



República Argentina - Poder Ejecutivo Nacional
Año de la Grandeza Argentina

Certificado - Redacción libre

Número:

Referencia: 1-0047-3110-005106-25-2

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

Nº 1-0047-3110-005106-25-2

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por GSJ 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: 1975-40

Nombre descriptivo: ANILLO CORNEAL INTRAESTROMAL

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
18-103 - Anillos Intracorneales

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

Modelos:

SEGMENTO DE ANILLO CORNEAL INTRAESTROMAL KERARING

SI5

Keraring SI5-60° 100µSI5A60M100;
Keraring SI5-60° 150µSI5A60M150;
Keraring SI5-60° 200µSI5A60M200;
Keraring SI5-60° 250µSI5A60M250;
Keraring SI5-60° 300µSI5A60M300;
Keraring SI5-60° 350µSI5A60M350;
Keraring SI5-60° 400µSI5A60M400;
Keraring SI5-90° 100µSI5A90M100;
Keraring SI5-90° 150µSI5A90M150;
Keraring SI5-90° 200µSI5A90M200;
Keraring SI5-90° 250µSI5A90M250;
Keraring SI5-90° 300µSI5A90M300;
Keraring SI5-90° 350µSI5A90M350;
Keraring SI5-90° 400µSI5A90M400;
Keraring SI5-95° 100µSI5A95M100;
Keraring SI5-95° 150µSI5A95M150;
Keraring SI5-95° 200µSI5A95M200;
Keraring SI5-95° 250µSI5A95M250;
Keraring SI5-95° 300µSI5A95M300;
Keraring SI5-95° 350µSI5A95M350;
Keraring SI5-95° 400µSI5A95M400;
Keraring SI5-100° 100µSI5A100M100;
Keraring SI5-100° 150µSI5A100M150;
Keraring SI5-100° 200µSI5A100M200;
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Keraring SI5-100° 300µSI5A100M300;
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SI6

Keraring SI6-60° 100µSI6A60M100;
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Keraring SI6-325° 200μSI6A325M200;

Keraring SI6-325° 250µSI6A325M250;
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Keraring SI6-325° 350µSI6A325M350;
Keraring SI6-325° 400µSI6A325M400;
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Keraring SI6-355° 250µSI6A355M250;
Keraring SI6-355° 300µSI6A355M300;
Keraring SI6-355° 350µSI6A355M350;
Keraring SI6-355° 400µSI6A355M400;

AS5

Keraring AS5-120° 100/200C: AS5120M10-20C;
Keraring AS5-120° 100/250C: AS5120M10-25C;
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Keraring AS5-120° 150/250C: AS5120M15-25C;
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Keraring AS5-120° 200/250C: AS5120M20-25C;
Keraring AS5-120° 200/300C: AS5120M20-30C;
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Keraring AS5-120° 250/300C: AS5120M25-30C;
Keraring AS5-120° 250/350C: AS5120M25-35C;
Keraring AS5-120° 250/400C: AS5120M25-40C;
Keraring AS5-120° 300/350C: AS5120M30-35C;
Keraring AS5-140° 100/200C: AS5140M10-20C;
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Keraring AS5-140° 150/250C: AS5140M15-25C;
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Keraring AS5-160° 150/250C: AS5160M15-25C;
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Keraring AS5-140° 250/350W: AS5140M25-35W;
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Keraring AS5-320° 150/300/150: AS5320M153015;
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Keraring AS5-325° 100/250/100: AS5325M102510;
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Keraring AS5-325° 250/400/250: AS5325M254025;
Keraring AS5-330° 100/200/100: AS5330M102010;
Keraring AS5-330° 100/250/100: AS5330M102510;
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Keraring AS5-330° 200/350/200: AS5330M203520;
Keraring AS5-330° 250/350/250: AS5330M253525;
Keraring AS5-330° 250/400/250: AS5330M254025;

AS6

Keraring AS6-120° 100/200C: AS6120M10-20C;
Keraring AS6-120° 100/250C: AS6120M10-25C;
Keraring AS6-120° 150/200C: AS6120M15-20C;
Keraring AS6-120° 150/250C: AS6120M15-25C;
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Keraring SG-330° 42D 240µSGA330D42M240;
Keraring SG-330° 42D 270µSGA330D42M270;
Keraring SG-330° 42D 300µSGA330D42M300;
Keraring SG-330° 42D 330µSGA330D42M330;
Keraring SG-330° 42D 360µSGA330D42M360;
Keraring SG-330° 42D 390µSGA330D42M390;
Keraring SG-330° 44D 150µSGA330D44M150;
Keraring SG-330° 44D 180µSGA330D44M180;
Keraring SG-330° 44D 210µSGA330D44M210;
Keraring SG-330° 44D 240µSGA330D44M240;
Keraring SG-330° 44D 270µSGA330D44M270;
Keraring SG-330° 44D 300µSGA330D44M300;
Keraring SG-330° 44D 330µSGA330D44M330;
Keraring SG-330° 44D 360µSGA330D44M360;
Keraring SG-330° 44D 390µSGA330D44M390;
Keraring SG-330° 46D 150µSGA330D46M150;
Keraring SG-330° 46D 180µSGA330D46M180;
Keraring SG-330° 46D 210µSGA330D46M210;
Keraring SG-330° 46D 240µSGA330D46M240;
Keraring SG-330° 46D 270µSGA330D46M270;
Keraring SG-330° 46D 300µSGA330D46M300;
Keraring SG-330° 46D 330µSGA330D46M330;
Keraring SG-330° 46D 360µSGA330D46M360;
Keraring SG-330° 46D 390µSGA330D46M390;
Keraring SG-330° 48D 150µSGA330D48M150;
Keraring SG-330° 48D 180µSGA330D48M180;
Keraring SG-330° 48D 210µSGA330D48M210;
Keraring SG-330° 48D 240µSGA330D48M240;
Keraring SG-330° 48D 270µSGA330D48M270;
Keraring SG-330° 48D 300µSGA330D48M300;
Keraring SG-330° 48D 330µSGA330D48M330;
Keraring SG-330° 48D 360µSGA330D48M360;
Keraring SG-330° 48D 390µSGA330D48M390

Clase de Riesgo: III

Indicación/es autorizada/s:

La implantación del dispositivo está indicada en los siguientes casos:

- Queratocono en pacientes con intolerancia a las lentes de contacto;
- Astigmatismo irregular tras una queratoplastia penetrante;
- Ectasia corneal tras una cirugía Lasik;
- Degeneración marginal pelúcida.

Puede ser implantado en niños (mayores de 8 años), adultos, hombres y mujeres.

La indicación correcta para la implantación de Keraring requiere una evaluación exhaustiva de las condiciones topográficas y paquimétricas de la córnea, además de un examen oftalmológico completo.

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/A

Forma de presentación: Por Unidad

Método de esterilización: Óxido de Etileno

Nombre del fabricante:

MEDIPHACOS INDÚSTRIAS MÉDICAS S/A.

Lugar de elaboración:

AV. DEPUTADO CRISTOVAM CHIARADIA N° 777 – BURITIS – BELO HORIZONTE-MG – CEP: 30575-815- BRASIL.

Se extiende el presente Certificado de Autorización e Inscripción del PM 1975-40 , con una vigencia cinco (5) años a partir de la fecha de la Disposición autorizante.

1-0047-3110-005106-25-2

N° Identificador Trámite: 69659

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