



República Argentina - Poder Ejecutivo Nacional
Año de la Grandeza Argentina

Certificado - Redacción libre

Número:

Referencia: 1-0047-3110-002138-24-2

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

Expediente N° 1-0047-3110-002138-24-2

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por Implantes Quirúrgicos S.A. ; se autoriza la inscripción en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM), de un nuevo producto con los siguientes datos identificatorios característicos:

DATOS IDENTIFICATORIOS CARACTERÍSTICOS

PM: 2249-30

Nombre descriptivo: Celdas de fusion intervertebral

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
15-766 Sistemas Ortopédicos de Fijación Interna, para Columna Vertebral

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

Modelos:

Celdas de fusión lumbar

SR-B254-241007-3S
SR-B254-281007-3S
SR-B254-321007-3S
SR-B254-361007-3S
SR-B254-241007-6S
SR-B254-281007-6S
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Celdas de fusión cervical
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SR-B701-141506FOS

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Celda de fusión lumbar expandible

F0301-B0024A743
F0301-B0024A746
F0301-B0024A749
F0301-B0024A74C
F0301-B0024A74F
F0301-B0024A753
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F0301-B0024A759
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F0301-B0036AE49S
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Instrumental asociado a la colocación

Clase de Riesgo: IV

Indicación/es autorizada/s:

Las celdas de fusión intervertebral son de un solo uso y están indicadas para la estabilización de uno o varios segmentos de la columna vertebral.

Período de vida útil: 5 años para los productos estériles.

No aplica vencimiento para los productos que no son estériles

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: Las celdas se presentan no estériles o estériles por radiación gamma.

El instrumental asociado a la colocación puede ser no estériles o estéril por óxido de etileno.

Nombre del fabricante:

SHANGHAI REACH MEDICAL INSTRUMENT CO., LTD

Lugar de elaboración:

Building 13, No. 999 Jiangyue Road, Minhang District

Shanghai, Shanghai

CHINA 201114

Se extiende el presente Certificado de Autorización e Inscripción del PM 2249-30 , con una vigencia cinco (5) años a partir de la fecha de la Disposición autorizante.

1-0047-3110-002138-24-2

Nº Identificador Trámite: 57687

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