



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

CERTIFICADO DE AUTORIZACIÓN DE MODIFICACIÓN**N° rev: 136-155#0004**

El Instituto Nacional de Productos Médicos de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por Corpomedica SA , se autoriza la modificación en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM), del PM 136-155 aprobado según:

Disposición autorizante N° 6428/15 de fecha 10 agosto 2015

Disposiciones modificatorias y reválidas N°: N° rev #0001; N° rev #0002

Del siguiente/s dato/s característico/s:

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACION/RECTIFICACION AUTORIZADA
Modelos	Stents Pilóricos No Cubiertos NitiS. OTW No Cubiertos: [Tipo-Cabezal]: P1806, P1808, P1810, P1812, P1814, P1815, P1816, P2006, P2008, P2010, P2012, P2014, P2015, P2016, P2206, P2208, P2210, P2212, P2214, P2215, P2216, P2406, P2408, P2410, P2412, P2414, P2415, P2416, P2606, P2608, P2610, P2612, P2614, P2615, P2616, P2806, P2808, P2810, P2812, P2814, P2815, P2816. [Tipo-D]: PD1806, PD1808, PD1810, PD1812, PD1814, PD1815, PD2006, PD2008, PD2010, PD2012, PD2014,	Stents Pilóricos No Cubiertos NitiS. OTW No Cubiertos: [Tipo-D]: PD1806, PD1808, PD1810, PD1812, PD1814, PD1815, PD2006, PD2008, PD2010, PD2012, PD2014, PD2015, PD2206, PD2208, PD2210, PD2212, PD2214, PD2215, PD2406, PD2408, PD2410, PD2412, PD2414, PD2415, PD2606, PD2608, PD2610, PD2612, PD2614, PD2615, PD2806, PD2808, PD2810, PD2812, PD2814, PD2815. TTS No Cubiertos: [Tipo-Cabezal]: PT1806, PT1808, PT1810, PT1812, PT2006,

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Quedando el producto inscripto con los siguientes datos característicos:

Nombre descriptivo: Stent pilórico/ duodenal.

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
17-748- Endoprótesis (Stents)

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

Clase de Riesgo: III

Indicación/es autorizada/s: El stent pilórico/duodenal Niti-S y el ComVi tienen como función mantener la apertura luminal pilórica/duodenal en estrechamientos causados por enfermedades malignas intrínsecas y/o extrínsecas o bien en estrechamientos benignos.

Modelos: Stents Pilóricos No Cubiertos NitiS. OTW No Cubiertos:

[Tipo-D]: PD1806, PD1808,
PD1810, PD1812, PD1814,
PD1815, PD2006, PD2008,
PD2010, PD2012, PD2014, PD2015, PD2206, PD2208,
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PD2215, PD2406, PD2408,
PD2410, PD2412, PD2414,
PD2415, PD2606, PD2608,
PD2610, PD2612, PD2614,
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PD2810, PD2812, PD2814,
PD2815.

TTS No Cubiertos:

[Tipo-Cabecal]: PT1806, PT1808,
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PT2008, PT2010, PT2012.

[Tipo-D]: PDT1806, PDT1808,
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Stents Pilóricos Cubiertos Niti-S.

OTW Cubiertos:

[Tipo-Cabezal; Totalmente

Cubiertos]: PS1806F, PS1808F, PS1810F, PS1812F, PS1814F,
PS1815F, PS1816F, PS2006F,
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PS2014F, PS2015F, PS2016F,
PS2206F, PS2208F, PS2210F,
PS2212F, PS2214F, PS2215F,
PS2216F, PS2406F, PS2408F,
PS2410F, PS2412F, PS2414F,
PS2415F, PS2416F, PS2606F,
PS2608F, PS2610F,
PS2612F, PS2614F, PS2615F,
PS2616F, PS2806F, PS2808F,
PS2810F, PS2812F, PS2814F,
PS2815F, PS2816F.

[Tipo-Cabezal; Extremo No Cubierto]: PS1806H, PS1808H, PS1810H, PS1812H, PS1814H, PS1815H, PS1816H, PS2006H, PS2008H, PS2010H, PS2012H, PS2014H, PS2015H, PS2016H, PS2206H, PS2208H, PS2210H, PS2212H, PS2214H, PS2215H, PS2216H, PS2406H, PS2408H, PS2410H, PS2412H, PS2414H, PS2415H, PS2416H, PS2606H, PS2608H, PS2610H, PS2612H, PS2614H, PS2615H, PS2616H, PS2806H, PS2808H, PS2810H, PS2812H, PS2814H, PS2815H, PS2816H.

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PST2010F-22, PST2012F-22,
PST2014F-22, PST2015F-22,
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PST2210F 22, PST2212F 22,
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[Tipo-Cabecal, Extremo No
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Cubierto]: PST1806B, PST1808B,

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[Tipo-ComVi: Ambos No
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TTS Cubiertos:

[Tipo-ComVi; Ambos No
Cubiertos]: PCT1806B,
PCT1808B, PCT1810B,
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PCT2008B-22, PCT2010B-22,
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[Tipo-ComVi: Ambos No
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[TTS, Tipo acampanado]

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PCT2606P-22, PCT2608P-22,
PCT2610P-22, PCT2612P-22.

Período de vida útil: 3 años a partir de su fecha de fabricación

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biotecnológico: N/A

Forma de presentación: Por unidad, estéril

Método de esterilización: óxido de etileno

Nombre del fabricante: TaeWoong Medical Co. Ltd.

Lugar de elaboración: 14 Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-Do, 10022, República de Corea

AUTORIZADO

Habiéndose cumplimentado con lo previsto en la Disposición ANMAT N° 64/25 y 9688/19, esta Administración autoriza las modificaciones solicitadas en Argentina, Ciudad de Buenos Aires, 25 septiembre 2026.



Dirección Evaluación y Registro de Productos Médicos
Firma y Sello

Firmado digitalmente por: TERRIZZANO Maria Lorena
Fecha y hora: 30.09.2026 11:23:53

Instituto Nacional de Productos Médicos
ANMAT
Firma y Sello

El presente certificado será válido únicamente cuando se presente junto con las Disposiciones previas del PM enunciadas anteriormente y sea verificado con su código QR a través de la página de ANMAT. Este certificado no modifica el período de vigencia.

Fecha de emisión: 25 septiembre 2026



La validez del presente documento deberá verificarse mediante el código QR.
RUGGIERO Florencia Elena
CUIL 27251883691

N° Identificador Trámite: 80582

