



República Argentina - Poder Ejecutivo Nacional
2018 - Año del Centenario de la Reforma Universitaria

Disposición

Número:

Referencia: 1-47-3110-527-18-8

VISTO el Expediente N° 1-47-3110-527-18-8 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y

CONSIDERANDO:

Que por las presentes actuaciones la firma PRINCE MEDICAL SUPPLIES S.A. solicita la autorización de modificación del Certificado de Inscripción en el RPPTM N° PM-2304-1, denominado: SISTEMA DE PLACAS Y TORNILLOS PARA HUESOS E INSTRUMENTAL, marca: JEIL MEDICAL CORPORATION.

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 la Dirección 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 Decreto N° 101 del 16 de diciembre de 2015.

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-2304-1,

denominado: SISTEMA DE PLACAS Y TORNILLOS PARA HUESOS E INSTRUMENTAL, marca: JEIL MEDICAL CORPORATION, según Disposición Autorizante de (RPPTM) N° 10038/17 y tramitado por expediente N° 1-47-3110-1821-17-7.

ARTÍCULO 2°.- Acéptase el Anexo de Autorización de Modificaciones documento N° IF2018-13890509-APN-DNPM#ANMAT el que deberá agregarse al Certificado de Inscripción en el RPPTM N° PM-2304-1.

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° 1-47-3110-527-18-8

ANEXO DE AUTORIZACIÓN DE MODIFICACIONES

El Administrador Nacional de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), autoriza a la firma PRINCE MEDICAL SUPPLIES S.A. la modificación de los datos característicos correspondientes al Certificado de Inscripción en el RPPTM N° PM-2304-1 de acuerdo con los datos que figuran en la tabla al pie, del producto:

Nombre genérico aprobado: SISTEMA DE PLACAS Y TORNILLOS PARA HUESOS E INSTRUMENTAL, marca: JEIL MEDICAL CORPORATION.

Disposición Autorizante de (RPPTM) N° 10038/17.

Tramitado por expediente N° 1-47-3110-1821-17-7.

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACIÓN RECTIFICACIÓN AUTORIZADA /
Modelos	12-ME-001	12-ME-001
	12-ME-002	12-ME-002
	12-ME-003	12-ME-003
	20-CV-006	20-CV-006
	20-IP-004	20-IP-004
	20-LL-004	20-LL-004
	20-LL-104	20-LL-104
	20-LL-204	20-LL-204
	20-LL-304	20-LL-304
	20-LL-404	20-LL-404
	20-LR-004	20-LR-004
	20-LR-104	20-LR-104
	20-LR-204	20-LR-204
	20-LR-304	20-LR-304
	20-LR-404	20-LR-404
	20-ME-003	20-ME-003
	20-SQ-004	20-SQ-004
	20-ST-018	20-ST-018
	20-TP-005	20-TP-005
	20-XP-004	20-XP-004
20-YP-007	20-YP-007	

20-ZL-004	20-ZL-004
20-ZL-104	20-ZL-104
20-ZR-004	20-ZR-004
20-ZR-104	20-ZR-104
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12-CV-003	12-CV-003
12-CV-004	12-CV-004
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12-DY-106	12-DY-106
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12-GM-002-01	12-GM-002-01
12-GM-002-02	12-GM-002-02
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12-HX-002	12-HX-002
12-HX-003	12-HX-003
12-HX-102	12-HX-102
12-LL-004	12-LL-004
12-LL-008	12-LL-008
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20-DY-126	20-DY-126
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N12-CV-002S	N12-CV-002S
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N12-DY-006S	N12-DY-006S
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N12-GP-020S	N12-GP-020S
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N12-SQ-004S	N12-SQ-004S

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N12-ST-002S	N12-ST-002S
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N12-ST-005	N12-ST-005
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N12-ST-006	N12-ST-006
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N12-XP-005S	N12-XP-005S
N12-YP-005S	N12-YP-005S
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N16-BR-011F	N16-BR-011F
N16-BR-011S	N16-BR-011S
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N16-CD-006S	N16-CD-006S
N16-CD-008S	N16-CD-008S
N16-CD-010S	N16-CD-010S
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N16-ST-002S	N16-ST-002S

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N16-ST-004S	N16-ST-004S
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N16-ST-006S	N16-ST-006S
N16-ST-102	N16-ST-102
N16-ST-102S	N16-ST-102S
N16-ST-104	N16-ST-104
N16-ST-104S	N16-ST-104S
N16-YP-005S	N16-YP-005S
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NS-3MA-100-06	NS-3MA-100-06
NS-3MB-100-04	NS-3MB-100-04
NS-3MC-100-04	NS-3MC-100-04
NS-3MD-100-04	NS-3MD-100-04
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NS-3MA-150-06	NS-3MA-150-06
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NS-3MA-200-06	NS-3MA-200-06
NS-3MB-100-06	NS-3MB-100-06
NS-3MC-100-05	NS-3MC-100-05
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12-TP-010	12-TP-010
12-YP-008	12-YP-008
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16-DL-012	16-DL-012
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16-OR-C10-03	16-OR-C10-03
16-OR-F10-02	16-OR-F10-02
16-OR-F10-03	16-OR-F10-03
16-OR-V10-02	16-OR-V10-02
16-OR-V10-03	16-OR-V10-03
16-OR-V20-02	16-OR-V20-02
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20L-AR-015	20L-AR-015
20L-CD-005	20L-CD-005
20L-CD-007	20L-CD-007
20L-CD-009	20L-CD-009
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20-LR-234B1	20-LR-234B1
20-LR-234B2	20-LR-234B2
20-LR-234B3	20-LR-234B3
20-LR-234B4	20-LR-234B4
20-LR-234B5	20-LR-234B5
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20L-RR-020	20L-RR-020
20L-RS-015	20L-RS-015
20L-RS-021	20L-RS-021
20L-RS-025	20L-RS-025
20L-SB-004	20L-SB-004
20L-SB-104	20L-SB-104
20L-SB-204	20L-SB-204
20L-ST-004-R	20L-ST-004-R
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20L-ST-006-R10	20L-ST-006-R10
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24L-RS-021	24L-RS-021
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N16-TM-010S	N16-TM-010S
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NL-3MD-100-03	NL-3MD-100-03
NL-BR-030	NL-BR-030

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16-NF-004-E	16-NF-004-E
16-NF-003	16-NF-003
16-NF-004	16-NF-004

	16-NF-005 19-NF-004-E 12-BS-006 12-BS-008 12-BS-010 23-MN-004 23-MN-005 27-MX-010 20-AT-012 20L-AT-004 20L-AT-005 20L-AT-006 20L-AT-008 20L-AT-010 20L-AT-012 24L-AT-004 24L-AT-006 24L-AT-008 20L-MN-004 20L-MN-005 20L-MN-006 20L-MN-008 20L-MN-010 20L-MN-012 20L-MN-014 20L-MN-016 20L-MN-018 23L-MN-006 23L-MN-008 23L-MN-010 23L-MN-012 23L-MN-014 23L-MN-016 24L-MX-004 24L-MX-005 24L-MX-006 24L-MX-008 24L-MX-010 24L-MX-012 24L-MX-014 24L-MX-016 24L-MX-018 27L-MX-006 27L-MX-008 27L-MX-010	16-NF-005 19-NF-004-E 12-BS-006 12-BS-008 12-BS-010 23-MN-004 23-MN-005 27-MX-010 20-AT-012 20L-AT-004 20L-AT-005 20L-AT-006 20L-AT-008 20L-AT-010 20L-AT-012 24L-AT-004 24L-AT-006 24L-AT-008 20L-MN-004 20L-MN-005 20L-MN-006 20L-MN-008 20L-MN-010 20L-MN-012 20L-MN-014 20L-MN-016 20L-MN-018 23L-MN-006 23L-MN-008 23L-MN-010 23L-MN-012 23L-MN-014 23L-MN-016 24L-MX-004 24L-MX-005 24L-MX-006 24L-MX-008 24L-MX-010 24L-MX-012 24L-MX-014 24L-MX-016 24L-MX-018 27L-MX-006 27L-MX-008 27L-MX-010
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H1-QD-112	H1-QD-112
H1-QD-206-L	H1-QD-206-L
H1-QD-206-R	H1-QD-206-R
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H1-QD-306-R	H1-QD-306-R
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H1-QD-408-R	H1-QD-408-R
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H2-QD-112	H2-QD-112
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H2-QD-306-L	H2-QD-306-L
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H2-ST-104-CP	H2-ST-104-CP
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H2-ST-106-CP	H2-ST-106-CP
H2-ST-208-CP	H2-ST-208-CP
H2-TP-006-CP	H2-TP-006-CP
H2-TP-010-CP	H2-TP-010-CP
H2-LL-006-CP	H2-LL-006-CP
H2-LR-006-CP	H2-LR-006-CP
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20L-HF-030	20L-HF-030
20-FC-006	20-FC-006
20-FC-007	20-FC-007
20-FC-008	20-FC-008
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20-FC-010	20-FC-010

	20-FC-011 20-FC-012 20-FC-013 20-FC-014 20-FC-015 20-FC-016 20-FC-018 20-FC-019 20-FC-020 20-FC-021 20-FC-022 20-FC-023 20-FC-024 20-FC-026 20-FC-028 20-FC-030 Placas y tornillos para huesos e instrumental.	20-FC-011 20-FC-012 20-FC-013 20-FC-014 20-FC-015 20-FC-016 20-FC-018 20-FC-019 20-FC-020 20-FC-021 20-FC-022 20-FC-023 20-FC-024 20-FC-026 20-FC-028 20-FC-030 35-FC-011 35-FC-013 35-FC-015 35-FC-017 35-FC-019 35-FC-021 35-FC-023 35-FC-025 35-FC-026 35-FC-027 35-FC-029 35-FC-030 35-FC-031 35-FC-033 35-FC-034 35-FC-035 35-FC-037 35-FC-038 35-FC-039 35-FC-041 35-FC-042 35-FC-043 35-FC-044 35-FC-046 35-FC-047 35-FC-048 35-FC-049 35-FC-051 35-FC-052
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El presente sólo tiene valor probatorio anexo al certificado de Autorización antes mencionado.

Expediente N° 1-47-3110-527-18-8



República Argentina - Poder Ejecutivo Nacional
2018 - Año del Centenario de la Reforma Universitaria

Hoja Adicional de Firmas
Anexo

Número:

Referencia: 1-47-3110-527-17-8

El documento fue importado por el sistema GEDO con un total de 44 pagina/s.