



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

DECLARACION JURADA DE REVÁLIDA

DISPOSICIÓN ANMAT N° 9688/2019

N° rev: 1436-37#0002

En nombre y representación de la firma OMNIMEDICA 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: 1436-37

Disposición autorizante N° 0458/2011 de fecha 21 enero 2011
Disposiciones modificatorias y reválidas N°: Disposición modificatoria 7997/2011
Disposición rectificatoria 3075/2012
Disp. reválida 0608/2017
DDJJ N° rev: 1436-37#0001

Datos Característicos del Producto Médico:

Nombre descriptivo: Catéteres Balón para Valvuloplastia transluminal percutánea

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
17-453 - Catéteres, para Valvuloplastia, con Dilatación por Balón

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

Clase de Riesgo: IV

Indicación/es autorizada/s: Valvuloplastia transluminal percutánea de la válvula pulmonar

Modelos: NUMED CANADA, INC.
TYSHAK

PDC001 PDC002 PDC003 PDC004 PDC005 PDC006 PDC007 PDC008 PDC009
PDC010 PDC011 PDC012 PDC013 PDC014 PDC015 PDC016 PDC017 PDC018
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PDC52655 PDC8465 SN012

TYSHAK II

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SN010 SN011 SN013 SN11290

SO001 SO002 SO003 SO004 SO007

SO008 SO009 SO014 SO017

SO018 SO019 SO020 SO021 SO029 SO030 SO031 SO032 SO033

SO034 SO035 SO036 SO037 SO038 SO069 SO086 SO100

COEfficient

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SN032

TYSHAK II-X

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TYSHAK Mini

PDC400 PDC401 PDC402 PDC403 PDC404 PDC405 PDC406 PDC407 PDC408

TYSHAK X

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PDZ394

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SN029 SN030 SN031

SO005 SO006 SO013 SO016 SO022 SO023 SO024 SO025 SO026

SO027 SO041 SO046 SO047 SO048 SO049 SO050 SO051 SO052

SO053 SO054 SO055 SO056 SO057 SO058 SO059 SO060 SO061

SO062 SO063 SO064 SO065 SO066 SO067 SO080 SO081 SO082

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Z-MED II

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NUMED INC., Estados Unidos

TYSHAK

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SN032

TYSHAK Mini

PDC400 PDC401 PDC402 PDC403 PDC404 PDC405 PDC406 PDC407 PDC408
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TYSHAK X

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Z-MED-X

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Z-MED II-X

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PDC745 PDC746 PDC747 PDC748 PDC749 PDC750 PDC751 PDC752 PDC753

Período de vida útil: 5 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biológico: No aplica.

Forma de presentación: Unitaria

Método de esterilización: Gas óxido de etileno

Nombre del fabricante: 1) NUMED CANADA, INC
2) NUMED INC.

Lugar de elaboración: 1) 45 Second Street West, Cornwall, Ontario, Canadá.
2) 2880 Main Street, Hopkinton, NY 12965, Estados Unidos

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

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BRANGOLD Mora Tali
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Firma y Sello

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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 OMNIMEDICA S.A. bajo el número PM 1436-37 siendo su nueva vigencia hasta el 21 enero 2031



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: 02 enero 2026



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

N° Identificador Trámite: 74617

Tramitada por Expediente N°: 1-0047-3110-000024-26-9



SCHUGURENSKY Gabriel Ernesto
CUIL 20201785767