



República Argentina - Poder Ejecutivo Nacional

Año de la Grandeza Argentina

Certificado - Redacción libre

Número:

Referencia: 1-0047-3110-003454-25-1

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

Expediente N° 1-0047-3110-003454-25-1

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por CROSS BONES 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: 2410-12

Nombre descriptivo: Sistema de implantes para osteosíntesis CMF y Fijación Mandibular – Titanio.

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): OSTEONIC

Modelos:

OPTIMUS

- PLACAS -

FAL207LR6; FAL207MR6; FAL207SR4; FAR207LR6; FAR207MR6; FAR207SR4; FBR206L00; FBR206L01;

FSQ306D04K; FSQ306DM4K; FSQ306L04; FSQ306L04K; FSQ306M04; FSQ306M04K; FSQ306MM4K;
FSQ306MS4K; FSQ306P00; FSQ306P03; FSQ306P04A; FSQ306P04B; FSQ306P04C; FSQ306P04D;
FSQ306P05; FSQ306S04K; FSQ307L04A; FSQ307M04A; FST105M16; FST204L02; FST204L02R;
FST204L04; FST204M02; FST204M04; FST204M05; FST204M06; FST204M08; FST204M12; FST204M20;
FST204X02; FST205M18G; FST206L02; FST206L04; FST206M02; FST206M02K; FST206M03; FST206M04;
FST206M05; FST206M06; FST206M08; FST206M10G; FST206M12; FST206M12G; FST206M20;
FST206S10S; FST206X02; FST207M04; FST208L04; FST208M04; FST208M05; FST208M06; FST208M08;
FST208M12; FST208M20; FST304I04A; FST304L04A; FST304M04A; FST304M06A; FST304M12A;
FST305I04A; FST305L02A; FST305L04A; FST305M02A; FST305M04A; FST305M05; FST305M06A;
FST305M08A; FST305M10; FST305M12A; FST305M20A; FST306L02; FST306L04; FST306L04BL;
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FST306X02; FST307I04A; FST307L04A; FST307M04A; FST307M06A; FST307M08A; FST307M12A;
FST307M20A; FST308L04; FST308M06; FST308M08; FST308M20; FSZ206A02G; FSZ206A03G;
FSZ206A04G; FSZ206A05G; FSZ206B02G; FSZ206B03G; FSZ206B04G; FSZ206B05G; FSZ206C02G;
FSZ206C03G; FSZ206C04G; FSZ206C05G; FXP204L05; FXP206L05; FXP206M04; FXP208L05;
FXP304M04A; FXP304M05A; FXP305M04A; FXP305M05A; FXP306M04; FXP307M04A; FXP307M05A;
FYP204M05; FYP206L06; FYP206L07; FYP206L08; FYP206M05; FYP207M07; FYP208M05; FYP304M05A;
FYP305M05A; FYP306L08; FYP307M05A; FZM102A01; FZM103A01; FZM104A01; FZP306L02A;
FZP308A05G; MAC315M06; MAC315M08; MAC315S04; MAC315S06; MAC320M04; MAC320M08;
MAC320S04; MAC320S06; MAL315M06; MAP213L04; MAP213R04; MCA315M06; MCC315L06;
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MRR326M26; MRR328M15; MRR328M16; MRR328M20; MSC315M04; MSC315M05; MSC315M06;

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- TORNILLOS -

D21606; D21608; D21610; D21612; D21806; D21808; D21810; D21812; D22006; D22006B; D22007B; D22008; D22008B; D22009B; D22010; D22010B; D22011B; D22012; D22012B; D31606; D31608; D31610; D31612; D31806; D31808; D31810; D31812; D32006; D32008; D32010; D32012; D42006B; D42007B; D42008B; D42009B; D42010B; D42011B; D42012B; F13003; F13004; F13005; F13006; F13008; F13010; F13012; F13A03; F13A04; F13A05; F13A06; F13A08; F13A10; F15003; F15004; F15005; F15006; F15008; F15010; F15012; F15014; F15A03; F15A04; F15A05; F15A06; F15A08; F15A10; F15A12; F15A14; F16A06M; F18003; F18004; F18005; F18006; F18008; F18010; G08T35; G08T45; G08T55; M20L04; M20L06; M20L08; M20L10; M20L12; M20L14; M20L16; M20L18; M20L20; M24004; M24006; M24008; M24010; M24012; M24014; M24016; M24018; M24020; M24120; M24L04; M24L06; M24L08; M24L10; M24L12; M24L14; M24L16; M24L18; M24L20; M27006; M27008; M27010; M27012; M27014; M27016; M27018; M27L09M; M27L11M; MAC315M04; O19003; O19004; O19005; O19006; O19008; O19010; O19012; O19014; O19016; O19018; O19020; O19A03; O19A04; O19A05; O19A06; O19A08; O19A10; O19A12; O20007M; O20A07M; O23004; O23005; O23006; O23008; O23010; O23012; O23014; O23016.

Instrumental asociado.

Clase de Riesgo: III

Indicación/es autorizada/s:

Cierre y/o fijación ósea en neurocirugía, reparación de defectos craneales, trauma cráneo-maxilofacial, reconstrucción mandibular, reparación de defectos óseos buco-maxilofaciales y/o mandibulares y en cirugías ortognática, craneofacial y 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: Implantes: Envase por 1, 2, 5, 6, 10, 20, 25, 50, 75, 100 unidades. No estéril.

Instrumental: Envase por 1, 5, 10, 20, 25, 50, 75, 100 unidades. No estéril.

Método de esterilización: N/A

Nombre del fabricante:

OSTEONIC Co., Ltd.

Lugar de elaboración:

505-2Ho, 505-3Ho, 1004Ho, 1005Ho, 1201Ho, 1202Ho, 38 Digital-ro 29-gil, Guro-gu Seoul, Republica de Corea; 102Ho, 103Ho, 24, Digital-ro 27-gil, Guro-gu, Seul, Corea.

Se extiende el presente Certificado de Autorización e Inscripción del PM 2410-12 , con una vigencia cinco (5) años a partir de la fecha de la Disposición autorizante.

1-0047-3110-003454-25-1

Nº Identificadorio Trámite: 68011

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