



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

DECLARACION JURADA DE REVÁLIDA

DISPOSICIÓN ANMAT N° 9688/2019

N° rev: 646-100#0002

En nombre y representación de la firma AXIMPORT SRL , el responsable legal y el responsable técnico declaran bajo juramento cumplir con la Disposición 9688/19 I Anexo V para el producto médico inscripto bajo el Número de PM: 646-100

Disposición autorizante N° 4550 de fecha 23 junio 2020
Disposiciones modificatorias y reválidas N°: N/A

Datos Característicos del Producto Médico:

Nombre descriptivo: STENTS PERIFÉRICOS CROMO-COBALTO NEPTUN C CON SISTEMA DE LIBERACIÓN DE INTERCAMBIO RÁPIDO/ OTW

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
17-461 Endoprótesis (Stents), Vasculares

Marca(s) de (los) producto(s) médico(s): BALTON

Clase de Riesgo: III

Indicación/es autorizada/s: Están destinados a mantener la luz del vaso abierta en casos de estenosis, oclusión o lesión, para el tratamiento de lesiones ateroscleróticas, inducidas por radiación y postraumáticas que resultan en arterio estenosis de importancia hemodinámica e intratables de otra manera. Los Stents para vasos periféricos se utilizan en los siguientes casos: efecto insatisfactorio de un procedimiento (PTA)/estenosis residual; delaminación interna de la túnica íntima o lesión vascular; estenosis recurrente o pérdida de permeabilidad después de procedimientos intravasculares previos; presión exterior ejercida sobre el vaso.

Modelos: RX - Sistema de liberación: Intercambio rápido
OTW Sistema de implantación - "Over the Wire"

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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 biológico: N/A

Forma de presentación: Unitario

Método de esterilización: Oxido de etileno

Nombre del fabricante: BALTON Sp.z.o.o

Lugar de elaboración: Nowy Swiat 7/14
00-496 Varsovia



BALDONEDO Sabrina Laura
CUIL 27263872563

El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento que el producto médico no ha sufrido modificaciones según Artículo 11° Disposición 9688/19, que cumple y satisface los Requisitos Esenciales de Seguridad y Eficacia (R.E.S.E.) previstos por la Disposición ANMAT N° 11467/24.

La empresa mantiene en su establecimiento y a disposición de la autoridad sanitaria la documentación requerida por disposición ANMAT N° 64/25 y 9688/19

Firmado digitalmente por: MAINARDI
Ana Valentina

Responsable Legal
Firma y Sello

Firmado digitalmente por: GAETA
Josefina Loredana
Motivo: CUIL: 27-17054571-6

Responsable Técnico
Firma y Sello

La presente DECLARACIÓN JURADA ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 9688/19, quedando inscripta la reválida en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de AXIMPORT SRL bajo el número PM 646-100 siendo su nueva vigencia hasta el 23 junio 2030



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.

Fecha de emisión: 23 mayo 2025



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

N° Identificador Trámite: 67568

Tramitada por Expediente N°: 1-0047-3110-003023-25-2