



República Argentina - Poder Ejecutivo Nacional
Las Malvinas son argentinas

Disposición

Número:

Referencia: 1-0047-3110-003405-22-7

VISTO el Expediente N° 1-0047-3110-003405-22-7 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y:

CONSIDERANDO:

Que por las presentes actuaciones BIOX S.A. solicita se autorice la inscripción en el Registro Productores y Productos de Tecnología Médica (RPPTM) de esta Administración Nacional, de un nuevo producto médico.

Que las actividades de elaboración y comercialización de productos médicos se encuentran contempladas por la Ley 16463, el Decreto 9763/64, y MERCOSUR/GMC/RES. N° 40/00, incorporada al ordenamiento jurídico nacional por Disposición ANMAT N° 2318/02 (TO 2004), y normas complementarias.

Que consta la evaluación técnica producida por el Instituto Nacional de Productos Médicos, en la que informa que el producto estudiado reúne los requisitos técnicos que contempla la norma legal vigente, y que los establecimientos declarados demuestran aptitud para la elaboración y el control de calidad del producto cuya inscripción en el Registro se solicita.

Que corresponde autorizar la inscripción en el RPPTM del producto médico objeto de la solicitud.

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 1º.- Autorízase la inscripción en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM) de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) del producto médico marca OSTEONIC nombre descriptivo Placas y Tornillos para Huesos y nombre técnico, Sistemas Ortopédicos de Fijación Interna, para Fracturas , de acuerdo con lo solicitado por BIOX S.A. , con los Datos Identificatorios Característicos que figuran al pie de la presente.

ARTÍCULO 2º.- Autorízase los textos de los proyectos de rótulo/s y de instrucciones de uso que obran en documento N° IF-2022-139600324-APN-INPM#ANMAT .

ARTÍCULO 3º.- En los rótulos e instrucciones de uso autorizados deberá figurar la leyenda "Autorizado por la ANMAT PM 1845-08 ", con exclusión de toda otra leyenda no contemplada en la normativa vigente.

ARTICULO 4º.- Extiéndase el Certificado de Autorización e Inscripción en el RPPTM con los datos característicos mencionados en esta disposición.

ARTÍCULO 5º.- La vigencia del Certificado de Autorización será de cinco (5) años, a partir de la fecha de la presente disposición.

ARTÍCULO 6º.- Regístrese. Inscríbese en el Registro Nacional de Productores y Productos de Tecnología Médica al nuevo producto. Por el Departamento de Mesa de Entrada, notifíquese al interesado, haciéndole entrega de la presente Disposición, conjuntamente con rótulos e instrucciones de uso autorizados y el Certificado mencionado en el artículo 4º.

Gírese a la Dirección de Gestión de Información Técnica a los fines de confeccionar el legajo correspondiente.

Cumplido, archívese.

DATOS IDENTIFICATORIOS CARACTERÍSTICOS

PM: 1845-08

Nombre descriptivo: Placas y Tornillos para Huesos

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
12-833 Sistemas Ortopédicos de Fijación Interna, para Fracturas

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

Modelos:

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IOC-080

Clase de Riesgo: III

Indicación/es autorizada/s:

El sistema CMF Optimus está destinado al cierre o fijación ósea con las siguientes indicaciones: trauma cráneo-maxilofacial, cirugía ortognática, cirugía craneofacial, neurocirugía mandibular, cirugía de reconstrucción de la base del cráneo.

Período de vida útil: N/ A

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: Unitaria . Envase individual

Método de esterilización: N/A

Nombre del fabricante:
Osteonic Co., Ltd.

Lugar de elaboración:
505-3 & 1206 Ho, 38, Digital-ro 29 gil, Guro-gu, Seúl, República de Corea.

Expediente N° 1-0047-3110-003405-22-7

N° Identificador Trámite: 39510

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