



República Argentina - Poder Ejecutivo Nacional
Año de la Grandeza Argentina

Certificado - Redacción libre

Número:

Referencia: 1-0047-3110-001285-26-7

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

Expediente N° 1-0047-3110-001285-26-7

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por ANGIOCOR 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: 416-189

Nombre descriptivo: Sistema de Vaina Introdutora

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

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

Modelos:

4F Straight-15 Introducer Sheath Regular (Ref: FG-04015)
4F Straight-45 Introducer Sheath Regular (Ref: FG-04045)
4F Straight-60 Introducer Sheath Regular (Ref: FG-04060)
4F Straight-90 Introducer Sheath Regular (Ref: FG-04090)

5F Straight-15 Introducer Sheath Regular (Ref: FG-05015)
5F Straight-45 Introducer Sheath Regular (Ref: FG-05045)
5F Straight-60 Introducer Sheath Regular (Ref: FG-05060)
5F Straight-90 Introducer Sheath Regular (Ref: FG-05090)

6F Straight-15 Introducer Sheath Regular (Ref: FG-06015)
6F Straight-45 Introducer Sheath Regular (Ref: FG-06045)
6F Straight-60 Introducer Sheath Regular (Ref: FG-06060)
6F Straight-90 Introducer Sheath Regular (Ref: FG-06090)

7F Straight-15 Introducer Sheath Regular (Ref: FG-07015)
7F Straight-45 Introducer Sheath Regular (Ref: FG-07045)
7F Straight-60 Introducer Sheath Regular (Ref: FG-07060)
7F Straight-90 Introducer Sheath Regular (Ref: FG-07090)

8F Straight-15 Introducer Sheath Regular (Ref: FG-08015)
8F Straight-45 Introducer Sheath Regular (Ref: FG-08045)
8F Straight-60 Introducer Sheath Regular (Ref: FG-08060)
8F Straight-90 Introducer Sheath Regular (Ref: FG-08090)

4F Straight-45 Introducer Sheath Firm (Ref: FG-04045-F)
4F Straight-60 Introducer Sheath Firm (Ref: FG-04060-F)
4F Straight-90 Introducer Sheath Firm (Ref: FG-04090-F)
4F Straight-130 Introducer Sheath Firm (Ref: FG-04130-F)

5F Straight-45 Introducer Sheath Firm (Ref: FG-05045-F)
5F Straight-60 Introducer Sheath Firm (Ref: FG-05060-F)
5F Straight-90 Introducer Sheath Firm (Ref: FG-05090-F)
5F Straight-130 Introducer Sheath Firm (Ref: FG-05130-F)

6F Straight-15 Introducer Sheath Firm (Ref: FG-06015-F)
6F Straight-45 Introducer Sheath Firm (Ref: FG-06045-F)
6F Straight-60 Introducer Sheath Firm (Ref: FG-06060-F)
6F Straight-90 Introducer Sheath Firm (Ref: FG-06090-F)
6F Straight-130 Introducer Sheath Firm (Ref: FG-06130-F)

7F Straight-45 Introducer Sheath Firm (Ref: FG-07045-F)
7F Straight-60 Introducer Sheath Firm (Ref: FG-07060-F)
7F Straight-90 Introducer Sheath Firm (Ref: FG-07090-F)

8F Straight-15 Introducer Sheath Firm (Ref: FG-08015-F)
8F Straight-45 Introducer Sheath Firm (Ref: FG-08045-F)
8F Straight-60 Introducer Sheath Firm (Ref: FG-08060-F)
8F Straight-90 Introducer Sheath Firm (Ref: FG-08090-F)

5F Shaped-45cm Introducer Sheath LIMA (Ref: FG-05045-F-LIMA)
5F Shaped-45cm Introducer Sheath Hockey Stick (Ref: FG-05045-F-HS)
5F Shaped-45cm Introducer Sheath Multipurpose (Ref: FG-05045-F-MP)
5F Shaped-45cm Introducer Sheath Renal Double Curve (Ref: FG-05045-F-RDC)

5F Shaped-60cm Introducer Sheath LIMA (Ref: FG-05060-F-LIMA)
5F Shaped-60cm Introducer Sheath Hockey Stick (Ref: FG-05060-F-HS)
5F Shaped-60cm Introducer Sheath Multipurpose (Ref: FG-05060-F-MP)
5F Shaped-60cm Introducer Sheath Renal Double Curve (Ref: FG-05060-F-RDC)

5F Shaped-90cm Introducer Sheath LIMA (Ref: FG-05090-F-LIMA)
5F Shaped-90cm Introducer Sheath Hockey Stick (Ref: FG-05090-F-HS)
5F Shaped-90cm Introducer Sheath Multipurpose (Ref: FG-05090-F-MP)
5F Shaped-90cm Introducer Sheath Renal Double Curve (Ref: FG-05090-F-RDC)

6F Shaped-45cm Introducer Sheath LIMA (Ref: FG-06045-F-LIMA)
6F Shaped-45cm Introducer Sheath Hockey Stick (Ref: FG-06045-F-HS)
6F Shaped-45cm Introducer Sheath Multipurpose (Ref: FG-06045-F-MP)
6F Shaped-45cm Introducer Sheath Renal Double Curve (Ref: FG-06045-F-RDC)

6F Shaped-60cm Introducer Sheath LIMA (Ref: FG-06060-F-LIMA)
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7F Shaped-90cm Introducer Sheath Renal Double Curve (Ref: FG-07090-F-RDC)

Clase de Riesgo: IV

Indicación/es autorizada/s:

El sistema de vaina introductora está indicado para su uso en la introducción de dispositivos de diagnóstico e intervención en la vasculatura humana, incluyendo, por ejemplo, el acceso femoral.

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: No corresponde.

Forma de presentación: Por unidad en pouch individual.
Caja por 5 unidades.

Método de esterilización: Óxido de etileno.

Nombre del fabricante:

Contract Medical International GmbH

Lugar de elaboración:

Lauensteiner Straße 37

01277 Dresden

Alemania

Se extiende el presente Certificado de Autorización e Inscripción del PM 416-189 , con una vigencia cinco (5) años a partir de la fecha de la Disposición autorizante.

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Nº Identificador Trámite: 75850

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