



República Argentina - Poder Ejecutivo Nacional
2019 - Año de la Exportación

Disposición

Número:

Referencia: 1-47-3110-1243-19-4

VISTO el Expediente N° 1-47-3110-1243-19-4 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y

CONSIDERANDO:

Que por las presentes actuaciones la firma PROMEDON S.A. solicita la autorización de modificación del Certificado de Inscripción en el RPPTM N° PM-189-224, denominado: Stent biliar, marca Micro-Tech.

Que lo solicitado se encuadra dentro de los alcances de la Disposición ANMAT N° 2318/02, sobre el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM).

Que la documentación aportada ha satisfecho los requisitos de la normativa aplicable.

Que el Instituto Nacional de Productos Médicos ha tomado la intervención que le compete.

Que se actúa en virtud de las facultades conferidas por el Decreto N° 1490/92 y sus modificatorios.

Por ello;

**EL ADMINISTRADOR NACIONAL DE LA ADMINISTRACIÓN NACIONAL DE
MEDICAMENTOS, ALIMENTOS Y TECNOLOGÍA MÉDICA**

DISPONE:

ARTÍCULO 1°.- Autorízase la modificación del Certificado de Inscripción en el RPPTM N° PM-189-224,

denominado Stent biliar, marca Micro-Tech según Disposición Autorizante de (RPPTM) N° DI-2017-10890-APN-ANMAT#MS y tramitado por expediente N° 1-47-3110-1681-17-3.

ARTÍCULO 2°.- Acéptase el Anexo de Autorización de Modificaciones documento N° IF-2019-80171520-APN-DNPM#ANMAT el que deberá agregarse al Certificado de Inscripción en el RPPTM N° PM-189-224.

ARTICULO 3°.- En los rótulos e instrucciones de uso deberán constar la modificación autorizadas.

ARTÍCULO 4°.- Regístrese; por el Departamento de Mesa de Entrada, notifíquese al interesado y hágasele entrega de copia autenticada de la presente Disposición conjuntamente con su Anexo, gírese a la Dirección de Gestión de Información Técnica para que efectúe la agregación del Anexo de Modificaciones al certificado. Cumplido, archívese.

Expediente N° 1-47-3110-1243-19-4

ANEXO DE AUTORIZACION DE MODIFICACIONES

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), autoriza a la firma PROMEDON S.A. la modificación de los datos característicos correspondientes al Certificado de Inscripción en el RPPTM N° PM-189-224 de acuerdo con los datos que figuran en tabla al pie, del producto:

Nombre genérico aprobado: Stent biliar.

Marca: Micro-Tech

Disposición Autorizante de (RPPTM) N° DI-2017-10890-APN- ANMAT#MS.

Tramitado por expediente N° 1-47-3110-1681-17-3.

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACIÓN / RECTIFICACIÓN AUTORIZADA
Modelo/s	ST03-101.06.040 , ST03-101.08.070 ST03-101.10.100 ST03-101.06.050 , ST03-101.08.080 ST03-102.10.040 ST03-101.06.060 , ST03-101.08.090 ST03-102.10.050 ST03-101.06.070 , ST03-101.08.100 ST03-102.10.060 ST03-101.06.080 , ST03-102.08.040 ST03-102.10.070 ST03-101.06.090 , ST03-102.08.050 ST03-102.10.080 ST03-101.06.100 , ST03-102.08.060 ST03-102.10.090 ST03-102.06.040 , ST03-102.08.070 ST03-102.10.100 ST03-102.06.050 , ST03-102.08.080 ST03-103.10.040 ST03-102.06.060 , ST03-102.08.090 ST03-103.10.050 ST03-102.06.070 , ST03-102.08.100 ST03-103.10.060 ST03-102.06.080 , ST03-103.08.040 ST03-103.10.070	ST03-001-06.040, ST03-001-06.050, ST03-001-06.060 ST03-001-06.070, ST03-001-06.080, ST03-001-06.090 ST03-001-06.100, ST03-002-06.040, ST03-002-06.050 ST03-002-06.060, ST03-002-06.070, ST03-002-06.080 ST03-002-06.090, ST03-002-06.100, ST03-004-06.040 ST03-004-06.050, ST03-004-06.060, ST03-004-06.070 ST03-004-06.080, ST03-004-06.090, ST03-004-06.100 ST13-001-06.040, ST13-001-06.050, ST13-001-06.060

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El presente sólo tiene valor probatorio anexo al certificado de Autorización antes mencionado.

EXPEDIENTE N° 1-47-3110-1243-19-4



República Argentina - Poder Ejecutivo Nacional
2019 - Año de la Exportación

Hoja Adicional de Firmas
Anexo

Número:

Referencia: 1-47-3110-1243-19-4

El documento fue importado por el sistema GEDO con un total de 51 pagina/s.

Digitally signed by GESTION DOCUMENTAL ELECTRONICA - GDE
DN: cn=GESTION DOCUMENTAL ELECTRONICA - GDE, c=AR, o=SECRETARIA DE GOBIERNO DE MODERNIZACION,
ou=SECRETARIA DE MODERNIZACION ADMINISTRATIVA, serialNumber=CUIT 30715117564
Date: 2019.09.04 16:50:28 -0300'

Digitally signed by GESTION DOCUMENTAL ELECTRONICA - GDE
DN: cn=GESTION DOCUMENTAL ELECTRONICA - GDE, c=AR, o=SECRETARIA DE GOBIERNO DE MODERNIZACION,
ou=SECRETARIA DE MODERNIZACION ADMINISTRATIVA, serialNumber=CUIT 30715117564
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