

República de Colombia
Ministerio de Salud y Protección Social
Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA

RESOLUCIÓN No. 2024009702 de 5 de Marzo de 2024
Por la cual se concede un Registro Sanitario

La Directora Técnica de Dispositivos Médicos y otras Tecnologías del Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, en ejercicio de las facultades Legales conferidas en el Decreto 2078 de 2012, Decreto Reglamentario 4725 de 2005, y ley 1437 de 2011.

ANTECEDENTES

Que mediante escrito número 20231215505 de fecha 14 de agosto de 2023, el Doctor Diego Javier Gómez actuando en calidad de representante legal de la empresa HEALTHSAFE CONSULTING S.A.S, solicitó Registro Sanitario para el producto SISTEMA DE ARTROSCOPIA AUXEIN MEDICAL/ SISTEMA DE ARTROSCOPIA a favor de la empresa HEALTHSAFE CONSULTING S.A.S con domicilio en BOGOTA COLOMBIA en la modalidad de IMPORTAR y VENDER.

CONSIDERACIONES DEL DESPACHO

Con base en la documentación allegada, previo estudio técnico y legal de la Dirección de Dispositivos Médicos y Otras Tecnologías del INVIMA, se emitió concepto favorable para la autorización de este Registro Sanitario en cumplimiento del Decreto 4725 de 2005 modificado por Decreto 582 de 2017 y en consecuencia el Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA;

RESUELVE

ARTICULO PRIMERO.- Conceder REGISTRO SANITARIO por el término de DIEZ (10) años al
PRODUCTO: SISTEMA DE ARTROSCOPIA AUXEIN MEDICAL/ SISTEMA DE ARTROSCOPIA
MARCA: AUXEIN MEDICAL
REGISTRO SANITARIO No.: INVIMA 2024DM-0028431
TIPO DE REGISTRO: IMPORTAR Y VENDER
TITULAR: HEALTHSAFE CONSULTING S.A.S con domicilio en BOGOTÁ
FABRICANTE: Auxein Medical Private Limited con domicilio en INDIA
IMPORTADOR: STEIN & CIA S.A.S con domicilio en BOGOTÁ
ACONDICIONADOR: STEIN & CIA S.A.S con domicilio en BOGOTÁ
TIPO DE DISPOSITIVO INVASIVO
RIESGO: IIB
COMPOSICIÓN:

PARTES QUE COMPONEN EL DISPOSITIVO MÉDICO	COMPOSICIÓN CUALITATIVA
GRAPAS	ACERO INOXIDABLE / ALEACION DE TITANIO
AGUJAS	ACERO INOXIDABLE
SUTURA	POLIETILENO DE ULTRA ALTO PESO MOLECULAR (UHMWPE)
ANCLA	POLIETER ETER CETONA (PEEK) / ALEACION DE TITANIO
TORNILLOS	POLIETER ETER CETONA (PEEK) / ALEACION DE TITANIO
BOTONES	ALEACION DE TITANIO

USOS: EL SISTEMA DE IMPLANTES DE ARTROSCOPIA ESTÁN INTENCIONADOS PARA FIJAR TEJIDOS BLANDOS/LIGAMENTOS DAÑADOS O DISLOCADOS Y REALINEARLOS A SU POSICIÓN ORIGINAL

PRESENTACIÓN

COMERCIAL: EMPAQUE UNITARIO ESTERIL Y NO ESTERIL

OBSERVACIONES: EL REGISTRO SANITARIO AMPARA LA SIGUIENTE REFERENCIA:

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Familia	Descripción
Grapas	Staple U - Type - Ø.(1.5 - 3)mm Length(15 - 25)mm
	Blount Grapas - (Ø 1.5 - 3.0mm ,Width 15 - 30mm)
	Thorny Grapas - (10 - 20mm)
	Straight Staple - width 25mm Length(10 - 36)mm
	Staple with Offset - width1 (24mm) width2(5 - 14)mm Length(36 - 44)mm
	Three Legged Staple - width1(26mm) width2(5mm) Length 34mm
	Ligament Staple - Inner width(6 - 16)mm Outer width(11 - 21)mm Length20mm - 25mm
	Staple Coventry - Step(5 - 15)mm
	Staple U - Type - Ø.(1.5 - 3)mm Length(15 - 25)mm
	Blount Grapas - (Ø 1.5 - 3.0mm ,Width 15 - 30mm)
	Thorny Grapas - (10 - 20mm)
	Straight Staple - width 25mm Length(10 - 36)mm
	Staple with Offset - width1 (24mm) width2(5 - 14)mm Length(36 - 44)mm
	Three Legged Staple - width1(26mm) width2(5mm) Length 34mm
	Ligament Staple - Inner width(6 - 16)mm Outer width(11 - 21)mm Length20mm - 25mm
	Staple Coventry - (5 - 15)mm
	Staple U - Type - Ø.(1.5 - 3)mm Length(15 - 25)mm
	Blount Grapas - (Ø 1.5 - 3.0mm ,Width 15 - 30mm)
	Thorny Grapas - (10 - 20mm)
	Straight Staple - width 25mm Length(10 - 36)mm
	Staple with Offset - width1 (24mm) width2(5 - 14)mm Length(36 - 44)mm
	Three Legged Staple - width1(26mm) width2(5mm) Length 34mm
	Ligament Staple - Inner width(6 - 16)mm Outer width(11 - 21)mm Length20mm - 25mm
	Staple Coventry - (5 - 15)mm
	Staple U - Type - Ø.(1.5 - 3)mm Length(15 - 25)mm
	Blount Grapas - (Ø 1.5 - 3.0mm ,Width 15 - 30mm)
	Thorny Grapas - (10 - 20mm)
	Straight Staple - width 25mm Length(10 - 36)mm
Staple with Offset - width1 (24mm) width2(5 - 14)mm Length(36 - 44)mm	
Three Legged Staple - width1(26mm) width2(5mm) Length 34mm	
Ligament Staple - Inner width(6 - 16)mm Outer width(11 - 21)mm Length20mm - 25mm	
Staple Coventry - (5 - 15)mm	
Implantes de Artroscopia	AUXILOCK 4.5mm Titanium Screw - In Suture Anchor w/Two #2 Braid: White/Blue & White/Black
	AUXILOCK 5.0mm Titanium Screw - In Suture Anchor w/Two #2 Braid: White/Blue & White/Black
	AUXILOCK 5.5mm Titanium Screw - In Suture Anchor w/Two #2 Braid: White/Blue & White/Black
	AUXILOCK 6.5mm Titanium Screw - In Suture Anchor w/Two #2 Braid: White/Blue & White/Black
	AUXILOCK 5.0mm Titanium Screw - In Suture Anchor w/Two #2 Braid: White & White/Blue, w/Needles : MO - 6
	AUXILOCK 5.0mm Titanium Screw - In Suture Anchor w/Two #2 Braid: White & White/Blue, w/Needles : MO - 6
	AUXILOCK 2.8mm Titanium Screw - In Suture Anchor w/One #2 Braid White/Blue

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Familia	Descripción
	AUXILOCK 3.5mm Titanium Screw - In Suture Anchor w/Two #2 Braid White/Blue & White/Black
	AUXILOCK 4.5mm Titanium Screw - In Suture Anchor w/Two #2 Braid: White & White/Blue, w/Needles : MO - 6
	AUXILOCK 5.5mm Titanium Screw - In Suture Anchor w/Two #2 Braid: White & White/Blue, w/Needles : MO - 6
	AUXILOCK 2.8mm Titanium Screw - In Suture Anchor w/One #2 Braid, White/Blue, w/Needles : MO - 6
	AUXILOCK 3.5mm Titanium Screw - In Suture Anchor w/Two #2 Braid, White & White/Blue, w/Needles :MO - 6
	AUXILOCK GFS Ultimate Mini Button, Button L: 12mm, W: 3.9mm
	AUXILOCK GFS Ultimate Large Button, Button L: 16.5mm, W: 3.9mm
	AUXILOCK GFS Mini, Loop : 12mm - 55mm, Button L: 12mm, W: 3.9mm
	AUXILOCK GFS II Large, Loop : 12mm - 55mm, Button L: 16.5mm, W: 4.4mm
	AUXILOCK 7 to 12mm x 20 to 35mm Titanium Interference Screw
	Ø4.0mm Low Profile Cannulated Cancellous Screw, Full Thread, Length 30mm - 45mm
	Spiked Washer for Ø4.0mm & 6.5mm Cancellous Screw
	Spiked Ligament Staple Small/Large
	AUXILOCK 1.8mm Draw Tight Suture - Based Anchor w/One #2 Braid
	AUXILOCK 1.8mm Draw Tight Suture - Based Anchor w/One Suture Tape
	AUXILOCK 3.2mm Draw Tight Suture - Based Anchor w/Two #2 Braid
	AUXILOCK 3.2mm Draw Tight Suture - Based Anchor w/One #2 Braid And One Suture Tape
	AUXILOCK 4.5mm PEEK OPTIMA Screw - In Suture Anchor w/Two #2 Braid, w/Needles - MO - 6
	AUXILOCK 5.0mm PEEK OPTIMA Screw - In Suture Anchor w/Two #2 Braid, w/Needles - MO - 6
	AUXILOCK 5.5mm PEEK OPTIMA Screw - In Suture Anchor w/Two #2 Braid, w/Needles - MO - 6
	AUXILOCK 6.5mm PEEK OPTIMA Screw - In Suture Anchor w/Two #2 Braid, w/Needles - MO - 6
	AUXILOCK 4.5mm PEEK OPTIMA Screw - In Suture Anchor w/Two #2 Braid
	AUXILOCK 5.0mm PEEK OPTIMA Screw - In Suture Anchor w/Two #2 Braid
	AUXILOCK 5.5mm PEEK OPTIMA Screw - In Suture Anchor w/Two #2 Braid
	AUXILOCK 6.5mm PEEK OPTIMA Screw - In Suture Anchor w/Two #2 Braid
	AUXILOCK 5mm - 15mm x 20mm - 40mm PEEK OPTIMA Interference Screw
	AUXILOCK SLIK 4.75mm x 15mm PEEK OPTIMA Screw - In Anchor
	AUXILOCK SLIK 5.5mm x 15mm PEEK OPTIMA Screw - In Anchor
	AUXILOCK SLIK 6.25mm x 15mm PEEK OPTIMA Screw - In Anchor
	AUXILOCK 2mm Braid Suture Tape : White/Blue, 7in Working Length, 39in Total Length
	AUXILOCK #1 Braid: Blue/White, 36in Total Length
	AUXILOCK #2 Braid: Blue/White, 36in Total Length
	AUXILOCK Two #2 Braid: White/Blue & White/Black, 36in Total Length
	AUXILOCK #2 Braid: Blue, w/Needles : MO - 6 & CE, 36in Total Length
	AUXILOCK #2 Braid: White, w/Needle : MO - 6, 36in Total Length
	AUXILOCK #2 Braid: White/Black, w/Needle : MO - 6, 36in Total Length
	AUXILOCK #5 Braid: White, w/Needle : CCS, 36in Total Length
	AUXILOCK #2 Braid: White/Blue, w/ Needle : MO - 6, 36in Total Length
	AUXILOCK#2 Braid: White/Black, 36in Total Length

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Familia	Descripción
	AUXILOCK #2 Braid: White/Green, w/ Needle : MO - 6, 36in Total Length
	AUXILOCK #2 Braid: White/Green, 36in Total Length
	AUXILOCK #2 Braid: Blue, 36in Total Length
	AUXILOCK #2 Braid:White, 36in Total Length
	AUXILOCK #2 Braid: Blue/ Blue, 36in Total Length
	AUXILOCK #7 Braid: White/Blue 32in Total Length
	AUXILOCK #7 Braid: White, 47in Total Length
	AUXILOCK #2 Braid: White/Blue, 36in Total Length
	AUXILOCK #9 Braid: White 13cm Total Length
	AUXILOCK #9 Braid: White 6cm Total Length
	AUXILOCK #9 Braid: White 7.5cm Total Length
	AUXILOCK #9 Braid: White 10cm Total Length
	AUXILOCK #9 Braid: White 12.5cm Total Length
	AUXILOCK #9 Braid: White 15cm Total Length
	AUXILOCK #9 Braid: White 17.5cm Total Length
	AUXILOCK #9 Braid: White 20cm Total Length
	AUXILOCK #9 Braid: White 22.5cm Total Length
	AUXILOCK #9 Braid: White 25cm Total Length
	AUXILOCK #9 Braid: White 27.5cm Total Length
	AUXILOCK #2 Custom Braid: White, 47in Total Length
	AUXILOCK #2 Braid Infinity Loop : White, w/Needle : Straight, 20in Loop Length, 24in Total Length
	AUXILOCK #2 Braid Infinity Loop : White/Blue, w/Needle : Straight, 20in Loop Length, 24in Total Length
	AUXILOCK #5 Braid Infinity Loop : White/Blue, w/Needle : Straight, 20in Loop Length, 24in Total Length
	AUXILOCK 3.5mm PEEK CF Push - In Suture Anchorw/Two #2 Braid
	AUXILOCK 3.5mm PEEK CF Push - In Suture Anchor w/Two #2 Braid w/Needles MO - 6 Short Length
	AUXILOCK 28 Knotless PEEK CF Push - In Suture Anchor w/Driver w/Suture Passer
	AUXILOCK 35 Knotless PEEK CF Push - In Suture Anchor w/Driver w/Suture Passer
	AUXILOCK 35 Knotless PEEK CF Push - In Suture Anchor w/Suture Passer
	AUXILOCK 45 Knotless PEEK CF Push - In Suture Anchor w/Suture Passer
	AUXILOCK 55 Knotless PEEK CF Push - In Suture Anchor w/Suture Passer
	AUXILOCK 4.5mm PEEK CF Screw - In Suture Anchor w/Two #2 Braid w/Needles MO - 6
	AUXILOCK 5.0mm PEEK CF Screw - In Suture Anchor w/Two #2 Braid w/Needles MO - 6
	AUXILOCK 5.5mm PEEK CF Screw - In Suture Anchor w/Two #2 Braid w/Needles MO - 6
	AUXILOCK 6.5mm PEEK CF Screw - In Suture Anchor w/Two #2 Braid w/Needles MO - 6
	AUXILOCK 4.5mm PEEK CF Screw - In Suture Anchor w/Two #2 Braid
	AUXILOCK 5.0mm PEEK CF Screw - In Suture Anchor w/Two #2 Braid
	AUXILOCK 5.5mm PEEK CF Screw - In Suture Anchor w/Two #2 Braid
	AUXILOCK 6.5mm PEEK CF Screw - In Suture Anchor w/Two #2 Braid
	AUXILOCK PEEK CF Interference Screw 5mm - 15mm x 20mm - 40mm
	AUXILOCK SLIK 4.75mm x 15mm PEEK CF Screw - In Anchor
	AUXILOCK SLIK 5.5mm x 15mm PEEK CF Screw - In Anchor

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Familia	Descripción
	AUXILOCK SLIK 6.25mm x 15mm PEEK CF Screw - In Anchor
	AUXILOCK 3.5mm PEEK CF Push - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6 Short Length
	AUXILOCK 4.5mm Knotless PEEK CF Push - In Suture Anchor With Driver With Suture Passer
	AUXILOCK 5.5mm Knotless PEEK CF Push - In Suture Anchor With Driver With Suture Passer
	AUXILOCK Rotador 4.75mm - 6.25mm x 15mm PEEK OPTIMA Screw - In Anchor
	AUXILOCK Rotador 4.75mm - 6.25mm x 15mm PEEK CF Screw - In Anchor
	AUXILOCK 2.8mm Knotless PEEK OPTIMA Push - In Suture Anchor With Driver With Suture Passer
	MENISCO Meniscus Root Repair Inside - Out
	AUXILOCK 4.5mm Knotless PEEK OPTIMA Push In Suture Anchor With Driver With Suture Passer
	AUXILOCK 5.5mm Knotless PEEK OPTIMA Push In Suture Anchor With Driver With Suture Passer
	AUXILOCK 5.5mm Knotless PEEK OPTIMA Push - In Suture Anchor With Suture Passer
	AUXILOCK 3.5mm PEEK OPTIMA Push - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black PEEK OPTIMA Push In Anchor With Needle (Todas las Referencias)
	AUXILOCK 2.8mm PEEK OPTIMA Push - In Suture Anchor With One 2 BioBraid White/Black With Needles MO - 6 Short Length
	AUXILOCK 3.5mm Knotless PEEK OPTIMA Push - In Suture Anchor With Driver With Suture Passer
	AUXILOCK 4.5mm Knotless PEEK OPTIMA Push - In Suture Anchor With Suture Passer
	AUXILOCK 3.5mm PEEK OPTIMA Push - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6 Short Length
	AuxSuture Anchor Without Needle (Todas las Referencias)
	AUXILOCK 4.5mm Knotless PEEK OPTIMA Push - In Suture Anchor With Suture Passer
	AUXILOCK 3.2mm Draw Tight Suture - Based Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Black & White/Blue
	AUXILOCK 2.8mm Knotless PEEK CF Push - In Suture Anchor With Driver With Suture Passer
	PEEK CF Knotless Anchor (Todas las Referencias)
	AUXILOCK 3.5mm Knotless PEEK CF Push - In Suture Anchor With Driver With Suture Passer
	AUXILOCK 4.5mm Knotless PEEK CF Push - In Suture Anchor With Suture Passer
	AUXILOCK 5.5mm Knotless PEEK CF Push - In Suture Anchor With Suture Passer
	AUXILOCK 1.8mm Draw Tight Suture - Based Anchor With One 1.4mm Suture Tape White/Blue
	AUXILOCK 2.8mm PEEK CF Push - In Suture Anchor With One 2 BioBraid White/Blue
	PEEK CF Push In Anchor Without Needle (Todas las Referencias)
	AUXILOCK 3.5mm PEEK CF Push - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black
	PEEK CF Push In Anchor With Needle (Todas las Referencias)
	AUXILOCK 2.8mm PEEK CF Push - In Suture Anchor With One 2 BioBraid White/Blue With Needles MO - 6 Short Length
	AUXILOCK 2.8mm PEEK OPTIMA Push - In Suture Anchor With One 2 BioBraid White/Black
	PEEK OPTIMA Screw In Knotless Anchor (Todas las Referencias)
	AUXILOCK GFS Mini Naked Button L12mm W 3.9mm
	AUXILOCKGFS II Large Naked Button L 16.5mm W 4.4mm
	AUXILOCK Ultimate Mini Naked Button L 12mm W 3.9mm
	AUXILOCK Ultimate Large Naked Button L 16.5mm W 3.9mm

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Familia	Descripción
	AUXILOCK GFS Ultimate Mini Button Button L 12mm W 3.9mm (Adjustable Loop)
	AUXILOCK GFS Ultimate Large Button Button L 16.5mm W 3.9mm (Adjustable Loop)
	AUXILOCK GFS Mini, Loop 12mm - 55mm, Button L 12mm, W 3.9mm
	AUXILOCK GFS II Large, Loop 12mm - 55mm, Button L 16.5mm, W 4.4mm
	AUXILOCK PEEK CF Interference Screw 7mm - 12mm x 20mm - 40mm
	AUXILOCK PEEK OPTIMA Interference Screw 7mm - 12mm x 20mm - 40mm
	AUXILOCK Titanium Interference Screw 7mm - 12mm x 20mm - 40mm
	AUXILOCK GFS Button Extender L 18mm W 5.0mm
	Ligament Staple 6mm - 16mm x 11mm - 21mm x 20mm - 25mm
	AUXILOCK 2.8mm Titanium Screw - In Suture Anchor with One #2 BioBraid - White/Blue With Needle MO - 6,Mini Loop Button ,Large Loop Button
	PEEK CF Interference Screw (Todas las Referencias)
	PEEK OPTIMA Interference Screw (Todas las Referencias)
	Naked Button
	AUXILOCK AC Joint Button
	Titanium Screw In Anchor with Without Needle
	PEEK CF Knotless Anchor (Todas las Referencias)
	Expert Syndesmosis Plate
	Meni - Fix Meniscus Root Repair Implant
	#2 - 0 BioBraid Meniscus Repair Needle
	Ligament Staple
	1.0mm BioBraid SutureTape Meniscus Repair Needle
	Titanium Interference Screw (Todas las Referencias)
	Button Extender
	Rotador PEEK CF Screw In Knotless Anchor (Todas las Referencias)
	AUXILOCK Syndesmosis Ultimate - Kit
	Advance Syndesmosis Plate
	BioBraid Meniscus Repair Needle
	1.0mm BioBraid SutureTape Meniscus Repair Needle
	Titanium Screw In Anchor with Needle
	#0 BioBraid Meniscus Repair Needle
	1.0mm BioBraid SutureTape Meniscus Repair Needle
	PEEK OPTIMA Push - In Suture Anchor (Todas las Referencias)
	PEEK OPTIMA Push In Anchor Without Needle (Todas las Referencias)
	PEEK OPTIMA Push In Anchor With Needle (Todas las Referencias)
	AuxSuture Anchor Without Needle (Todas las Referencias)
	AuxSuture Anchor With Needle (Todas las Referencias)
	AUXILOCKTendo Screw - In Anchor (Todas las Referencias)
	PEEK OPTIMA Interference Screw 4mm - 10mm x 8mm - 30mm
	PEEK CF Interference Screw 4mm - 10mm x 8mm - 30mm
	Expert Syndesmosis Plate

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Familia	Descripción
	Expert Syndesmosis Ultimate Kit
	1.0mm BioBraid SutureTape Meniscus Repair Needle
	AUXILOCK 2.8mm PEEK CF Push - In Suture Anchor with One 2 BioBraid : White/Blue
	AUXILOCK 2.8mm PEEK CF Push - In Suture Anchor with One 2 BioBraid : White/Blue, With Needle : MO - 6, Short Length
	AUXILOCK 2.8mm PEEK OPTIMA Push - In Suture Anchor with One 2 BioBraid :White/Black
	AUXILOCK 2.8mm PEEK OPTIMA Push - In Suture Anchor with One 2 BioBraid : White/Black, With Needle : MO - 6, Short Length
	AUXILOCK 4.5mm PEEK OPTIMA Screw - In Suture Anchor with One 2 BioBraid and One 1.4mm Suture Tape :White/Blue & White/Black
	AUXILOCK 5.5mm PEEK OPTIMA Screw - In Suture Anchor with One 2 BioBraid and One 1.4mm Suture Tape : White/Blue & White/Black
	AUXILOCK 6.5mm PEEK OPTIMA Screw - In Suture Anchor with One 2 BioBraid and One1.4mm Suture Tape : White/Blue & White/Black
	AUXILOCK 4.5mm PEEK CF Screw - In Suture Anchor with One 2 BioBraid and One 1.4mm Suture Tape : White/Black & White/Blue
	AUXILOCK 5.5mm PEEK CF Screw - In Suture Anchor with One 2 BioBraid and One 1.4mm Suture Tape : White/Black & White/Blue
	AUXILOCK 6.5mm PEEK CF Screw - In Suture Anchor with One 2 BioBraid and One 1.4mm Suture Tape : White/Black & White/Blue
	AUXILOCK 4.5mm PEEK OPTIMA Screw - In Suture Anchor with Two 1.4mm Suture Tape : White/Blue & White/Black
	AUXILOCK 5.5mm PEEK OPTIMA Screw - In Suture Anchor with Two 1.4mm Suture Tape : White/Blue & White/Black
	AUXILOCK 6.5mm PEEK OPTIMA Screw - In Suture Anchor with Two 1.4mm Suture Tape : White/Blue & White/Black
	AUXILOCK 4.5mm PEEK CF Screw - In Suture Anchor with Two 1.4mm Suture Tape : White/Blue & White/Black
	AUXILOCK 5.5mm PEEK CF Screw - In Suture Anchor with Two 1.4mm Suture Tape : White/Blue & White/Black
	AUXILOCK 6.5mm PEEK CF Screw - In Suture Anchor with One #2 BioBraid and One 1.4mm Suture Tape : White/Black & White/Blue
	AUXILOCK 2.9mm AuxSuture Anchor with Two 1.4mm Suture Tape : White/Black & White/Blue
	AUXILOCK GFS Ultimate Mini Button, Button L:12mm, W:3.9mm (Adjustable Loop)
	AUXILOCK GFS Ultimate Large Button, Button L:16.5mm, W:3.9mm (Adjustable Loop)
	AUXILOCK 4mm - 16mm x 10mm - 60mm PEEK CF Interference Screw
	AUXILOCK 4mm - 16mm x 10mm - 60mm PEEK OPTIMA Interference Screw
	AUXILOCK 4mm - 16mm x 10mm - 60mm Titanium Interference Screw
	AUXILOCK GFS Button Extender, L18mm, W5.0mm - ,Ligament Staple 8mm - 16mm x 13mm - 21mm x 20mm - 25mm
	AUXILOCK 2.8mm Titanium Screw - In Suture Anchor With One 2 BioBraid White/Blue, With Needles MO - 6
	AUXILOCK 3.5mm Titanium Screw - In Suture Anchor With One 2 BioBraid White/Blue, With Needles MO - 6
	AUXILOCK 3.5mm Titanium Screw - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6
	AUXILOCK 5.0mm Titanium Screw - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6

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La Directora Técnica de Dispositivos Médicos y otras Tecnologías del Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, en ejercicio de las facultades Legales conferidas en el Decreto 2078 de 2012, Decreto Reglamentario 4725 de 2005, y ley 1437 de 2011.

Familia	Descripción
	AUXILOCK 5.0mm Twix Titanium Screw - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6
	AUXILOCK 6.5mm Titanium Screw - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6
	AUXILOCK 5.0mm Twix Titanium Screw - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6
	AUXILOCK 6.5mm Twix Titanium Screw - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6
	AUXILOCK 2.8mm Titanium Screw - In Suture Anchor With One 2 BioBraid White/Blue
	AUXILOCK 3.5mm Titanium Screw - In Suture Anchor With One 2 BioBraid White/Blue
	AUXILOCK 3.5mm Titanium Screw - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black
	AUXILOCK 5.0mm Titanium Screw - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black
	AUXILOCK 5.0mm Titanium Screw - In Suture Anchor With Three 2 BioBraid White White/Blue & White/Black
	AUXILOCK 6.5mm Titanium Screw - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black
	AUXILOCK 4.5mm PEEK OPTIMA Screw - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6
	AUXILOCK 5.5mm PEEK OPTIMA Screw - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6
	AUXILOCK 6.5mm PEEK OPTIMA Screw - In Suture Anchor With Two 2 BioBraid White & White/Blue With Needles MO - 6
	AUXILOCK 4.5mm PEEK OPTIMA Screw - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black
	AUXILOCK 5.5mm PEEK OPTIMA Screw - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black
	AUXILOCK 6.5mm PEEK OPTIMA Screw - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black
	AUXILOCK 4.5mm PEEK OPTIMA Screw - In Suture Anchor With Three 2 BioBraid White White/Blue & White/Black
	AUXILOCK 5.5mm PEEK OPTIMA Screw - In Suture Anchor With Three 2 BioBraid WhiteWhite/Blue & White/Black
	AUXILOCK 4.5mm PEEK OPTIMA Screw - In Suture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Blue & White/Black
	AUXILOCK 5.5mm PEEK OPTIMA Screw - In Suture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Blue & White/Black
	AUXILOCK 6.5mm PEEK OPTIMA Screw - In Suture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Blue & White/Black
	AUXILOCK 4.5mm PEEK OPTIMA Screw - In Suture Anchor With Two 1.4mm Suture Tape White/Blue & White/Black
	AUXILOCK 5.5mm PEEK OPTIMA Screw - In Suture Anchor With Two 1.4mm Suture Tape White/Blue & White/Black
	AUXILOCK 6.5mm PEEK OPTIMA Screw - In Suture Anchor With Two 1.4mm Suture Tape White/Blue & White/Black
	AUXILOCK 4.5mm PEEK CF Screw - In Suture Anchor With Three 2 BioBraid White White/Blue & White/Black
	AUXILOCK 4.5mm PEEK CF Screw - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black
	AUXILOCK 5.5mm PEEK CF Screw - In Suture Anchor With Three 2 BioBraid WhiteWhite/Blue & White/Black
	AUXILOCK 5.5mm PEEK CF Screw - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black

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Familia	Descripción
	AUXILOCK 6.5mm PEEK CF Screw - In Suture Anchor With Two 2 BioBraid White/Blue & White/Black
	AUXILOCK 4.5mm PEEK CF Screw - In Suture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Black & White/Blue
	AUXILOCK 5.5mm PEEK CF Screw - In Suture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Black & White/Blue
	AUXILOCK 6.5mm PEEK CF Screw - In Suture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Black & White/Blue
	AUXILOCK 4.5mm PEEK CF Screw - In Suture Anchor With Two 1.4mm Suture Tape White/Blue & White/Black
	AUXILOCK 6.5mm PEEK CF Screw - In Suture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Black & White/Blue
	AUXILOCK 5.5mm PEEK CF Screw - In Suture Anchor With Two 1.4mm Suture Tape White/Blue & White/Black
	PEEK OPTIMA Draw Tight Suture - Based Anchor (Todas las Referencias)
	AUXILOCK 1.8mm Draw Tight Suture - Based Anchor With One 2 BioBraid White/Blue
	AUXILOCK 3.2mm Draw Tight Suture - Based Anchor With Two 2 BioBraid White/Blue & White/Black
	AUXILOCK 1.5mm AuxSuture Anchor With One 2 BioBraid White/Blue
	AUXILOCK 1.5mm AuxSuture Anchor With One 1.4mm Suture Tape White/Blue
	AUXILOCK 1.8mm AuxSuture Anchor With Two 2 BioBraid White/Blue & White/Green
	AUXILOCK 1.8mm AuxSuture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Black & White/Blue
	AUXILOCK 2.9mm AuxSuture Anchor With Two 2 BioBraid White/Blue & White/Green
	AUXILOCK 2.9mm AuxSuture Anchor With Three 2 BioBraid White White/Blue & White/Green
	AUXILOCK 2.9mm AuxSuture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Black & White/Blue
	AUXILOCK 2.9mm AuxSuture Anchor With Two 1.4mm Suture Tape White/Black & White/Blue
	AUXILOCK GFS No - Button Adjustable Loop
	AuxSuture Anchor With Needle (Todas las Referencias)
	AUXILOCK 1.5mm AuxSuture Anchor With One 2 BioBraid White/Blue With Needles MO - 6
	AUXILOCK 1.8mm AuxSuture Anchor With Two 2 BioBraid White/Blue & White/Green With Needles MO - 6
	AUXILOCK 1.8mm AuxSuture Anchor With One 2 BioBraid and One 1.4mm Suture Tape White/Black & White/Blue With Needles MO - 6
	AUXILOCK 2.9mm AuxSuture Anchor With Two 2 BioBraid White/Blue & White/Green With Needles MO - 6
	AUXILOCK Tendo 7.0mm - 9.0mm x 15mm PEEK OPTIMA Screw - In Anchor
	AUXILOCK Tendo 7.0mm - 9.0mm x 15mm PEEK CF Screw - In Anchor - PEEK OPTIMA Tendo Screw - In Anchor
	AUXILOCK AuxFix Button (AC Joint)
	PEEK CF Tendo Screw - In Anchor (Todas las Referencias)
	AUXILOCK 1.2mm AuxSuture Anchor With One 0 BioBraid White/Blue
	AUXILOCK 1.2mm AuxSuture Anchor With One 0 BioBraid White/Blue With Needles
	AUXILOCK 2.0mm Titanium Screw - In Suture Anchor With One 0 BioBraid White/Blue With Needles
	AUXILOCK 2.0mm Titanium Screw - In Suture Anchor With One 0 BioBraid White/Blue
	AUXILOCK 2.5mm Titanium Screw - In Suture Anchor With One 1 BioBraid White/Blue With Needles MO - 6
	AUXILOCK 2.5mm Titanium Screw - In Suture Anchor With One 1 BioBraid White/Blue

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Familia	Descripción
	AUXILOCK Rotador 4.75mm x 15mm PEEK OPTIMA Screw - In Anchor
	AUXILOCK 1.3mm Titanium Fin Anchor With One 4 - 0 BioBraid White/Blue
	AUXILOCK 1.8mm Titanium Fin Anchor With One 2 - 0 BioBraid White/Blue
	AUXILOCK 2.4mm Titanium Fin Anchor With One 2 BioBraid White/Green
	AUXILOCK 2.8mm Titanium Fin Anchor With One 2 BioBraid White/Blue
	Titanium FIN Anchor (Todas las Referencias)
	AUXILOCK 1.3mm Titanium Fin Anchor With One 4 - 0 BioBraid White/Blue
	AUXILOCK 1.8mm Titanium Fin Anchor With One 2 - 0 BioBraid White/Blue
	AUXILOCK 2.4mm Titanium Fin Anchor With One 2 BioBraid White/Green
	AUXILOCK 2.8mm Titanium Fin Anchor With One 2 BioBraid White/Blue
	PEEK OPTIMA Interference Screw (Todas las Referencias)
	AUXILOCK 2.8mm Knotless PEEK CF Push - In Suture Anchor With Hip Length Driver With Suture Passer (Hip)
	AUXILOCK 2.8mm Knotless PEEK OPTIMA Push - In Suture Anchor With Hip Length Driver With Suture Passer (Hip)
	AUXILOCK 2 BioBraid White/Blue & White/Black 36in Total Length
	AUXILOCK 2 BioBraid Blue With Needles MO - 6 & CE 36in Total Length
	AUXILOCK 2 BioBraid White With Needle MO - 6 36in Total Length
	AUXILOCK 2 BioBraid White/Black With Needle MO - 6 36in Total Length
	AUXILOCK 2 BioBraid White/Blue With Needle MO - 6 36in Total Length
	AUXILOCK 2 BioBraid White/Black 36in Total Length
	AUXILOCK 2 BioBraid White/Green With Needle MO - 6 36in Total Length
	AUXILOCK 2 BioBraid White/Green 36in Total Length
	AUXILOCK 2 BioBraid Blue 36in Total Length
	AUXILOCK 2 BioBraid White 36in Total Length
	AUXILOCK 2 BioBraid White/Blue 36in Total LengthAUXILOCK 2 BioBraid White With Needle CCS 36in Total Length
	AUXILOCK 2 BioBraid White With Needle CCS 36in Total Length
	AUXILOCK 5 BioBraid White With Needle CCS 36in Total Length
	AUXILOCK 1.8mm BioBraid Suture Tape White/Blue 15in Working Length 39in Total Length
	AUXILOCK 1.4mm BioBraid Suture Tape White/Blue 15in Working Length 36in Total Length
	AUXILOCK 2 BioBraid Infinity Loop White With Needle straight 20in Loop Length 24in Total Length
	AUXILOCK 2 BioBraid Infinity Loop White/Blue With Needle straight 20in Loop Length 24in Total Length
	AUXILOCK 5 BioBraid Infinity Loop White/Blue With Needle straight 20in Loop Length 24in Total Length
	AUXILOCK GFS Ultimate Large Button Button L:16.5mm W:3.9mm (Adjustable Loop)
	AUXILOCK GFS Concave Button 11mm with 4mm Collar
	AUXILOCK GFS Concave Button 14mm with 7mm Collar
	AUXILOCK GFS Concave Button 20mm with 9mm Collar
	AUXILOCK GFS Round Button without Collar, 14mm
	AUXILOCK Syndemosis Ultimate Kit
	AUXILOCK GFS Ultimate Mini Button Button L:12mm W:3.9mm (Adjustable Loop)
	AUXILOCK GFS Mini Naked Button L12mm W3.9mm

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Familia	Descripción
	AUXILOCK Ultimate Mini Naked Button L 12mm W3.9mm
	AUXILOCK GFS II Large Naked Button L16.5mm W4.4mm
	AUXILOCK Ultimate Mini Naked Button L12mm W3.9mm
	AUXILOCK Advance Syndesmosis Ultimate Kit
	Meni - Fix Meniscus Root Repair Implant (Todas las Referencias)
	AUXILOCK MENI - FIX All - Inside Meniscal Repair System - Straight Needle
	AUXILOCK MENI - FIX All - Inside Meniscal Repair System - Curve Needle
	AUXILOCK MENI - FIX All - Inside Meniscal Repair System - Reverse Curve Needle
	MENISCO Meniscus Root Repair, Inside - Out
	AUXILOCK MENISCO Inside - Out Meniscal Repair Needle with #2 - 0 BioBraid: White/Blue, Length 75cm, Needle Length 25cm
	AUXILOCK MENISCO Inside - Out Meniscal Repair Needle with #0 BioBraid: White/Blue, Length 75cm, Needle Length 25cm
	AUXILOCK MENISCO Inside - Out Meniscal Repair Needle with 1.0mm Suture Tape: White/Blue, Length 75cm, Needle Length 25cm
	#2 - 0 BioBraid Meniscus Repair Needle
	#0 BioBraid Meniscus Repair Needle
	1.0mm BioBraid SutureTape Meniscus Repair Needle - NA

VIDA UTIL: 5 AÑOS PRODUCTOS ESTERILES
EXPEDIENTE No.: 20260889
RADICACIÓN: 20231215505
FECHA: 14/08/2023

ARTICULO SEGUNDO: SE APRUEBAN las etiquetas de fabrica allegadas bajo radicado 20231215505 del 14 de agosto de 2023.

ARTICULO TERCERO. - Contra la presente resolución procede únicamente el Recurso de Reposición, que deberá interponerse ante LA DIRECTORA DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS, dentro de los DIEZ (10) días siguientes a su notificación, en los términos señalados en el Código de Procedimiento Administrativo y de lo Contencioso Administrativo.

ARTICULO CUARTO: La presente resolución rige a partir de la fecha de su expedición.

COMUNIQUESE, NOTIFIQUESE Y CUMPLASE

Dada en Bogotá D.C. a los 5 días de Marzo de 2024
Este espacio, hasta la firma se considera en blanco.



DORIS YOLIMA GOMEZ PARADA
DIRECTOR TÉCNICO DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS
Proyectó: Legal: salbam, Técnico: gmonroyb Revisó: cordina_varios