



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

CERTIFICADO DE AUTORIZACIÓN DE MODIFICACIÓN

N° rev: 136-153#0003

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 136-153 aprobado según:

Disposición autorizante N° 8865/15 de fecha 26 octubre 2015

Disposiciones modificatorias y reválidas N°: Modificación: CRT N° 136-153#0001

Reválida: DJ N° 136-153#0002

Del siguiente/s dato/s característico/s:

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACION/RECTIFICACION AUTORIZADA
Modelos	Niti-S y ComVi Stents Esofágicos No Cubiertos Niti-S. Liberador Distal No Cubierto. [Tipo-Cabezal]: E1006, E1008, E1010, E1012, E1014, E1015, E1206, E1208, E1210, E1212, E1214, E1215, E1406, E1408, E1410, E1412, E1414, E1415, E1606, E1608, E1610, E1612, E1614, E1615, E1806, E1808, E1810, E1812, E1814, E1815, E2006, E2008, E2010, E2012, E2014, E2015, E2206, E2208, E2210, E2212, E2214, E2215, E2406, E2408, E2410, E2412, E2414, E2415, E2806, E2808,	ES1006F, ES1008F, ES1010F, ES1012F, ES1014F, ES1015F, ES1206F, ES1208F, ES1210F, ES1212F, ES1214F, ES1215F, ES1406F, ES1408F, ES1410F, ES1412F, ES1414F, ES1415F, ES1606F, ES1608F, ES1610F, ES1612F, ES1614F, ES1615F, ES1806F, ES1808F, ES1810F, ES1812F, ES1814F, ES1815F, ES2006F, ES2008F, ES2010F, ES2012F, ES2014F, ES2015F, ES2206F, ES2208F, ES2210F, ES2212F, ES2214F, ES2215F, ES2218F, ES2223F, ES2406F, ES2408F, ES2410F, ES2412F, ES2414F, ES2415F, ES2418F, ES2423F, ES2806F, ES2808F, ES2810F, ES2812F, ES2814F, ES2815F, ES2818F, ES2823F. ES1006FR2, ES1008FR2, ES1010FR2,

E2810, E2812, E2814, E2815. Liberador Proximal No Cubierto. [Tipo-Cabezal]: EP1006, EP1008, EP1010, EP1012, EP1014, EP1015, EP1206, EP1208, EP1210, EP1212, EP1214, EP1215, EP1406, EP1408, EP1410, EP1412, EP1414, EP1415, EP1606, EP1608, EP1610, EP1612, EP1614, EP1615, EP1806, EP1808, EP1810, EP1812, EP1814, EP1815, EP2006, EP2008, EP2010, EP2012, EP2014, EP2015, EP2206, EP2208, EP2210, EP2212, EP2214, EP2215, EP2406, EP2408, EP2410, EP2412, EP2414, EP2415, EP2806, EP2808, EP2810, EP2812, EP2814, EP2815. Stents Esofágicos Cubiertos Niti-S. Liberador Distal Cubierto: [Tipo-Cabezal, Totalmente Cubiertos]: ES1006F, ES1008F, ES1010F, ES1012F, ES1014F, ES1015F, ES1206F, ES1208F, ES1210F, ES1212F, ES1214F, ES1215F, ES1406F, ES1408F, ES1410F, ES1412F, ES1414F, ES1415F, ES1606F, ES1608F, ES1610F, ES1612F, ES1614F, ES1615F, ES1806F, ES1808F, ES1810F, ES1812F, ES1814F, ES1815F, ES2006F, ES2008F, ES2010F, ES2012F, ES2014F, ES2015F, ES2206F, ES2208F, ES2210F, ES2212F, ES2214F, ES2215F, ES2218F, ES2223F, ES2406F, ES2408F, ES2410F, ES2412F, ES2414F, ES2415F, ES2418F, ES2423F, ES2806F, ES2808F, ES2810, ES2812F, ES2814F, ES2815F, ES2818F, ES2823F. [Tipo-Cabezal, Totalmente Cubiertos]: ES1006FR, ES1008FR, ES1010FR, ES1012FR, ES1014FR, ES1015FR, ES1206FR,	S1012FR2, ES1014FR2, ES1015FR2, ES1206FR2, S1208FR2, ES1210FR2, ES1212FR2, ES1214FR2, S1215FR2, ES1406FR2, ES1408FR2, ES1410FR2, S1412FR2, ES1414FR2, ES1415FR2, ES1606FR2, S1608FR2, ES1610FR2, ES1612FR2, ES1614FR2, S1615FR2, ES1806FR2, ES1808FR2, ES1810FR2, S1812FR2, ES1814FR2, ES1815FR2, ES2006FR2, S2008FR2, ES2010FR2, ES2012FR2, ES2014FR2, ES2015FR2, ES2206FR2, ES2208FR2, ES2210FR2, S2212FR2, ES2214FR2, ES2215FR2, ES2218FR2, S2223FR2, ES2406FR2, ES2408FR2, ES2410FR2, S2412FR2, ES2414FR2, ES2415FR2, ES2418FR2, S2423FR2, ES2806FR2, ES2808FR2, ES2810FR2, S2812FR2, ES2814FR2, ES2815FR2, ES2818FR2, S2823FR2. ES1006FV, ES1008FV, ES1010FV, ES1012FV, ES1014FV, ES1015FV, ES1206FV, ES1208FV, ES1210FV, ES1212FV, ES1214FV, ES1215FV, ES1406FV, ES1408FV, ES1410FV, ES1412FV, ES1414FV, ES1415FV, ES1606FV, ES1608FV, ES1610FV, ES1612FV, ES1614FV, ES1615FV, ES1806FV, ES1808FV, ES1810FV, ES1812FV, ES1814FV, ES1815FV, ES2006FV, ES2008FV, ES2010FV, ES2012FV, ES2014FV, ES2015FV, ES2206FV, ES2208FV, ES2210FV, ES2212FV, ES2214FV, ES2215FV, ES2406FV, ES2408FV, ES2410FV, ES2412FV, ES2414FV, ES2415FV, ES2806FV, ES2808FV, ES2810FV, ES2812FV, ES2814FV, ES2815FV. ES1006FVR2, ES1008FVR2, ES1010FVR2, ES1012FVR2, ES1014FVR2, ES1015FVR2, ES1206FVR2, ES1208FVR2, ES1210FVR2, ES1212FVR2, ES1214FVR2, ES1215FVR2, ES1406FVR2, ES1408FVR2, ES1410FVR2, ES1412FVR2, ES1414FVR2, ES1415FVR2,
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	[Tipo doble con un solo cabezal] EK1008FN, EK1010FN, EK1012FN, EK1208FN, EK1210FN, EK1212FN, EK1408FN, EK1410FN, EK1412FN, EK1608FN, EK1610FN, EK1612FN [Tipo de cubierta completa con introdutor de liberación distal / de cuerda] EK1806F, EK1808F, EK1810F, EK1812F, EK1814F, EK1815F, EK1818F, EK1820F, EK2006F, EK2008F, EK2010F, EK2012F, EK2014F, EK2015F, EK2018F, EK2020F, EK2206F, EK2208F, EK2210F, EK2212F, EK2214F, EK2215F, EK2218F, EK2406F, EK2408F, EK2410F, EK2412F, EK2414F, EK2415F, EK2806F, EK2808F, EK2810F, EK2812F, EK2814F, EK2815F [Tipo-Cabezal; Totalmente Cubiertos; Ambos Cordón para Remoción de Extremos]: ES1006FR2, ES1008FR2, ES1010FR2, ES1012FR2, ES1014FR2, ES1015FR2, ES1206FR2, ES1208FR2, ES1210FR2, ES1212FR2, ES1214FR2, ES1215FR2, ES1406FR2, ES1408FR2, ES1410FR2, ES1412FR2, ES1414FR2, ES1415FR2, ES1606FR2, ES1608FR2, ES1610FR2, ES1612FR2, ES1614FR2, ES1615FR2, ES1806FR2, ES1808FR2, ES1810FR2, ES1812FR2, ES1814FR2, ES1815FR2, ES2006FR2, ES2008FR2, ES2010FR2, ES2012FR2, ES2014FR2, ES2015FR2, ES2206FR2, ES2208FR2, ES2210FR2, ES2212FR2, ES2214FR2, ES2215FR2, ES2406FR2, ES2408FR2, ES2410FR2, ES2412FR2, ES2414FR2, ES2415FR2, ES2418FR2, ES2423FR2,	EST1806B-18, EST1808B-18, EST1810B-18, EST1812B-18, EST1814B-18, EST1815B-18, EST2006B-18, EST2008B-18, EST2010B-18, EST2012B-18, EST2014B-18, EST2015B-18, EST2206B-18, EST2208B-18, EST2210B-18, EST2212B-18, EST2214B-18, EST2215B-18. EST1806B-22, EST1808B-22, EST1810B-22, EST1812B-22, EST1814B-22, EST1815B-22, EST2006B-22, EST2008B-22, EST2010B-22, EST2012B-22, EST2014B-22, EST2015B-22, EST2206B-22, EST2208B-22, EST2210B-22, EST2212B-22, EST2214B-22, EST2215B-22. EST1806FR2, EST1808FR2, EST1810FR2, EST1812FR2, EST1814FR2, EST1815FR2, EST2006FR2, EST2008FR2, EST2010FR2, EST2012FR2, EST2014FR2, EST2015FR2, EST2206FR2, EST2208FR2, EST2210FR2, EST2212FR2, EST2214FR2, EST2215FR2. ESP1006F, ESP1008F, ESP1010F, ESP1012F, ESP1014F, ESP1015F, ESP1206F, ESP1208F, ESP1210F, ESP1212F, ESP1214F, ESP1215F, ESP1406F, ESP1408F, ESP1410F, ESP1412F, ESP1414F, ESP1415F, ESP1606F, ESP1608F, ESP1610F, ESP1612F, ESP1614F, ESP1615F, ESP1806F, ESP1808F, ESP1810F, ESP1812F, ESP1814F, ESP1815F, ESP2006F, ESP2008F, ESP2010F, ESP2012F, ESP2014F, ESP2015F, ESP2206F, ESP2208F, ESP2210F, ESP2212F, ESP2214F, ESP2215F, ESP2406F, ESP2408F, ESP2410F, ESP2412F, ESP2414F, ESP2415F, ESP2806F, ESP2808F, ESP2810F, ESP2812F, ESP2814F, ESP2815F. ESP1006FR2, ESP1008FR2, ESP1010FR2, ESP1012FR2, ESP1014FR2, ESP1015FR2,
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Quedando el producto inscripto con los siguientes datos característicos:

Nombre descriptivo: Stent esofágicos

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
 17-928- Endoprótesis (stents), Esofágicos

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

Clase de Riesgo: III

Indicación/es autorizada/s: Los stents esofágicos están indicados para el mantenimiento de la luz esofágica en los casos de obstrucciones malignas.

Los stents esofágicos con cubierta completa están indicados, además, para tratar las obstrucciones benignas y fístulas traqueoesofágicas

Modelos: ES1006F, ES1008F, ES1010F, ES1012F, ES1014F, ES1015F, ES1206F, ES1208F, ES1210F, ES1212F, ES1214F, ES1215F, ES1406F, ES1408F, ES1410F, ES1412F, ES1414F, ES1415F, ES1606F, ES1608F, ES1610F, ES1612F, ES1614F, ES1615F, ES1806F, ES1808F, ES1810F, ES1812F, ES1814F, ES1815F, ES2006F, ES2008F, ES2010F, ES2012F, ES2014F, ES2015F, ES2206F, ES2208F, ES2210F, ES2212F, ES2214F, ES2215F, ES2218F, ES2223F, ES2406F, ES2408F, ES2410F, ES2412F, ES2414F, ES2415F, ES2418F, ES2423F, ES2806F, ES2808F, ES2810F, ES2812F, ES2814F, ES2815F, ES2818F, ES2823F.

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Período de vida útil: 3 años desde su 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: Unitaria, esterilizada

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, 22 enero 2026.



BODNAR Andrea Veronica

CUIL 27254978472

Dirección Evaluación y Registro de Productos

Médicos

Firma y Sello



TERRIZZANO Maria Lorena

CUIL 23242965604

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: 22 enero 2026



ABRIOLA Leticia Adriana

CUIL 27323186494



La validez del presente documento deberá verificarse mediante el código QR.

N° Identificador Trámite: 69580

SCHUGURENSKY Gabriel Ernesto

CUIL 20201785767