



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

CERTIFICADO DE AUTORIZACIÓN DE MODIFICACIÓN

N° rev: 1728-46#0002

El Instituto Nacional de Productos Médicos de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por BLODEC S.R.L. , se autoriza la modificación en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM), del PM 1728-46 aprobado según:

Disposición autorizante N° 7471 de fecha 15 agosto 2024
Disposiciones modificatorias y reválidas N°: ---

Del siguiente/s dato/s característico/s:

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACION/RECTIFICACION AUTORIZADA
Modelos	- IMPLANTES - Placas no estériles: 12-GM-001-01 12-GM-001-02 12-GM-002-01 12-GM-002-02 12-ME-001-01 12-ME-001-02 12-ME-001-03 12-ME-001-04 12-ME-001-05 12-ME-002-01 12-ME-002-02 12-ME-002-03 12-ME-002-04 12-ME-002-05 12-ME-003-01 12-ME-003-02	IMPLANTES - Placas estériles - SN16-BR-010S SN16-BR-011S SN16-BR-020S SN16-BR-021S SN16-DY-006 SN16-GP-010F SN16-GP-020F SN16-GP-030F SN16-SQ-004 SN16-ST-002 SN16-ST-004 SN16-ST-006 SN16-ST-102 SN16-ST-104 SNL-BR-030 SNL-BR-031

12-ME-003-03	SNL-BR-032
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12-ME-003-05	SNL-BR-041
16-DL-003	SNL-BR-042
16-DL-007	SNL-DY-006
16-DL-012	SNL-DY-106
16-ME-001	SNL-GP-020
16-ME-002	SNL-SQ-004
16-OR-C10-02	SNL-SQ-104
16-OR-C10-03	SNL-ST-002
16-OR-F10-02	SNL-ST-004
16-OR-F10-03	SNL-ST-006
16-OR-V10-02	SNL-ST-102
16-OR-V10-03	SNL-ST-104
16-OR-V20-02	MD46-ST102
16-OR-V20-03	- Tornillos estériles -
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16-RCL-006	S19-NF-004-E-2
16-RCL-008	S14-NL-003-2
16-RCL-010	S16-NF-003-2
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16-RCR-002	S14-NL-005-2
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20-LL-234B4	S16-NF-005-6
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241.032414	
241.032416	
241.032418	
241.032420	

Instrumental asociado.	

Quedando el producto inscripto con los siguientes datos característicos:

Nombre descriptivo: Sistema para osteosíntesis craneomaxilofacial.

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
16-027, Sistemas Ortopédicos de Fijación Interna.

Marca(s) de (los) producto(s) médico(s): Leforte, Leforte NS.

Clase de Riesgo: III

Indicación/es autorizada/s: Traumatismos selectivos de la cara y estructura craneal en general, cirugía craneal, cirugía reparadora, procedimientos de reconstrucción y cirugía ortognática selectiva del maxilar y de la barbilla.

Modelos: IMPLANTES

- Placas estériles -

SN16-BR-010S

SN16-BR-011S

SN16-BR-020S

SN16-BR-021S

SN16-DY-006

SN16-GP-010F

SN16-GP-020F

SN16-GP-030F

SN16-SQ-004

SN16-ST-002
SN16-ST-004
SN16-ST-006
SN16-ST-102
SN16-ST-104
SNL-BR-030
SNL-BR-031
SNL-BR-032
SNL-BR-040
SNL-BR-041
SNL-BR-042
SNL-DY-006
SNL-DY-106
SNL-GP-020
SNL-SQ-004
SNL-SQ-104
SNL-ST-002
SNL-ST-004
SNL-ST-006
SNL-ST-102
SNL-ST-104
MD46-ST102
- Tornillos estériles -
S16-NL-004-E
S16-NL-004-E-2
S19-NF-004-E
S19-NF-004-E-2
S14-NL-003-2
S16-NF-003-2
S14-NL-004-2
S16-NF-004-2
S14-NL-005-2
S16-NF-005-2
S14-NL-003-3
S16-NF-003-3
S14-NL-004-3
S16-NF-004-3
S14-NL-005-3
S16-NF-005-3
S14-NL-003-6
S16-NF-003-6
S14-NL-004-6
S16-NF-004-6
S14-NL-005-6
S16-NF-005-6
- Placas no estériles -
16-DL-003
16-DL-007
16-DL-012
16-RCL-000
16-RCL-002

16-RCL-004
16-RCL-006
16-RCL-008
16-RCL-010
16-RCL-012
16-RCR-000
16-RCR-002
16-RCR-004
16-RCR-006
16-RCR-008
16-RCR-010
16-RCR-012
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20-DR-008
20-DR-013
20-DR-018
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20-LR-234B2
20-LR-234B3
20-LR-234B4
20-LR-234B5
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20-MG-010
20-MG-015
20-SS-008
20-SS-013
20-SS-018
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242.21ST04

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N16-BR-011S
N16-BR-020F
N16-BR-020S
N16-BR-021F
N16-BR-021S
N16-BR-030S
N16-CV-006
N16-CV-106
N16-DY-006
N16-DY-106
N16-GP-010F
N16-GP-010S
N16-GP-020F
N16-GP-020S
N16-GP-030F
N16-GP-030S
N16-SQ-004
N16-SQ-104
N16-ST-002
N16-ST-004
N16-ST-006
N16-ST-102
N16-ST-104
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NL-BR-031
NL-BR-032
NL-BR-040
NL-BR-041

NL-BR-042
NL-DY-006
NL-DY-106
NL-GP-020
NL-SQ-004
NL-SQ-104
NL-ST-002
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NL-ST-006
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NL-ST-104
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16-OR-F10-03
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16-OR-V20-03
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- Placa-malla no estéril -
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N16-QD-006
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- Tornillos no estériles -
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241.032420

Instrumental asociado

Período de vida útil: 5 (cinco) años para los dispositivos estériles

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

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

Forma de presentación: Implantes: Envase unitario, no estéril. Envase unitario, estéril.
Instrumental asociado: Envase unitario, no estéril.

Método de esterilización: Irradiación gamma, para los dispositivos estériles.

Nombre del fabricante: Jeil Medical Corporation

Lugar de elaboración: 704, 705, 706, 707, 804, 805-ho, 55, Digital-ro 34-gil, Gurogu, Seul, República de Corea.

AUTORIZADO

Habiéndose cumplimentado con lo previsto en la Disposición ANMAT N° 2318/02 y 9688/19, esta Administración autoriza las modificaciones solicitadas en Argentina, Ciudad de Buenos Aires, 22 octubre 2024.



BODNAR Andrea Veronica
CUIL 27254978472

Dirección Evaluación y Registro de Productos
Médicos
Firma y Sello



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. Este certificado no modifica el período de vigencia.

Fecha de emisión: 22 octubre 2024



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

N° Identificador Trámite: 62014



ABRIOLA Leticia Adriana
CUIL 27323186494