL 6x170 CATH 80 CM EX061003C LifeStent XL 6x100 CATH 130 CM EX061203C LifeStent XL 6x120 CATH 130 CM EX061503C LifeStent XL 6x150 CATH 130 CM EX061703C LifeStent XL 6x170 CATH 130 CM EX071001C LifeStent XL 7x100 CATH 80 CM EX071201C LifeStent XL 7x120 CATH 80 CM EX071501C LifeStent XL 7x150 CATH 80 CM EX071701C LifeStent XL 7x170 CATH 80 CM EX071003C LifeStent XL 7x100 CATH 130 CM EX071203C LifeStent XL 7x120 CATH 130 CM EX071503C LifeStent XL 7x150 CATH 130 CM EX071703C LifeStent XL 7x170 CATH 130 CM	
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	STENT VASCULAR LIFESTENT 5F 5F050201C LifeStent 5F 5/20/800 vas. 5F050301C LifeStent 5F 5/30/800 vas. 5F050401C LifeStent 5F 5/40/800 vas. 5F050601C LifeStent 5F 5/60/800 vas. 5F050801C LifeStent 5F 5/80/800 vas. 5F051001C LifeStent 5F 5/100/800 vas. 5F051201C LifeStent 5F 5/120/800 vas. 5F051501C LifeStent 5F 5/150/800 vas. 5F051701C LifeStent 5F 5/170/800 vas. 5F060201C LifeStent 5F 6/20/800 vas. 5F060301C LifeStent 5F 6/30/800 vas. 5F060401C LifeStent 5F 6/40/800 vas. 5F060601C LifeStent 5F 6/60/800 vas. 5F060801C LifeStent 5F 6/80/800 vas. 5F061001C LifeStent 5F 6/100/800 vas. 5F061201C LifeStent 5F 6/120/800 vas. 5F061501C LifeStent 5F 6/150/800 vas. 5F070201C LifeStent 5F 7/20/800 vas. 5F070301C LifeStent 5F 7/30/800 vas. 5F070401C LifeStent 5F 7/40/800 vas. 5F070601C LifeStent 5F 7/60/800 vas. 5F070801C LifeStent 5F 7/80/800 vas. 5F071001C LifeStent 5F 7/100/800 vas. 5F071201C LifeStent 5F 7/120/800 vas.	
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5F050203C LifeStent 5F 5/20/1350 vas.	
5F050303C LifeStent 5F 5/30/1350 vas.	
5F050403C LifeStent 5F 5/40/1350 vas.	
5F050603C LifeStent 5F 5/60/1350 vas.	
5F050803C LifeStent 5F 5/80/1350 vas.	
5F051003C LifeStent 5F 5/100/1350 vas.	
5F051203C LifeStent 5F 5/120/1350 vas.	
5F051503C LifeStent 5F 5/150/1350 vas.	
5F051703C LifeStent 5F 5/170/1350 vas.	
5F060203C LifeStent 5F 6/20/1350 vas.	
5F060303C LifeStent 5F 6/30/1350 vas.	
5F060403C LifeStent 5F 6/40/1350 vas.	
5F060603C LifeStent 5F 6/60/1350 vas.	
5F060803C LifeStent 5F 6/80/1350 vas.	
5F061003C LifeStent 5F 6/100/1350 vas.	
5F061203C LifeStent 5F 6/120/1350 vas.	
5F061503C LifeStent 5F 6/150/1350 vas.	
5F070203C LifeStent 5F 7/20/1350 vas.	
5F070303C LifeStent 5F 7/30/1350 vas.	
5F070403C LifeStent 5F 7/40/1350 vas.	
5F070603C LifeStent 5F 7/60/1350 vas.	
5F070803C LifeStent 5F 7/80/1350 vas.	
5F071003C LifeStent 5F 7/100/1350 vas.	
5F071203C LifeStent 5F 7/120/1350 vas.	

Quedando el producto inscripto con los siguientes datos característicos:

Nombre descriptivo: SISTEMA DE STENT VASCULAR PERIFERICO

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
18-238 – Endoprótesis (Stents), vasculares, periféricos

Marca(s) de (los) producto(s) médico(s): Life Stent

Clase de Riesgo: III

Indicación/es autorizada/s: Indicado para el tratamiento de lesiones ateroscleróticas en la arteria femoral superficial (AFS) y la arteria poplitea

Modelos: SISTEMA DE STENT VASCULAR LIFESTENT SOLO
EX062003L Sistema de stent vascular Lifestent Solo

STENT VASCULAR LIFESTENT 5F

5F050201C LifeStent 5F 5/20/800 vas.
5F050301C LifeStent 5F 5/30/800 vas.
5F050401C LifeStent 5F 5/40/800 vas.
5F050601C LifeStent 5F 5/60/800 vas.
5F050801C LifeStent 5F 5/80/800 vas.
5F051001C LifeStent 5F 5/100/800 vas.
5F051201C LifeStent 5F 5/120/800 vas.
5F051501C LifeStent 5F 5/150/800 vas.
5F051701C LifeStent 5F 5/170/800 vas.
5F060201C LifeStent 5F 6/20/800 vas.
5F060301C LifeStent 5F 6/30/800 vas.
5F060401C LifeStent 5F 6/40/800 vas.
5F060601C LifeStent 5F 6/60/800 vas.
5F060801C LifeStent 5F 6/80/800 vas.
5F061001C LifeStent 5F 6/100/800 vas.
5F061201C LifeStent 5F 6/120/800 vas.
5F061501C LifeStent 5F 6/150/800 vas.
5F070201C LifeStent 5F 7/20/800 vas.
5F070301C LifeStent 5F 7/30/800 vas.
5F070401C LifeStent 5F 7/40/800 vas.
5F070601C LifeStent 5F 7/60/800 vas.
5F070801C LifeStent 5F 7/80/800 vas.
5F071001C LifeStent 5F 7/100/800 vas.
5F071201C LifeStent 5F 7/120/800 vas.
5F050203C LifeStent 5F 5/20/1350 vas.
5F050303C LifeStent 5F 5/30/1350 vas.
5F050403C LifeStent 5F 5/40/1350 vas.
5F050603C LifeStent 5F 5/60/1350 vas.
5F050803C LifeStent 5F 5/80/1350 vas.
5F051003C LifeStent 5F 5/100/1350 vas.
5F051203C LifeStent 5F 5/120/1350 vas.
5F051503C LifeStent 5F 5/150/1350 vas.
5F051703C LifeStent 5F 5/170/1350 vas.
5F060203C LifeStent 5F 6/20/1350 vas.
5F060303C LifeStent 5F 6/30/1350 vas.
5F060403C LifeStent 5F 6/40/1350 vas.
5F060603C LifeStent 5F 6/60/1350 vas.

5F060803C LifeStent 5F 6/80/1350 vas.
5F061003C LifeStent 5F 6/100/1350 vas.
5F061203C LifeStent 5F 6/120/1350 vas.
5F061503C LifeStent 5F 6/150/1350 vas.
5F070203C LifeStent 5F 7/20/1350 vas.
5F070303C LifeStent 5F 7/30/1350 vas.
5F070403C LifeStent 5F 7/40/1350 vas.
5F070603C LifeStent 5F 7/60/1350 vas.
5F070803C LifeStent 5F 7/80/1350 vas.
5F071003C LifeStent 5F 7/100/1350 vas.
5F071203C LifeStent 5F 7/120/1350 vas.

Período de vida útil: LifeStent Solo : 2 años
LifeStent 5F: 3 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biotecnológico: N/A

Forma de presentación: POR UNIDAD

Método de esterilización: Oxido de etileno

Nombre del fabricante: Angiomed GMBH & CO. Medizintechnik KG

Lugar de elaboración: Wachausstrasse 6, 76227 Karlsruhe, Alemania

AUTORIZADO

Habiéndose cumplimentado con lo previsto en la Disposición ANMAT N° 2318/02 y 9688/19, esta Administración autoriza las modificaciones solicitadas en Argentina, Ciudad de Buenos Aires, 16 septiembre 2024.



BODNAR Andrea Veronica

CUIL 27254978472

Dirección Evaluación y Registro de Productos
Médicos

Firma y Sello



TERRIZZANO Maria Lorena

CUIL 23242965604

Instituto Nacional de Productos Médicos
ANMAT

Firma y Sello

El presente certificado será válido únicamente cuando se presente junto con las Disposiciones previas del PM enunciadas anteriormente y sea verificado con su código QR a través de la página de ANMAT. Este certificado no modifica el período de vigencia.

Fecha de emisión: 16 septiembre 2024



La validez del presente documento deberá verificarse mediante el código QR.

N° Identificador Trámite: 59927



ABRIOLA Leticia Adriana
CUIL 27323186494