



República Argentina - Poder Ejecutivo Nacional
2020 - Año del General Manuel Belgrano

Disposición

Número:

Referencia: 1-47-4939-19-1

VISTO el Expediente N° 1-47-4939-19-1 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y

CONSIDERANDO:

Que por las presentes actuaciones la firma Photonix S.R.L. solicita la autorización de modificación del Certificado de Inscripción en el RPPTM N° PM-2202-3, denominado: Equipo de Carga Diferida para Braquiterapia de Altas Tasas de Radiación, marca Varían.

Que lo solicitado se encuadra dentro de los alcances de la Disposición ANMAT N° 2318/02, sobre el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM).

Que la documentación aportada ha satisfecho los requisitos de la normativa aplicable.

Que el Instituto Nacional de Productos Médicos ha tomado la intervención que le compete.

Que se actúa en virtud de las facultades conferidas por el Decreto N° 1490/92 y sus modificatorios.

Por ello;

EL ADMINISTRADOR NACIONAL DE LA ADMINISTRACIÓN NACIONAL DE
MEDICAMENTOS, ALIMENTOS Y TECNOLOGÍA MÉDICA

DISPONE:

ARTÍCULO 1º.- Autorízase la modificación del Certificado de Inscripción en el RPPTM N° PM-2202-3,

denominado: Equipo de Carga Diferida para Braquiterapia de Altas Tasas de Radiación, marca Varían según Disposición Autorizante de (RPPTM) N° 6057/15 y tramitado por expediente N° 1-47-3110-2936-15-8.

ARTÍCULO 2°.- Acéptase el Anexo de Autorización de Modificaciones documento N°IF-2020-06389676-APN-INPM#ANMAT, el que deberá agregarse al Certificado de Inscripción en el RPPTM N° PM-2202-3.

ARTICULO 3°.- En los rótulos e instrucciones de uso deberán constar la modificación autorizadas.

ARTÍCULO 4°.- Regístrese; por el Departamento de Mesa de Entrada, notifíquese al interesado y hágasele entrega de copia autenticada de la presente Disposición conjuntamente con su Anexo, gírese a la Dirección de Gestión de Información Técnica para que efectúe la agregación del Anexo de Modificaciones al certificado. Cumplido, archívese.

Expediente N° 1-47-4939-19-1

Digitally signed by GARAY Valeria Teresa
Date: 2020.03.06 17:45:13 ART
Location: Ciudad Autónoma de Buenos Aires

Digitally signed by GESTION DOCUMENTAL
ELECTRÓNICA - GDE
Date: 2020.03.06 17:45:52 -03:00

ANEXO DE AUTORIZACION DE MODIFICACIONES

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), autoriza a la firma Photonix S.R.L. la modificación de los datos característicos correspondientes al Certificado de Inscripción en el RPPTM N° PM 2202-3 de acuerdo con los datos que figuran en tabla al pie, del producto:

Nombre descriptivo aprobado: Equipo de Carga Diferida para Braquiterapia de Altas Tasas de Radiación.

Marca: Varían.

Disposición Autorizante de (RPPTM) N° 6057/15

Tramitado por expediente N° 1-47-3110-2936-15-8

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACIÓN / RECTIFICACIÓN AUTORIZADA
Accesorios:	GM11004140 - Vaginal Applicator Set GM11004150 - Segmented Cylinder Applicator Set GM11004160 - Stump Applicator Set with CT Cylinders GM11004380 - Shielded Applicator Set	GM11004140 - Vaginal Applicator Set GM11004150 - Segmented Cylinder Applicator Set GM11004160 - Stump Applicator Set with CT Cylinders GM11004380 - Shielded Applicator Set

	<p>GM11004040 - Cervix Applicator Set</p> <p>GM11004540 - Segmented Cervix Applicator Set</p> <p>GM11009840 - Universal Endometrial Applicator Set</p> <p>GM11004580 - Heyman Packing Applicator Set</p> <p>GM11000810 - Fletcher- style Applicator Set</p> <p>GM11006200 - Titanium Fletcher-style Applicator Set</p> <p>AL13030001 - Titanium Fletcher-Suit-Delelos- style Applicator Set</p> <p>GM11006940 - Manchester-style Applicator Set</p> <p>AL13017000 - Ring & Tandem Combination Applicator Set</p>	<p>GM11004040 - Cervix Applicator Set</p> <p>GM11004540 - Segmented Cervix Applicator Set</p> <p>GM11009840 - Universal Endometrial Applicator Set</p> <p>GM11004580 - Heyman Packing Applicator Set</p> <p>GM11000810 - Fletcher- style Applicator Set</p> <p>GM11006200 - Titanium Fletcher-style Applicator Set</p> <p>AL13030001 - Titanium Fletcher-Suit-Delelos- style Applicator Set</p> <p>GM11006940 - Manchester-style Applicator Set</p> <p>AL13017000 - Ring & Tandem Combination Applicator Set</p>
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	<p>GM11001220 - Ring Applicator. 45' Set</p> <p>GM11000760 - Ring Applicator, 60' Set</p> <p>GM11000240 - Ring Applicator, 90' Set</p> <p>AL13025000 - Miami-style Applicator Set</p> <p>GM11008880 Esophagus Bougie Set</p> <p>GM11008890 - Centering Intraluminal Applicator Set</p> <p>GM11000620 - Intraluminal Applicator Set</p> <p>Standard Catheters</p> <p>GM11004690 - Nasopharynx Applicator Set</p> <p>MRNI Prostate Contour Template for Flexiguides</p> <p>DK-Technologies Fixation Template</p>	<p>GM11001220 - Ring Applicator. 45' Set</p> <p>GM11000760 - Ring Applicator, 60' Set</p> <p>GM11000240 - Ring Applicator, 90' Set</p> <p>AL13025000 - Miami-style Applicator Set</p> <p>GM11008880 Esophagus Bougie Set</p> <p>GM11008890 - Centering Intraluminal Applicator Set</p> <p>GM11000620 - Intraluminal Applicator Set</p> <p>Standard Catheters</p> <p>GM11004690 - Nasopharynx Applicator Set</p> <p>MRNI Prostate Contour Template for Flexiguides</p> <p>DK-Technologies Fixation Template</p>
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	<p>GM11004650 - Prostate and Perineal Implant Template Set</p> <p>GM11004680 Flexible Interstitial Implant Tube Set</p> <p>Flexible Interstitial Implant Tubes 530mm Interstitial/Breast Catheter Kits</p> <p>GM11004660 - Breast Implant Template Set</p> <p>AL13011000 - Breast Bridge and Template System</p> <p>AL13012000 - Advanced Breast Template System</p> <p>Interstitial Stainless Steel Needles</p> <p>Interstitial Titanium Needles 17 Gauge (1.47mm)</p> <p>Interstitial Titanium Needles 16 Gauge</p>	<p>GM11004650 - Prostate and Perineal Implant Template Set</p> <p>GM11004680 Flexible Interstitial Implant Tube Set</p> <p>Flexible Interstitial Implant Tubes 530mm Interstitial/Breast Catheter Kits</p> <p>GM11004660 - Breast Implant Template Set</p> <p>AL13011000 - Breast Bridge and Template System</p> <p>AL13012000 - Advanced Breast Template System</p> <p>Interstitial Stainless Steel Needles</p> <p>Interstitial Titanium Needles 17 Gauge (1.47mm)</p> <p>Interstitial Titanium Needles 16 Gauge</p>
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	(1.65mm)	(1.65mm)
	GM11004670 Interstitial Applicator Set Interstitial Plastic Needles GM11004440 Mould Applicator Set	GM11004670 Interstitial Applicator Set Interstitial Plastic Needles GM11004440 Mould Applicator Set
	GM11004370 - Catheter Flap Set	GM11004370 - Catheter Flap Set
	GM11010080 - Surface Applicator Set with Leipzig-style Cone GM11008920 MammoSite Balloon Catheter	GM11010080 - Surface Applicator Set with Leipzig-style Cone GM11008920 MammoSite Balloon Catheter
	GM11008680 - GammaMed Adjustable Luer Source Guide Tube GammaMedplus Source Guide Tubes PDR Quick Connectors	GM11008680 - GammaMed Adjustable Luer Source Guide Tube GammaMedplus Source Guide Tubes PDR Quick Connectors
		Intracavitary Applicators GM11010490 - Ring Applicator, 45° Set

		<p>GM11011040 - Ring Applicator, 60° Set</p> <p>GM11011210 - Ring Applicator, 90° Set</p> <p>GM11010190 - 3D Interstitial Ring Applicator 60° Set</p> <p>GM11010290 - 3D Interstitial Ring Applicator 90° Set</p> <p>GM11011100 - Universal Segmented Cylinder Applicator Set</p> <p>GM11011160 - Universal Stump Applicator Set</p> <p>GM11011500 - Universal Cervix Probe Set, odd lengths</p> <p>GM11011700 - Universal Cervix Probe Set, even lengths</p> <p>Intraluminal Applicators</p> <p>GM11009010 - Centering Intraluminal</p>
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		<p>Applicator Sets</p> <p>AL13112000 - Standard Catheter Set</p> <p>AL13113000 - Standard Catheter Set</p> <p>AL13114000 - Standard Catheter Set</p> <p>AL13115000 - Standard Catheter Set</p> <p>AL13113001 - 4.7 Fr. plastic-tipped catheter, 100 cm, pack of 10</p> <p>AL13113002 - 4.7 Fr. plastic-tipped catheter, 100 cm, pack of 20</p> <p>AL13112001 - 4.7 Fr. metal-tipped catheter, 100 cm, pack of 10</p> <p>AL13112002 - 4.7 Fr. metal-tipped catheter, 100 cm, pack of 20</p> <p>AL13114001 - 4.7 Fr. metal-tipped catheter, 150 cm, pack of 10</p>
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		<p>AL13114002 - 4.7 Fr. metal-tipped catheter, 150 cm, pack of 20</p> <p>AL13115001 - 4.7 Fr. plastic-tipped catheter, 150 cm, pack of 10</p> <p>AL13115002 - 4.7 Fr. plastic-tipped catheter, 150 cm, pack of 20</p> <p>Interstitial Applicators</p> <p>GM11008570 - Flexible Interstitial Implant Tube, 530mm</p> <p>GM11008580 - Flexible Interstitial Implant Tube, 530mm</p> <p>GM11009500 - Interstitial Stainless Steel Needles</p> <p>GM11009510 - Interstitial Stainless Steel Needles</p> <p>GM11009520 - Interstitial Stainless</p>
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		<p>Steel Needles</p> <p>GM11009530 -</p> <p>Interstitial Stainless</p> <p>Steel Needles</p> <p>GM11009550 -</p> <p>Interstitial Stainless</p> <p>Steel Needles</p> <p>GM11009560 -</p> <p>Interstitial Stainless</p> <p>Steel Needles</p> <p>GM11009570 -</p> <p>Interstitial Stainless</p> <p>Steel Needles</p> <p>GM11009580 -</p> <p>Interstitial Stainless</p> <p>Steel Needles</p> <p>GM11009700 -</p> <p>Interstitial Titanium</p> <p>Needles 17 Gauge</p> <p>(1.47mm)</p> <p>GM11009710 -</p> <p>Interstitial Titanium</p> <p>Needles 17 Gauge</p> <p>(1.47mm)</p>
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		<p>GM11009720 - Interstitial Titanium Needles 17 Gauge (1.47mm)</p> <p>GM11009730 - Interstitial Titanium Needles 17 Gauge (1.47mm)</p> <p>GM11010210 - Interstitial Titanium Needles 16 Gauge (1.65mm)</p> <p>GM11010220 - Interstitial Titanium Needles 16 Gauge (1.65mm)</p> <p>GM11010230 - Titanium Needles 16 Gauge (1.65mm)</p> <p>GM11010240 - Interstitial Titanium Needles 16 Gauge (1.65mm)</p> <p>GM11010410 -</p>
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		<p>Interstitial Titanium Needles 16 Gauge (1.65mm) GM11010420 -</p> <p>Interstitial Titanium Needles 16 Gauge (1.65mm) GM11010430 -</p> <p>Interstitial Titanium Needles 16 Gauge (1.65mm) GM11010440 -</p> <p>Interstitial Titanium Needles 16 Gauge (1.65mm) GM11007560 -</p> <p>Interstitial Plastic Needles GM11007570 -</p> <p>Interstitial Plastic Needles GM11007580 -</p> <p>Interstitial Plastic Needles</p>
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		<p>GM11010750 - Interstitial Plastic Needles</p> <p>GM11012200 - Kelowna GYN Template for 2.0 mm needles, including locking collets (pack of 25) and needle collet wrench</p> <p>GM11012210 - Kelowna GYN Template for 16 gauge (1.65 mm) needles, including locking collets (pack of 25) and needle collet wrench</p> <p>GM11012220 - Kelowna GYN Template for 17 gauge (1.47 mm) needles, including locking collets (pack of 25) and needle collet wrench</p> <p>GM11012230 - Crook</p>
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		<p>Prostate Template for 2.0 mm needles, B-K labelling, including locking collets (pack of 25) and needle collet wrench</p> <p>GM11012240 - Crook</p> <p>Prostate Template for 17 gauge (1.47 mm) needles, B-K labelling, including locking collets (pack of 25) and needle collet wrench</p> <p>GM11012250 - Crook</p> <p>Prostate Template for 2.0 mm needles, Siemens labelling, including locking collets (pack of 25) and needle collet wrench</p> <p>GM11012260 - Crook</p> <p>Prostate Template for 17 gauge (1.47 mm) needles, Siemens</p>
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		<p>labelling, including locking collets (pack of 25) and needle collet wrench</p> <p>Intraoperative and Surface Applicators</p> <p>GM11004590 - Surface Applicator Set Accessories</p> <p>AL13142000 - Cervical Sleeves</p> <p>AL13142001 - Cervical Sleeves</p> <p>AL13142002 - Cervical Sleeves</p> <p>AL13142003 - Cervical Sleeves</p> <p>GM11000520 - Source Guide Tubes for GammaMedplus</p> <p>GM11000320 - Source Guide Tubes for GammaMedplus</p> <p>GM11008960 - Source</p>
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		<p>Guide Tubes for GammaMedplus GM11000340 - Source</p> <p>Guide Tubes for GammaMedplus GM11000380 - Source</p> <p>Guide Tubes for GammaMedplus GM11007280 - Source</p> <p>Guide Tubes for GammaMedplus GM11007270 - Source</p> <p>Guide Tubes for GammaMedplus GM11007610 - Source</p> <p>Guide Tubes for GammaMedplus GM11007620 - Source</p> <p>Guide Tubes for GammaMedplus GM11007630 - Source</p> <p>Guide Tubes for GammaMedplus</p>
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		GM11000460 - Source Guide Tubes for GammaMedplus GM11000370 - Source Guide Tubes for GammaMedplus GM11010020 - Source Guide Tubes for GammaMedplus GM11000310 - Source Guide Tubes for GammaMedplus GM11006650 - Source Guide Tubes for GammaMedplus GM11006060 - Source Guide Tubes for GammaMedplus GM11010760 - Source Guide Tubes for GammaMedplus GM11010780 - Source Guide Tubes for GammaMedplus
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		<p>GM19003000 - VariSource Catheter Transfer Guide Tube Set - 200 Series</p> <p>GM19003001 - VariSource Catheter Transfer Guide Tube Set - 200 Series</p> <p>GM19001000 - VariSource ClickFit™ Transfer Guide Tube Set - 200 Series</p> <p>GM19002000 - VariSource Needle ClickFit™ Transfer Guide Tube Set - 200</p> <p>GM19002001 - VariSource Needle ClickFit™ Transfer Guide Tube Set - 200</p> <p>AL12500000 - VariSource Quick Connects</p> <p>AL12500001 -</p>
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		<p>VariSource Quick Connects AL12500002 -</p> <p>VariSource Quick Connects AL12500003 -</p> <p>VariSource Quick Connects AL12500004 -</p> <p>VariSource Quick Connects AL12550000 -</p> <p>VariSource Quick Connects GM11007090 - PDR Quick Connectors - 5 - fold Quick Connectors with Source Guide Tubes</p> <p>GM11007100 - PDR Quick Connectors - 5 - fold Quick Connectors with Source Guide Tubes</p> <p>GM11007110 - PDR Quick Connectors - 5 -</p>
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		<p>fold Quick Connectors with Source Guide Tubes</p> <p>GM11007120 - PDR</p> <p>Quick Connectors - 5 - fold Quick Connectors with Source Guide Tubes</p> <p>GM11007130 - PDR</p> <p>Quick Connectors - 5 - fold Quick Connectors with Source Guide Tubes</p> <p>GM11007140 - PDR</p> <p>Quick Connectors - 5 - fold Quick Connectors with Source Guide Tubes</p> <p>GM11007150PDR Quick C</p> <p>GM11007160 - PDR</p> <p>quick connector socket, 16-20, patient side</p> <p>GM11007170 - Connecting tube, 113mm needle</p> <p>GM11007180 - Connecting tube, 200mm needle</p>
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		<p>GM11007190 - Connecting tube, 320mm needle</p> <p>GM11007200 - Connecting tube, 113mm interstitial tube</p> <p>GM11007210 - Connecting tube, 200mm interstitial tube</p> <p>GM11007220 - Connecting tube, 320mm interstitial tube</p> <p>GM19004000 - VariSource 200 and iX Luer Transfer Guide Tube Set</p> <p>GM11009600 - Marker Wire Products - GammaMedplus</p> <p>GM11009610 - Marker Wire Products - GammaMedplus</p> <p>GM11009620 - Marker Wire Products -</p>
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		GammaMedplus GM11009630 - Marker Wire Products - GammaMedplus GM11009640 - Marker Wire Products - GammaMedplus GM11009650 - Marker Wire Products - GammaMedplus GM11009660 - Marker Wire Products - GammaMedplus GM11009670 - Marker Wire Products - GammaMedplus GM11009680 - Marker Wire Products - GammaMedplus GM11000330 - Length Gauge, Gmplus AL13116000 - VS Marker Wire AL13117000 - VS
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		<p>Marker Wire</p> <p>AL13118000 - VS</p> <p>Marker Wire</p> <p>AL13134000 - VS</p> <p>Marker Wire</p> <p>AL13154000 - Marker Wire & Clip</p> <p>AL13119000 - Marker Wire & Clip</p> <p>GM11010770 - Cleaning Cap, dark blue, pack of 25</p> <p>GM11003940 - Channel marker clips coded 1-12</p> <p>GM11003770 - Channel marker clips, coded 13- 24</p> <p>GM11003810 - Leak stop button (pack of 50), non-sterile</p> <p>GM11010340 - Universal Sterilization Box</p> <p>GM11010510 - Leak stop channel markers</p>
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		Set, 1-12 GM11010520 - Leak stop channel markers Set, 13-24 GM11010610 - Leak stop channel markers, 25-30 GM11001960 - Flexible Fixation Device for Gynecological Applicators
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El presente sólo tiene valor probatorio anexo al certificado de Autorización antes mencionado.

EXPEDIENTE N° 1-47-0000-4939-19-1



República Argentina - Poder Ejecutivo Nacional
2020 - Año del General Manuel Belgrano

Hoja Adicional de Firmas
Anexo

Número:

Referencia: 1-47-4939-19-1 PHOTONIX S.R.L

El documento fue importado por el sistema GEDO con un total de 23 pagina/s.

Digitally signed by GESTION DOCUMENTAL ELECTRONICA - GDE
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