



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

2025 - AÑO DE LA RECONSTRUCCIÓN DE LA
NACIÓN ARGENTINA

DECLARACION JURADA DE REVÁLIDA

DISPOSICIÓN ANMAT N° 9688/2019

N° rev: 310-149#0004

En nombre y representación de la firma BIOSUD S.A. , 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: 310-149

Disposición autorizante N° DC N° 00 de fecha 17 julio 2020
Disposiciones modificatorias y reválidas N°: DC N° 01 de fecha 22 de octubre de 2020; DC N° 310-149#0001 de fecha 09 de mayo de 2023; DC N° 310-149#0002 de fecha 15 de abril de 2024; DC N° 310-149#0003 de fecha 12 de julio de 2024

Datos Característicos del Producto Médico:

Nombre descriptivo: Introdutores

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
12-727 Introdutores de Agujas

Marca(s) de (los) producto(s) médico(s): APT Medical

Clase de Riesgo: II

Indicación/es autorizada/s: El introductor de hemostasia esta indicado para introducir catéteres en el sistema circulatorio para diagnóstico y cirugía de intervención endovascular.

Modelos: Introdutor de hemostasia Braidin™ estéril:

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Período de vida útil: 3 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biológico: NA

Forma de presentación: Caja x 5 unidades

Método de esterilización: Óxido de etileno

Nombre del fabricante: APT Medical Inc.

Lugar de elaboración: No. 009, Xiangxiang Road, Xiangxiang Economic Development Zone, Ciudad de Xiangxiang, Hunan 411400, China

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

Responsable Legal
Firma y Sello

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 BIOSUD S.A. bajo el número PM 310-149 siendo su nueva vigencia hasta el 17 julio 2030

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: 05 noviembre 2025



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

N° Identificador Trámite: 68654

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