



República Argentina - Poder Ejecutivo Nacional
Las Malvinas son argentinas

Certificado - Redacción libre

Número:

Referencia: 1-0047-3110-007753-21-2

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

Expediente N° 1-0047-3110-007753-21-2

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por SOLOIMPORTACION S.R.L ; 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: 2501-36

Nombre descriptivo: Kits Introductorios

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
10-678 Introductores de cateteres

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

Modelos:

LS061638-SS70-IN18-K-S, LS061638-SJ70-IN18-K-S, LS061638-SW70-IN18-K-S,
LS062338-SS70-IN18-K-S, LS062338-SJ70-IN18-K-S, LS062338-SW70-IN18-K-S,
LS071638-SS70-IN18-K-S, LS071638-SJ70-IN18-K-S, LS071638-SW70-IN18-K-S,
LS072338-SS70-IN18-K-S, LS072338-SJ70-IN18-K-S, LS072338-SW70-IN18-K-S,
LS081638-SS70-IN18-K-S, LS081638-SJ70-IN18-K-S, LS081638-SW70-IN18-K-S,
LS082338-SS70-IN18-K-S, LS082338-SJ70-IN18-K-S, LS082338-SW70-IN18-K-S,

[illegible]

FS071138-SS45-IN18-K-S, FS071138-SJ45-IN18-K-S, FS071138-SW45-IN18-K-S,
 FS080535-SS45-IN18-K-S, FS080535-SJ45-IN18-K-S, FS080535-SW45-IN18-K-S,
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 FS101138-SS45-IN18-K-S, FS101138-SJ45-IN18-K-S, FS101138-SW45-IN18-K-S,
 FS111138-SS45-IN18-K-S, FS111138-SJ45-IN18-K-S, FS111138-SW45-IN18-K-S,
 LS061638-NJ80-IN18-K-S, LS061638-NW80-IN18-K-S, LS062338-NS80-IN18-K-S,
 LS062338-NJ80-IN18-K-S, LS062338-NW80-IN18-K-S, LS071638-NS80-IN18-K-S,
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 RS040518-NJ45-IN20-K-S, RS040518-NW45-IN20-K-S, RS040521-NS45-IN20-K-S,
 RS040521-NJ45-IN20-K-S, RS040521-NW45-IN20-K-S, RS040525-NS45-IN20-K-S,
 RS040525-NJ45-IN20-K-S, RS040525-NW45-IN20-K-S, RS040718-NS45-IN20-K-S,
 RS040718-NJ45-IN20-K-S, RS040718-NW45-IN20-K-S, RS040721-NS45-IN20-K-S,
 RS040721-NJ45-IN20-K-S, RS040721-NW45-IN20-K-S, LS061638-NS80-IN18-K-S,
 RS040725-NS45-IN20-K-S, RS040725-NJ45-IN20-K-S, RS040725-NW45-IN20-K-S,
 RS050518-NS45-IN20-K-S, RS050518-NJ45-IN20-K-S, RS050518-NW45-IN20-K-S,
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 RS060725-NS45-IN20-K-S, RS060725-NJ45-IN20-K-S, RS060725-NW45-IN20-K-S,
 RS041121-NS45-IN20-K-S, RS041121-NJ45-IN20-K-S, RS041121-NW45-IN20-K-S,
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FS111138-NS45-IN18-K-S, FS111138-NJ45-IN18-K-S, FS111138-NW45-IN18-K-S

Clase de Riesgo: IV

Indicación/es autorizada/s:

El Kit de Introduccion está indicado para el uso en procedimientos arteriales que requieran la introducción percutánea de dispositivos intravasculares.

Período de vida útil: 3 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biológico: N/A

Forma de presentación: Cada caja contiene 1 unidad

Método de esterilización: Esterilizado por óxido de etileno

Nombre del fabricante:

Lepu Medical Technology (Beijing) Co., Ltd

Lugar de elaboración:

Nº 37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China

Se extiende el presente Certificado de Autorización e Inscripción del PM 2501-36 , con una vigencia cinco (5)

años a partir de la fecha de la Disposición autorizante.

Expediente Nro: 1-0047-3110-007753-21-2

N° Identificador Trámite: 34409