



Ministerio de Salud
Secretaría de Políticas,
Regulación e Institutos
ANMAT

DISPOSICIÓN N° 8019

BUENOS AIRES, 17 JUL 2017

VISTO el Expediente N° 1-47-3110-004759-16-1 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y

CONSIDERANDO:

Que por las presentes actuaciones AUDITRÓN S.A. solicita la corrección de la Disposición ANMAT N° 2419/2017 con fecha 13 de MARZO de 2017, por la cual se autorizó la modificación de el RPPTM del producto N° PM-619-51, denominado: AUDIFONOS INTRACANALES DIGITALES, marca BELTONE.

Que por error se omitieron los modelos "AY4CIC UP, AY4CIC HP, AY4CIC MP, AY4CIC LP, AY3CIC UP, AY3CIC HP, AY3CIC MP, AY3CIC LP, AY2CIC UP, AY2CIC HP, AY2CIC MP, AY2CIC LP, AY4ITC-DW UP, AY4ITC-DW HP, AY4ITC-DW MP, AY4ITC-DW LP" en el Anexo de Autorización de modificaciones de la Disposición ANMAT N°9162/2015.

Que dichos errores materiales se consideran subsanables en los términos de lo normado por el artículo 101 del Reglamento de Procedimientos Administrativos aprobado por Decreto N° 1759/72 (T.O. 1991).

Que la Dirección Nacional de Productos Médicos ha tomado la intervención de su competencia.

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Que se actúa en virtud de las atribuciones conferidas por el Decreto N° 1490/92 y por el decreto N° 101/15 de fecha 16 de diciembre de 2015.

Por ello;

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

DISPONE:

ARTÍCULO 1º.- Rectifícase el dato Modelos del Anexo de Autorización de modificaciones de la Disposición ANMAT N°2419/2017 del 13 de MARZO de 2017, el que quedará redactado del siguiente modo:

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACIÓN / RECTIFICACIÓN AUTORIZADA
MODELOS	MODELO ONE: ONE 15, ONE 15 HPG, ONE 15 PB, ONE 15 PB HPG, ONE 25, ONE 25 HPG, ONE 35, ONE 35 HPG, ONE 35 D: ONE 35 D HPG, ONE 45, ONE 45 HPG, ONE 45 DONE 45 D HPG MODELO LINQ: LINQ 15LINQ 15 HPG, LINQ 15 PB, LINQ 15 PB HPG, LINQ 25, LINQ 25 HPGLINQ 35, LINQ 35 HPGLINQ 35 D LINQ 35 D HPG, LINQ 45 LINQ 45 HPG, LINQ 45 D, LINQ 45 D HPG LÍNEA ACCESS:	LÍNEA ACCESS: ACS 15 HPG, ACS 25 HPG, ACS 35 HPG, ACS 45 HPG, ACS 15, ACS 25, ACS 35, ACS 35D, ACS35 D HPG, ACS 45, ACS 45D, ACS 45D HPG. LINEA IDENTITY: IDT15, IDT15HPG, IDT15PB, IDT15PB HPG, IDT25, IDT25 HPG, IDT35, IDT 35HPG, IDT35D, IDT35D HPG, IDT45, IDT45HPG, IDT45D, IDT45DHPG. LINEA REACH: RCH 15, RCH15 HPG, RCH15PB, RCH15PBHPG, RHC 25, RHC25HPG, RCH35,

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	<p>ACS 15 HPG, ACS 25 HPG, ACS 35 HPG, ACS 45 HPG, ACS 15, ACS 25, ACS 35, ACS 35D, ACS35 D HPG, ACS 45, ACS 45D, ACS 45D HPG.</p> <p>LINEA IDENTITY: IDT15, IDT15HPG, IDT15PB, IDT15PB HPG, IDT25, IDT25 HPG, IDT35, IDT 35HPG, IDT35D, IDT35D HPG, IDT45, IDT45HPG, IDT45D, IDT45DHPG,</p> <p>LINEA REACH: RCH 15, RCH15 HPG, RCH15PB, RCH15PBHPG, RHC 25, RHC25HPG, RCH35, RCH35D, RCH35D HPG, RCH 45, RCH 45D, RCH 45HPG, RCH45D HPG.</p> <p>LINEA TOUCH: TO1705, TO1715, TO1715 SPG, TO905, TO915, TO915 SPG.</p> <p>LINEA CHANGE: CHG15, CHG15HPG, CHG15PB, CHG15PB HPG, CHG15 xs, CHG25, CHG25 HPG, CHG35, CHG35 HPG, CHG35D, CHG35D HPG, CHG45, CHG45 HPG, CHG45D, CHG45D HPG.</p> <p>LINEA TRUE: TRU1715, TRU 1715M, TRU1715MP, TRU1715P, TRU1725, TRU1725P, TRU1735, TRU1735P, TRU1735DP, TRU1735DPW, TRU1735DW, TRU1735M, TRU1735MP, TRU1735MPW, TRU1735MU, TRU1735MUW, TRU1735MW, TRU1735PW, TRU1735W, TRU1745, TRU1745D, TRU1745DP, TRU1745DPW, TRU1745DW, TRU1745P, TRU1745PW, TRU1745W, TRU315, TRU315P, TRU325, TRU325P, TRU335, TRU335D, TRU335DP, TRU335P, TRU345, TRU345D, TRU345DP, TRU345P, TRU615, TRU615M, TRU615MP, TRU615P, TRU625, TRU625P, TRU635, TRU635D, TRU635DP, TRU635DPW, TRU635DW, TRU635M, TRU635MP, TRU635MPW, TRU635MU, TRU635MUW, TRU635MW, TRU635P, TRU635PW, TRU635W, TRU645, TRU645D, TRU645DP, TRU645DPW, TRU645DW, TRU645P, TRU645PW, TRU645W, TRU915, TRU915M, TRU915MP,</p>	<p>RCH35D, RCH35D HPG, RCH 45, RCH 45D, RCH 45HPG, RCH45D HPG.</p> <p>LINEA TOUCH: TO1705, TO1715, TO1715 SPG, TO905, TO915, TO915 SPG.</p> <p>LINEA CHANGE: CHG15, CHG15HPG, CHG15PB, CHG15PB HPG, CHG15 xs, CHG25, CHG25 HPG, CHG35, CHG35 HPG, CHG35D, CHG35D HPG, CHG45, CHG45 HPG, CHG45D, CHG45D HPG.</p> <p>LINEA TRUE: TRU1715, TRU 1715M, TRU1715MP, TRU1715P, TRU1725, TRU1725P, TRU1735, TRU1735P, TRU1735DP, TRU1735DPW, TRU1735DW, TRU1735M, TRU1735MP, TRU1735MPW, TRU1735MU, TRU1735MUW, TRU1735MW, TRU1735PW, TRU1735W, TRU1745, TRU1745D, TRU1745DP, TRU1745DPW, TRU1745DW, TRU1745P, TRU1745PW, TRU1745W, TRU315, TRU315P, TRU325, TRU325P, TRU335, TRU335D, TRU335DP, TRU335P, TRU345, TRU345D, TRU345DP, TRU345P, TRU615, TRU615M, TRU615MP, TRU615P, TRU625, TRU625P, TRU635, TRU635D, TRU635DP, TRU635DPW, TRU635DW, TRU635M, TRU635MP, TRU635MPW, TRU635MU, TRU635MUW, TRU635MW, TRU635P, TRU635PW, TRU635W, TRU645, TRU645D, TRU645DP, TRU645DPW, TRU645DW, TRU645P, TRU645PW, TRU645W, TRU915, TRU915M, TRU915MP,</p>
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	TRU1735MP, TRU1735MPW, TRU1735MU, TRU1735MUW, TRU1735MW, TRU1735PW, TRU1735W, TRU1745, TRU1745D, TRU1745DP, TRU1745DPW, TRU1745DW, TRU1745P, TRU1745PW, TRU1745W, TRU315, TRU315P, TRU325, TRU325P, TRU335, TRU335D, TRU335DP, TRU335P, TRU345, TRU345D, TRU345DP, TRU345P, TRU615, TRU615M, TRU615MP, TRU615P, TRU625, TRU625P, TRU635, TRU635D, TRU635DP, TRU635DPW, TRU635DW, TRU635M, TRU635MP, TRU635MPW, TRU635MU, TRU635MUW TRU635MW, TRU635P, TRU635PW, TRU635W, TRU645, TRU645D, TRU645DP, TRU645DPW, TRU645DW, TRU645P, TRU645PW, TRU645W, TRU915, TRU915M, TRU915MP, TRU915P, TRU925, TRU925P, TRU935, TRU935D, TRU935DP, TRU935DPW, TRU935DW, TRU935M, TRU935MP, TRU935MPW, TRU935MU, TRU935MUW, TRU935MW, TRU935P, TRU935PW, TRU935W, TRU945, TRU945D, TRU945DP,	TRU915P, TRU925, TRU925P, TRU935, TRU935D, TRU935DP, TRU935DPW, TRU935DW, TRU935M, TRU935MP, TRU935MPW, TRU935MU, TRU935MUW, TRU935MW, TRU935P, TRU935PW, TRU935W, TRU945, TRU945D, TRU945DP, TRU945DPW, TRU945DW, TRU945P, TRU945PW, TRU945W. LINEA ORIGIN: OR115, OR115P, OR135, OR135P, OR145, OR145P, OR215, OR215P, OR235, OR235D, OR235DP, OR235P, OR245, OR245D, OR245DP, OR245P, OR315, OR315P, OR335, OR335D, OR335DP, OR335P, OR345, OR345D, OR345DP, OR345P. LINEA PROMISE: PSE1715, PSE1715M, PSE1715MP, PSE1715P, PSE1725, PSE1725P, PSE1735, PSE1735D, PSE1735DP, PSE1735DPW, PSE1735DW, PSE1735M, PSE1735MP, PSE1735MPW, PSE1735MU, PSE1735MUW, PSE1735MW, PSE1735P, PSE1735PW, PSE1735W, PSE1745, PSE1745D, PSE1745DP, PSE1745DPW, PSE1745DW, PSE1745P, PSE1745PW, PSE1745W, PSE915, PSE915M, PSE915MP, PSE915P, PSE925, PSE925P, PSE935, PSE935D, PSE935DP, PSE935DPW, PSE935DW, PSE935M, PSE935MP, PSE935MPW, PSE935MU, PSE935MUW, PSE935MW, PSE935P, PSE935PW, PSE935W, PSE945, PSE945D, PSE945DP, PSE945DPW, PSE945DW, PSE945P, PSE945PW, PSE945W, PSE635-W, PSE635-DW,
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<p>TRU945DPW, TRU945DW, TRU945P, TRU945PW, TRU945W. LINEA ORIGIN: OR115, OR115P, OR135, OR135P, OR145, OR145P, OR215, OR215P, OR235, OR235D, OR235DP, OR235P, OR245, OR245D, OR245DP, OR245P, OR315, OR315P, OR335, OR335D, OR335DP, OR335P, OR345, OR345D, OR345DP, OR345P. LINEA PROMISE: PSE1715, PSE1715M, PSE1715MP, PSE1715P, PSE1725, PSE1725P, PSE1735, PSE1735D, PSE1735DP, PSE1735DPW, PSE1735DW, PSE1735M, PSE1735MP, PSE1735MPW, PSE1735MU, PSE1735MUW, PSE1735MW, PSE1735P, PSE1735PW, PSE1735W, PSE1745, PSE1745D, PSE1745DP, PSE1745DPW, PSE1745DW, PSE1745P, PSE1745PW, PSE1745W, PSE915, PSE915M, PSE915MP, PSE915P, PSE925, PSE925P, PSE935, PSE935D, PSE935DP, PSE935DPW, PSE935DW, PSE935M, PSE935MP, PSE935MPW, PSE935MU, PSE935MUW, PSE935MW, PSE935P, PSE935PW, PSE935W, PSE945, PSE945D, PSE945DP,</p>	<p>PSE635-PW, PSE635-DPW, PSE615, PSE615-P. LINEA MICRO INVISIA: MIV1715, MIV915. LINEA LEGEND: LND17ITE-DW UP, LND17ITE-DW HP, LND17ITE-DW MP, LND9ITE-DW UP, LND9ITE-DW HP, LND9ITE-DW-MP, LND6ITE-DW UP, LND6ITE-DW HP, LND6ITE-DW MP, LND17ITE-W UP, LND17ITE-W HP, LND17ITE-W MP, LND9ITE-W UP, LND9ITE-W HP, LND9ITE-W MP, LND6ITE-W UP, LND6ITE-W HP, LND6ITE-W MP, LND17ITC-DW UP, LND17ITC-DW HP, LND17ITC-DW MP, LND17ITC-DW LP, LND9ITC-DW UP, LND9ITC-DW HP, LND9ITC-DW MP, LND9ITC-DW LP, LND6ITC-DW UP, LND6ITC-DW HP, LND6ITC-DW MP, LND6ITC-DW LP, LND17ITC-W UP, LND17ITC-W HP, LND17ITC-W MP, LND17ITC-W LP, LND9ITC-W UP, LND9ITC-W HP, LND9ITC-W MP, LND9ITC-W LP, LND6ITC-W UP, LND6ITC-W HP, LND6ITC-W MP, LND6ITC-W LP, LND17MIH-W UP, LND17MIH-W HP, LND17MIH-W MP, LND17MIH-W LP, LND9MIH-W UP, LND9MIH-W HP, LND9MIH-W MP, LND9MIH-W LP, LND6MIH-W UP, LND6MIH-W HP, LND6MIH-W MP, LND6MIH-W LP, LND17ITE-D UP, LND17ITE-D HP, LND17ITE-D MP,</p>
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	<p>PSE945DPW, PSE945DW, PSE945P, PSE945PW, PSE945W. LINEA MICRO INVISIBLE: MIV1715, MIV915 LINEA LEGEND: LND17ITE-DW UP, LND17ITE-DW HP, LND17ITE-DW MP, LND9ITE-DW UP, LND9ITE-DW HP, LND9ITE-DW-MP, LND6ITE-DW UP, LND6ITE-DW HP, LND6ITE-DW MP, LND17ITE-W UP, LND17ITE-W HP,LND17ITE-W MP, LND9ITE-W UP, LND9ITE- W HP, LND9ITE-W MP, LND6ITE-W UP, LND6ITE- W HP, LND6ITE-W MP, LND17ITC-DW UP, LND17ITC-DW HP, LND17ITC-DW MP, LND17ITC-DW LP, LND9ITC-DW UP, LND9ITC-DW HP, LND9ITC-DW MP, LND9ITC-DW LP, LND6ITC- DW UP, LND6ITC-DW HP, LND6ITC-DW MP, LND6ITC-DW LP, LND17ITC-W UP, LND17ITC-W HP,LND17ITC-W MP, LND17ITC-W LP, LND9ITC- W UP, LND9ITC-W HP, LND9ITC-W MP, LND9ITC- W LP, LND6ITC-W UP, LND6ITC-W HP, LND6ITC- W MP, LND6ITC-W</p>	<p>LND9ITE-D UP, LND9ITE-D HP, LND9ITE-D MP, LND6ITE-D UP, LND6ITE-D HP, LND6ITE-D MP, LND17ITE UP, LND17ITE HP, LND17ITE MP, LND9ITE UP, LND9ITE HP, LND9ITE MP, LND6ITE UP, LND6ITE HP, LND6ITE MP, LND17ITC-D UP, LND17ITC-D HP, LND17ITC-D MP, LND17ITC-D LP, LND9ITC-D UP, LND9ITC-D HP, LND9ITC-D MP, LND9ITC-D LP, LND6ITC-D UP, LND6ITC-D HP, LND6ITC-D MP, LND6ITC-D LP, LND17ITC UP, LND17ITC HP, LND17ITC MP, LND17ITC LP, LND9ITC UP, LND9ITC HP, LND9ITC MP, LND9ITC LP, LND6ITC UP, LND6ITC HP, LND6ITC MP, LND6ITC LP, LND17MIH UP, LND17MIH HP, LND17MIH MP, LND17MIH LP, LND9MIH UP, LND9MIH HP, LND9MIH MP, LND9MIH LP, LND6MIH UP, LND6MIH HP, LND6MIH MP, LND6MIH LP, LND17 IIC, LND9 IIC, LND6 IIC, LND17CIC UP UP, LND17CIC HP, LND17CIC MP, LND17CIC LP, LND9CIC UP, LND9CIC HP, LND9CIC MP, LND9CIC LP, LND6CIC UP, LND6CIC HP, LND6CIC MP, LND6CIC LP, LND17MIH-S UP, LND17MIH-S HP, LND17MIH-S MP, LND17MIH-S LP, LND9MIH-S UP, LND9MIH-S HP, LND9MIH-S MP, LND9MIH-S LP, LND6MIH-S UP, LND6MIH-S HP, LND6MIH-S MP, LND6MIH-S LP. LINEA PEGASUS: PGS135P, PGS115P. LINEA SCORPIUS:</p>
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	<p>LP, LND17MIH-W UP, LND17MIH-W HP, LND17MIH-W MP, LND17MIH-W LP, LND9MIH-W UP, LND9MIH- W HP, LND9MIH-W MP, LND9MIH-W LP, LND6MIH- W UP, LND6MIH-W HP, LND6MIH-W MP, LND6MIH-W LP, LND17ITE-D UP, LND17ITE-DHP, LND17ITE- D MP, LND9ITE-D UP, LND9ITE-D HP, LND9ITE-D MP, LND6ITE-D UP, LND6ITE-D HP, LND6ITE-D MP, LND17ITE UP, LND17ITE HP, LND17ITE MP, LND9ITE UP, LND9ITE HP, LND9ITE MP, LND6ITE UP, LND6ITE HP, LND6ITE MP, LND17ITC-D UP, LND17ITC-D HP, LND17ITC-D MP, LND17ITC-D LP, LND9ITC- D UP, LND9ITC-D HP, LND9ITC-D MP, LND9ITC- D LP, LND6ITC-D UP, LND6ITC-D HP, LND6ITC-D MP, LND6ITC-D LP, LND17ITC UP, LND17ITC HP, LND17ITC MP, LND17ITC LP, LND9ITC UP, LND9ITC HP, LND9ITC MP, LND9ITC LP, LND6ITC UP, LND6ITC HP, LND6ITC MP, LND6ITC LP, LND17MIH UP, LND17MIH HP, LND17MIH MP, LND17MIH LP, LND9MIH UP, LND9MIH</p>	<p>SCS135P, SCS115P. LINEA TAURUS: TRS135P, TRS115P. LINEA ALLY: AY4CIC UP, AY4CIC HP, AY4CIC MP, AY4CIC LP, AY3CIC UP, AY3CIC HP, AY3CIC MP, AY3CIC LP, AY2CIC UP, AY2CIC HP, AY2CIC MP, AY2CIC LP, AY4ITC-DW UP, AY4ITC-DW HP, AY4ITC-DW MP, AY4ITC-DW LP AY4ITC-D UP, AY4ITC-D HP, AY4ITC-D MP, AY4ITC-D LP, AY4ITC-W UP, AY4ITC-W HP, AY4ITC-W MP, AY4ITC-W LP, AY4ITC UP, AY4ITC HP, AY4ITC MP, AY4ITC LP, AY3ITC-DW UP, AY3ITC-DW HP, AY3ITC-DW MP, AY3ITC-DW LP, AY3ITC-D UP, AY3ITC-D HP, AY3ITC-D MP, AY3ITC-D LP, AY3ITC-W UP, AY3ITC-W HP, AY3ITC-W MP, AY3ITC-W LP, AY3ITC UP, AY3ITC HP, AY3ITC MP, AY3ITC LP, AY2ITC-DW UP, AY2ITC-DW HP, AY2ITC-DW MP, AY2ITC-DW LP, AY2ITC-D UP, AY2ITC-D HP, AY2ITC-D MP, AY2ITC-D LP, AY2ITC-W UP, AY2ITC-W HP, AY2ITC-W MP, AY2ITC-W LP, AY2ITC UP, AY2ITC HP, AY2ITC MP, AY2ITC LP, AY4ITE-DW UP, AY4ITE-DW HP, AY4ITE-DW MP, AY4ITE-D UP, AY4ITE-D HP, AY4ITE-D MP, AY4ITE-W UP, AY4ITE-W HP, AY4ITE-W MP, AY4ITE UP, AY4ITE HP, AY4ITE MP, AY3ITE-DW UP, AY3ITE-DW HP, AY3ITE-DW MP, AY3ITE-D UP, AY3ITE-D HP, AY3ITE-D MP, AY3ITE-W UP, AY3ITE-W HP, AY3ITE-W MP,</p>
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	HP, LND9MIH MP, LND9MIH LP, LND6MIH UP, LND6MIH HP, LND6MIH MP, LND6MIH LP, LND17 IIC, LND9 IIC, LND6 IIC, LND17CIC UP UP, LND17CIC HP, LND17CIC MP, LND17CIC LP, LND9CIC UP, LND9CIC HP, LND9CIC MP, LND9CIC LP, LND6CIC UP, LND6CIC HP, LND6CIC MP, LND6CIC LP, LND17MIH-S UP, LND17MIH-S HP, LND17MIH-S MP, LND17MIH-S LP, LND9MIH-S UP, LND9MIH- S HP, LND9MIH-S MP, LND9MIH-S LP, LND6MIH- S UP, LND6MIH-S HP, LND6MIH-S MP, LND6MIH-S LP. LINEA PEGASUS: PGS135P, PGS115P. LINEA SCORPIUS: SCS135P, SCS115P. LINEA TAURUS: TRS135P, TRS115P.	AY3ITE UP, AY3ITE HP, AY3ITE MP, AY2ITE-DW UP, AY2ITE-DW HP, AY2ITE-DW MP, AY2ITE-D UP, AY2ITE-D HP, AY2ITE-D MP, AY2ITE-W UP, AY2ITE-W HP, AY2ITE-W MP, AY2ITE UP, AY2ITE HP, AY2ITE MP.
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ARTÍCULO 2º.- Practíquese la atestación correspondiente en el certificado PM-619-51 cuando el mismo se presente acompañado de la copia autenticada de la presente Disposición.

ARTÍCULO 3º.- Regístrese; por el Departamento de Mesa de Entradas notifíquese al interesado y hágasele entrega de copia autenticada de la presente Disposición;



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gírese a la Dirección de Gestión de Información Técnica a sus efectos; notifíquese a la Dirección Nacional de Productos Médicos. Cumplido, archívese.

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Dr. CARLOS CHIALE
Administrador Nacional
A.N.M.A.T.

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