



República Argentina - Poder Ejecutivo Nacional

Año de la Grandeza Argentina

Certificado - Redacción libre

Número:

Referencia: 1-0047-3110-005712-25-5

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

Expediente N° 1-0047-3110-005712-25-5

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por IMPLANTES FICO ALEMANA SA. ; 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: 14-87

Nombre descriptivo: PROTESIS PARA REEMPLAZO DE RODILLA (CON INSTRUMENTAL)

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
16-096 PROTESIS DE ARTICULACION PARA RODILLA

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

Modelos:

BIDEGAIN

CODIGO DESCRIPCIÓN

03ROBGNFEM1155 BIDEGAIN - Femoral STD N1 Izq 55x48 - CrCo

03ROBGNFEM2158 BIDEGAIN - Femoral STD N2 Izq 58x50.5 - CrCo

03ROBGNFEM3161 BIDEGAIN - Femoral STD N3 Izq 61x53 - CrCo

03ROBGNFEM4164 BIDEGAIN - Femoral STD N4 Izq 64x55.5 - CrCo

03ROBGNFEM5167 BIDEGAIN - Femoral STD N5 Izq 67x58.5 - CrCo

03ROBGNFEM6170 BIDE GAIN - Femoral STD N6 Izq 70x61.5 - CrCo
03ROBGNFEM7173 BIDE GAIN - Femoral STD N7 Izq 73x65 - CrCo
03ROBGNFEM8176 BIDE GAIN - Femoral STD N8 Izq 76x68 - CrCo
03ROBGNFEM9179 BIDE GAIN - Femoral STD N9 Izq 79x71 - CrCo
03ROBGNFEM1D55 BIDE GAIN - Femoral STD N1 Der 55x48 - CrCo
03ROBGNFEM2D58 BIDE GAIN - Femoral STD N2 Der 58x50.5 - CrCo
03ROBGNFEM3D61 BIDE GAIN - Femoral STD N3 Der 61x53 - CrCo
03ROBGNFEM4D64 BIDE GAIN - Femoral STD N4 Der 64x55.5 - CrCo
03ROBGNFEM5D67 BIDE GAIN - Femoral STD N5 Der 67x58.5 - CrCo
03ROBGNFEM6D70 BIDE GAIN - Femoral STD N6 Der 70x61.5 - CrCo
03ROBGNFEM7D73 BIDE GAIN - Femoral STD N7 Der 73x65 - CrCo
03ROBGNFEM8D76 BIDE GAIN - Femoral STD N8 Der 76x68 - CrCo
03ROBGNFEM9D79 BIDE GAIN - Femoral STD N9 Der 79x71 - CrCo
03ROBGNINT5810 BIDE GAIN - Inseto Tibial N1 58x37 10mm - UHMWPE
03ROBGNINT5811 BIDE GAIN - Inseto Tibial N1 58x37 11mm - UHMWPE
03ROBGNINT5812 BIDE GAIN - Inseto Tibial N1 58x37 12mm - UHMWPE
03ROBGNINT5813 BIDE GAIN - Inseto Tibial N1 58x37 13mm - UHMWPE
03ROBGNINT5814 BIDE GAIN - Inseto Tibial N1 58x37 14mm - UHMWPE
03ROBGNINT5816 BIDE GAIN - Inseto Tibial N1 58x37 16mm - UHMWPE
03ROBGNINT5818 BIDE GAIN - Inseto Tibial N1 58x37 18mm - UHMWPE
03ROBGNINT6010 BIDE GAIN - Inseto Tibial N2 60x38.5 10mm - UHMWPE
03ROBGNINT6011 BIDE GAIN - Inseto Tibial N2 60x38.5 11mm - UHMWPE
03ROBGNINT6012 BIDE GAIN - Inseto Tibial N2 60x38.5 12mm - UHMWPE
03ROBGNINT6013 BIDE GAIN - Inseto Tibial N2 60x38.5 13mm - UHMWPE
03ROBGNINT6014 BIDE GAIN - Inseto Tibial N2 60x38.5 14mm - UHMWPE
03ROBGNINT6016 BIDE GAIN - Inseto Tibial N2 60x38.5 16mm - UHMWPE
03ROBGNINT6018 BIDE GAIN - Inseto Tibial N2 60x38.5 18mm - UHMWPE
03ROBGNINT6310 BIDE GAIN - Inseto Tibial N3 63x40.5 10mm - UHMWPE
03ROBGNINT6311 BIDE GAIN - Inseto Tibial N3 63x40.5 11mm - UHMWPE
03ROBGNINT6312 BIDE GAIN - Inseto Tibial N3 63x40.5 12mm - UHMWPE
03ROBGNINT6313 BIDE GAIN - Inseto Tibial N3 63x40.5 13mm - UHMWPE
03ROBGNINT6314 BIDE GAIN - Inseto Tibial N3 63x40.5 14mm - UHMWPE
03ROBGNINT6316 BIDE GAIN - Inseto Tibial N3 63x40.5 16mm - UHMWPE
03ROBGNINT6318 BIDE GAIN - Inseto Tibial N3 63x40.5 18mm - UHMWPE
03ROBGNINT6510 BIDE GAIN - Inseto Tibial N4 65x41.5 10mm - UHMWPE
03ROBGNINT6511 BIDE GAIN - Inseto Tibial N4 65x41.5 11mm - UHMWPE
03ROBGNINT6512 BIDE GAIN - Inseto Tibial N4 65x41.5 12mm - UHMWPE
03ROBGNINT6513 BIDE GAIN - Inseto Tibial N4 65x41.5 13mm - UHMWPE
03ROBGNINT6514 BIDE GAIN - Inseto Tibial N4 65x41.5 14mm - UHMWPE
03ROBGNINT6516 BIDE GAIN - Inseto Tibial N4 65x41.5 16mm - UHMWPE
03ROBGNINT6518 BIDE GAIN - Inseto Tibial N4 65x41.5 18mm - UHMWPE
03ROBGNINT6910 BIDE GAIN - Inseto Tibial N5 69x43.5 10mm - UHMWPE
03ROBGNINT6911 BIDE GAIN - Inseto Tibial N5 69x43.5 11mm - UHMWPE
03ROBGNINT6912 BIDE GAIN - Inseto Tibial N5 69x43.5 12mm - UHMWPE
03ROBGNINT6913 BIDE GAIN - Inseto Tibial N5 69x43.5 13mm - UHMWPE
03ROBGNINT6914 BIDE GAIN - Inseto Tibial N5 69x43.5 14mm - UHMWPE
03ROBGNINT6916 BIDE GAIN - Inseto Tibial N5 69x43.5 16mm - UHMWPE
03ROBGNINT6918 BIDE GAIN - Inseto Tibial N5 69x43.5 18mm - UHMWPE
03ROBGNINT7210 BIDE GAIN - Inseto Tibial N6 72x46 10mm - UHMWPE
03ROBGNINT7211 BIDE GAIN - Inseto Tibial N6 72x46 11mm - UHMWPE
03ROBGNINT7212 BIDE GAIN - Inseto Tibial N6 72x46 12mm - UHMWPE
03ROBGNINT7213 BIDE GAIN - Inseto Tibial N6 72x46 13mm - UHMWPE
03ROBGNINT7214 BIDE GAIN - Inseto Tibial N6 72x46 14mm - UHMWPE
03ROBGNINT7216 BIDE GAIN - Inseto Tibial N6 72x46 16mm - UHMWPE
03ROBGNINT7218 BIDE GAIN - Inseto Tibial N6 72x46 18mm - UHMWPE
03ROBGNINT7510 BIDE GAIN - Inseto Tibial N7 75x47.5 10mm - UHMWPE
03ROBGNINT7511 BIDE GAIN - Inseto Tibial N7 75x47.5 11mm - UHMWPE
03ROBGNINT7512 BIDE GAIN - Inseto Tibial N7 75x47.5 12mm - UHMWPE
03ROBGNINT7513 BIDE GAIN - Inseto Tibial N7 75x47.5 13mm - UHMWPE
03ROBGNINT7514 BIDE GAIN - Inseto Tibial N7 75x47.5 14mm - UHMWPE
03ROBGNINT7516 BIDE GAIN - Inseto Tibial N7 75x47.5 16mm - UHMWPE
03ROBGNINT7518 BIDE GAIN - Inseto Tibial N7 75x47.5 18mm - UHMWPE

03ROBGNINT7810 BIDE GAIN - Inserto Tibial N8 78x49 10mm - UHMWPE
03ROBGNINT7811 BIDE GAIN - Inserto Tibial N8 78x49 11mm - UHMWPE
03ROBGNINT7812 BIDE GAIN - Inserto Tibial N8 78x49 12mm - UHMWPE
03ROBGNINT7813 BIDE GAIN - Inserto Tibial N8 78x49 13mm - UHMWPE
03ROBGNINT7814 BIDE GAIN - Inserto Tibial N8 78x49 14mm - UHMWPE
03ROBGNINT7816 BIDE GAIN - Inserto Tibial N8 78x49 16mm - UHMWPE
03ROBGNINT7818 BIDE GAIN - Inserto Tibial N8 78x49 18mm - UHMWPE
03ROBGNINT8110 BIDE GAIN - Inserto Tibial N9 81x51.5 10mm - UHMWPE
03ROBGNINT8111 BIDE GAIN - Inserto Tibial N9 81x51.5 11mm - UHMWPE
03ROBGNINT8112 BIDE GAIN - Inserto Tibial N9 81x51.5 12mm - UHMWPE
03ROBGNINT8113 BIDE GAIN - Inserto Tibial N9 81x51.5 13mm - UHMWPE
03ROBGNINT8114 BIDE GAIN - Inserto Tibial N9 81x51.5 14mm - UHMWPE
03ROBGNINT8116 BIDE GAIN - Inserto Tibial N9 81x51.5 16mm - UHMWPE
03ROBGNINT8118 BIDE GAIN - Inserto Tibial N9 81x51.5 18mm - UHMWPE
03ROBGNITIB1L60 BIDE GAIN - Bandeja Tibial N1 Izq 60x40.5 - Ti
03ROBGNITIB2L63 BIDE GAIN - Bandeja Tibial N2 Izq 63x42 - Ti
03ROBGNITIB3L66 BIDE GAIN - Bandeja Tibial N3 Izq 66x43.5 - Ti
03ROBGNITIB4L69 BIDE GAIN - Bandeja Tibial N4 Izq 69x45 - Ti
03ROBGNITIB5L72 BIDE GAIN - Bandeja Tibial N5 Izq 72x47 - Ti
03ROBGNITIB6L75 BIDE GAIN - Bandeja Tibial N6 Izq 75x49 - Ti
03ROBGNITIB7L78 BIDE GAIN - Bandeja Tibial N7 Izq 78x51 - Ti
03ROBGNITIB8L81 BIDE GAIN - Bandeja Tibial N8 Izq 81x54 - Ti
03ROBGNITIB9L84 BIDE GAIN - Bandeja Tibial N9 Izq 84x57 - Ti
03ROBGNITIB1R60 BIDE GAIN - Bandeja Tibial N1 Der 60x40.5 - Ti
03ROBGNITIB2R63 BIDE GAIN - Bandeja Tibial N2 Der 63x42 - Ti
03ROBGNITIB3R66 BIDE GAIN - Bandeja Tibial N3 Der 66x43.5 - Ti
03ROBGNITIB4R69 BIDE GAIN - Bandeja Tibial N4 Der 69x45 - Ti
03ROBGNITIB5R72 BIDE GAIN - Bandeja Tibial N5 Der 72x47 - Ti
03ROBGNITIB6R75 BIDE GAIN - Bandeja Tibial N6 Der 75x49 - Ti
03ROBGNITIB7R78 BIDE GAIN - Bandeja Tibial N7 Der 78x51 - Ti
03ROBGNITIB8R81 BIDE GAIN - Bandeja Tibial N8 Der 81x54 - Ti
03ROBGNITIB9R84 BIDE GAIN - Bandeja Tibial N9 Der 84x57 - Ti
03ROBGNPAE2808 BIDE GAIN - Patella Excentrica Ø28x8 - UHMWPE
03ROBGNPAE3008 BIDE GAIN - Patella Excentrica Ø30x8 - UHMWPE
03ROBGNPAE3308 BIDE GAIN - Patella Excentrica Ø33x8 - UHMWPE
03ROBGNPAE3608 BIDE GAIN - Patella Excentrica Ø36x8 - UHMWPE
03ROBGNPAE2810 BIDE GAIN - Patella Excentrica Ø28x10 - UHMWPE
03ROBGNPAE3010 BIDE GAIN - Patella Excentrica Ø30x10 - UHMWPE
03ROBGNPAE3310 BIDE GAIN - Patella Excentrica Ø33x10 - UHMWPE
03ROBGNPAE3610 BIDE GAIN - Patella Excentrica Ø36x10 - UHMWPE
03ROBGNPAE2812 BIDE GAIN - Patella Excentrica Ø28x12 - UHMWPE
03ROBGNPAE3012 BIDE GAIN - Patella Excentrica Ø30x12 - UHMWPE
03ROBGNPAE3312 BIDE GAIN - Patella Excentrica Ø33x12 - UHMWPE
03ROBGNPAE3612 BIDE GAIN - Patella Excentrica Ø36x12 - UHMWPE
03ROBGNPAC2808 BIDE GAIN - Patella Concentrica Ø28x8 - UHMWPE
03ROBGNPAC3008 BIDE GAIN - Patella Concentrica Ø30x8 - UHMWPE
03ROBGNPAC3308 BIDE GAIN - Patella Concentrica Ø33x8 - UHMWPE
03ROBGNPAC3608 BIDE GAIN - Patella Concentrica Ø36x8 - UHMWPE
03ROBGNBDI1627 BIDE GAIN - Bloque Distal A Ø16x27.5 - Ti
03ROBGNBDI1630 BIDE GAIN - Bloque Distal B Ø16x30.5 - Ti
03ROBGNBDI1633 BIDE GAIN - Bloque Distal C Ø16x33.5 - Ti
03ROBGNTOR0517 BIDE GAIN - Tornillo M5x17.5 - Ti
INTRUMENTAL ASOCIADO

Clase de Riesgo: IV

Indicación/es autorizada/s:

- Dolor severo y discapacidad debido a artritis reumatoidea
- Osteoartritis
- Artrosis traumática primaria y secundaria
- Desordenes de colágeno
- Necrosis vascular del cóndilo femoral

- Varo, valgo o deformaciones en flexión
- Pérdida post-traumática de la configuración de la articulación

Período de vida útil: 5 AÑOS

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

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

Forma de presentación: POR UNIDAD

Método de esterilización: Por Radiación Gamma u Óxido de Etileno.

Nombre del fabricante:
IMPLANTES FICO ALEMANA SA

Lugar de elaboración:
STEPHENSON 3048 TORTUGUITAS BUENOS AIRES ARGENTINA

Se extiende el presente Certificado de Autorización e Inscripción del PM 14-87 , con una vigencia cinco (5) años a partir de la fecha de la Disposición autorizante.

1-0047-3110-005712-25-5

Nº Identificador Trámite: 70276

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