



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

DECLARACIÓN DE CONFORMIDAD DE MODIFICACIÓN – PM CLASE III - IV

Número de revisión: 594-603#0005

Nombre Descriptivo del producto:

Vaina larga

Marca:

STRYKER

Número de PM:

594-603

Disposición Autorizante o reválida: 175/19

Expediente de Autorización original: 1-47-3110-6157-18-8

MODIFICACIONES SOLICITADAS

DATO A MODIFICAR	DATOS AUTORIZADOS	MODIFICACION/RECTIFICACION AUTORIZADA
Nombre del fabricante	1) Stryker Neurovascular 2) Stryker Neurovascular 3) InNeuroCo, Inc.	1) Stryker Neurovascular 2) Stryker Neurovascular 3) CPE1 LLC dba Greatbatch Medical

CUMPLIMIENTO DE REQUISITOS ESENCIALES DE SEGURIDAD Y DESEMPEÑO.
DISPOSICIÓN ANMAT N° 11467/24 Y GESTIÓN DE RIESGO

ENSAYO/VALIDACION/GESTION DE RIESGO	LABORATORIO/N° DE PROTOCOLO	FECHA DE EMISIÓN
1. Quality System: EN ISO 13485 90641781 Stryker Neurovascular Quality Manual Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Clinical: MEDDEV 2.7/1 NV00023585, Clinical Evaluation Report SOP 90755654, Post Market Data Review SOP Labeling: ISO 10555-1 EN 556-1 EN 1041 EN ISO 15223-1 90714057, Stryker Neurovascular Labeling SOP Packaging/Distribution: ISO 11607-1 ISO 11607-2 90714056, Packaging Requirements SOP 90714058, Packaging Testing Overview SOP 90722964, Distribution Challenge of Packaging SOP	N/A	N/A
2. Quality System: EN ISO 13485 90641781 Stryker Neurovascular Quality Manual Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific:	N/A	N/A

ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Labeling: ISO 10555-1 EN 556-1 EN 1041 EN ISO 15223-1 90714057, Stryker Neurovascular Labeling SOP Risk Management: ISO 14971 90797415, Risk Management SOP		
3. Quality System: EN ISO 13485 90641781 Stryker Neurovascular Quality Manual Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Clinical: MEDDEV 2.7/1 NV00023585, Clinical Evaluation Report SOP 90755654, Post Market Data Review SOP Labeling: ISO 10555-1 EN 556-1 EN 1041 EN ISO 15223-1 90714057, Stryker Neurovascular Labeling SOP Neurovascular Labeling	N/A	N/A
4. Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Labeling:	N/A	N/A

ISO 10555-1 EN 556-1 EN 1041 EN ISO 15223-1 90714057, Stryker Neurovascular Labeling SOP Risk Management: ISO 14971 90797415, Risk Management SOP		
5. Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Labeling: ISO 10555-1 EN 556-1 EN 1041 EN ISO 15223-1 90714057, Stryker Neurovascular Labeling SOP Risk Management: ISO 14971 90797415, Risk Management SOP	N/A	N/A
6. Clinical: MEDDEV 2.7/1 NV00023585, Clinical Evaluation Report SOP 90755654, Post Market Data Review SOP 6a. Risk Management: ISO 14971 90797415, Risk Management SOP	N/A	N/A
7. 7.1 Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Biocompatibility: ISO 10993-1 Environmental Controls: ISO 14644-1 ISO 14644-2 ISO 14664-4 ISO 14698-1 SOP-13013*, Cleanroom Environmental	N/A	N/A

Control Requirements SOP-13014*, Microbiological Monitoring Policy WI-13044*, Controlled Area Environmental Requirements WI-13045*, Controlled Area Microbiological Monitoring Procedure WI-13047*, Miramar Cleanroom Environmental & Microbiological Requirements SOP-13015*, Bioburden Evaluation Policy WI-12455*, Pembroke Pines Cleanroom Environmental & Microbiological Requirements WI-13048*, Pembroke Pines Cleanroom Cleaning Procedure WI-12502*, Pembroke Pines Production Area Environmental & Microbiological Requirements WI-12545*, Pembroke Pines Production Area Cleaning Procedure 7.2 Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Biocompatibility: ISO 10993-1 Environmental Controls: ISO 14644-1 ISO 14644-2 ISO 14664-4 ISO 14698-1 SOP-13013*, Cleanroom Environmental Control Requirements SOP-13014*, Microbiological Monitoring Policy WI-13044*, Controlled Area Environmental Requirements WI-13045*, Controlled Area Microbiological Monitoring Procedure WI-13047*, Miramar Cleanroom Environmental & Microbiological Requirements SOP-13015*, Bioburden Evaluation Policy WI-12455*, Pembroke Pines Cleanroom Environmental & Microbiological Requirements		
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WI-13048*, Pembroke Pines Cleanroom Cleaning Procedure WI-12502*, Pembroke Pines Production Area Environmental & Microbiological Requirements WI-12545*, Pembroke Pines Production Area Cleaning Procedure 7.3 Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Risk Management: ISO 14971 90797415, Risk Management SOP 7.4 N/A 7.5 Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Biocompatibility: ISO 10993-1 Risk Management: ISO 14971 90797415, Risk Management SOP		
8. 8.1 Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Environmental Controls: ISO 14644-1 ISO 14644-2 ISO 14664-4 ISO 14698-1 SOP-13013*, Cleanroom Environmental Control Requirements SOP-13014*, Microbiological Monitoring Policy Risk Management:	N/A	N/A

ISO 14971 90797415, Risk Management SOP 8.3 Shelf Life: 90797408 Design Control SOP 90797413 Design Verification WI 90714056 Packaging Requirements SOP Sterilization: ANSI/AAMI/ISO 11135-1 EN ISO 10993-7 EN ISO 11737-1 ISO 11138-2 WI-10401*, Ethylene Oxide Sterilization SOP FM-12008*, Sterilization Load Review SOP-13016*, LAL Samples for Nonpyrogenic Products Risk Management: ISO 14971 90797415, Risk Management SOP 8.4 Environmental Controls: ISO 14644-1 ISO 14644-2 ISO 14664-4 ISO 14698-1 SOP-13013*, Cleanroom Environmental Control Requirements SOP-13014*, Microbiological Monitoring Policy WI-13044*, Controlled Area Environmental Requirements WI-13045*, Controlled Area Microbiological Monitoring Procedure WI-13047*, Miramar Cleanroom Environmental & Microbiological Requirements SOP-13015*, Bioburden Evaluation Policy WI-12455*, Pembroke Pines Cleanroom Environmental & Microbiological Requirements WI-13048*, Pembroke Pines Cleanroom Cleaning Procedure WI-12502*, Pembroke Pines Production Area Environmental & Microbiological Requirements WI-12545*, Pembroke Pines Production Area Cleaning Procedure Sterilization: ANSI/AAMI/ISO 11135-1 EN ISO 10993-7 EN ISO 11737-1 ISO 11138-2 WI-10401*, Ethylene Oxide Sterilization SOP FM-12008*, Sterilization Load Review SOP-13016*, LAL Samples for Nonpyrogenic Products 8.5 Environmental Controls:		
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ISO 14644-1 ISO 14644-2 ISO 14664-4 ISO 14698-1 SOP-13013*, Cleanroom Environmental Control Requirements SOP-13014*, Microbiological Monitoring Policy WI-13044*, Controlled Area Environmental Requirements WI-13045*, Controlled Area Microbiological Monitoring Procedure WI-13047*, Miramar Cleanroom Environmental & Microbiological Requirements SOP-13015*, Bioburden Evaluation Policy WI-12455*, Pembroke Pines Cleanroom Environmental & Microbiological Requirements WI-13048*, Pembroke Pines Cleanroom Cleaning Procedure WI-12502*, Pembroke Pines Production Area Environmental & Microbiological Requirements WI-12545*, Pembroke Pines Production Area Cleaning Procedure 8.6 Y 8.7 N/A		
9. 9.1 Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1 ISO 594-2 USP-788 Labeling: ISO 10555-1 EN 556-1 EN 1041 EN ISO 15223-1 90714057, Stryker Neurovascular Labeling SOP Risk Management: ISO 14971 90797415, Risk Management SOP 9.2 Design and Development: 90797408, Design Control Procedure EN 62366 Device Specific: ISO 10555-1 ISO 594-1	N/A	N/A

ISO 594-2 USP-788 Labeling: ISO 10555-1 EN 556-1 EN 1041 EN ISO 15223-1 90714057, Stryker Neurovascular Labeling SOP Shelf Life: 90797408 Design Control SOP 90797413 Design Verification WI 90714056 Packaging Requirements SOP Risk Management: ISO 14971 90797415, Risk Management SOP 9.3 N/A		
10. N/A 11. N/A 12. N/A	N/A	N/A
13. Labeling: ISO 10555-1 EN 556-1 EN 1041 EN ISO 15223-1 90714057, Stryker Neurovascular Labeling SOP	N/A	N/A

El responsable legal y su responsable técnico en nombre y representación de la firma STRYKER CORPORATION SUCURSAL ARGENTINA, declaran bajo juramento lo antes declarado y son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento mantener en su establecimiento y a disposición de la autoridad sanitaria la documentación allí declarada y la que establece la Disposición ANMAT N° 64/25 y la Disposición 9688/19, bajo apercibimiento de lo que establece la Ley N° 16.463, el Decreto N° 341/92 y las que correspondan del Código Penal en caso de falsedad.

En caso de inexactitud o falsedad de la información o documentación, la Administración Nacional podrá suspender, cancelar, prohibir la comercialización y solicitar retiro del mercado de lo ya autorizado e iniciar los sumarios que pudieran corresponder.

Firma del Responsable Técnico

Firma del Representante Legal



CETRARO IRISARRI Lucía
CUIL 27343383555

Habiéndose cumplimentado con lo previsto en la Disposición ANMAT N° 9688/19, se autoriza las modificaciones solicitadas.

LUGAR Y FECHA: Argentina, 02 septiembre 2025



BODNAR Andrea Veronica
CUIL 27254978472
Dirección de Evaluación y Registro de
Productos Médicos ANMAT
Firma y Sello



TERRIZZANO Maria Lorena
CUIL 23242965604

Instituto Nacional de Productos Médicos de
Productos Médicos ANMAT
Firma y Sello



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

Tramitada por Expediente N°: 1-0047-3110-005999-25-8



ABRIOLA Leticia Adriana
CUIL 27323186494