



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

CERTIFICADO DE AUTORIZACIÓN DE MODIFICACIÓN

N° rev: 1991-202#0002

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 1991-202 aprobado según:

Disposición autorizante N° 11256/24 de fecha 19 diciembre 2024

Disposiciones modificatorias y reválidas N°: N/A

Del siguiente/s dato/s característico/s:

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACION/RECTIFICACION AUTORIZADA
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Quedando el producto inscripto con los siguientes datos característicos:

Nombre descriptivo: Sistema de endoprótesis torácica Talos

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): Talos / Microport Endovascular

Clase de Riesgo: IV

Indicación/es autorizada/s: Reparación vascular de la disección aórtica tipo B de Stanford. Los pacientes deben tener una morfología del vaso de acceso a la arteria femoral o ilíaca compatible con las técnicas, dispositivos y accesorios de acceso vascular.

Modelos: Sistema de endoprótesis torácica Talos™

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Período de vida útil: 2 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biotecnológico: no corresponde

Forma de presentación: Por unidad

Método de esterilización: Óxido de Etileno

Nombre del fabricante: Shanghai Microport Endovascular MedTech (Group) Co., Ltd.

Lugar de elaboración: Building #1, 3399 Kangxin Road, 201318 Shanghai, República Popular China.

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, 10 enero 2025.



BODNAR Andrea Veronica
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: 10 enero 2025



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

N° Identificadorio Trámite: 63717