



República Argentina - Poder Ejecutivo Nacional

Año de la Grandeza Argentina

Certificado - Redacción libre

Número: CE-2026-99645182-APN-ANMAT#MS

CIUDAD DE BUENOS AIRES

Martes 13 de Octubre de 2026

Referencia: 1-0047-3110-007491-25-4

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

Expediente N° 1-0047-3110-007491-25-4

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por Driplan 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: 1608-118

Nombre descriptivo: Desfibrilador Externo Automático

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
18-499 - Desfibriladores externos

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

Modelos:

97882 PRIMEDIC HeartSave YA0
97883 PRIMEDIC HeartSave YA1
97884 PRIMEDIC HeartSave YA2
97885 PRIMEDIC HeartSave YA3
97896 PRIMEDIC HeartSave YA5
97887 PRIMEDIC HeartSave YA6
97888 PRIMEDIC HeartSave YA7

97889 PRIMEDIC HeartSave YA8
97892 PRIMEDIC HeartSave Y0
97893 PRIMEDIC HeartSave Y1
97894 PRIMEDIC HeartSave Y2
97895 PRIMEDIC HeartSave Y3
97886 PRIMEDIC HeartSave Y5
97897 PRIMEDIC HeartSave Y6
97898 PRIMEDIC HeartSave Y7
97899 PRIMEDIC HeartSave Y8
97915 PRIMEDIC HeartSave YA0 (with optional display)
97916 PRIMEDIC HeartSave YA1 (with optional display)
97917 PRIMEDIC HeartSave YA2 (with optional display)
97918 PRIMEDIC HeartSave YA3 (with optional display)
97919 PRIMEDIC HeartSave YA5 (with optional display)
97920 PRIMEDIC HeartSave YA6 (with optional display)
97921 PRIMEDIC HeartSave YA7 (with optional display)
97922 PRIMEDIC HeartSave YA8 (with optional display)
97907 PRIMEDIC HeartSave Y0 (with optional display)
97908 PRIMEDIC HeartSave Y1 (with optional display)
97909 PRIMEDIC HeartSave Y2 (with optional display)
97910 PRIMEDIC HeartSave Y3 (with optional display)
97911 PRIMEDIC HeartSave Y5 (with optional display)
97912 PRIMEDIC HeartSave Y6 (with optional display)
97913 PRIMEDIC HeartSave Y7 (with optional display)
97914 PRIMEDIC HeartSave Y8 (with optional display)
97924 HeartSave myPAD 670 (non-rechargeable)
97925 HeartSave myPAD 670 (non-rechargeable/ CPR)
97967 HeartSave myPAD 670 (non-rechargeable/ WALN)
97968 HeartSave myPAD 670 (non-rechargeable/ WALN/ CPR)
97969 HeartSave myPAD 670 (non-rechargeable/ LTE)
97970 HeartSave myPAD 670 (non-rechargeable/ LTE/ CPR)
97971 HeartSave myPAD 670 (non-rechargeable/ WALN/ LTE)
97972 HeartSave myPAD 670 (non-rechargeable/ WALN/ LTE/ CPR)
97951 HeartSave myPAD 671 (non-rechargeable)
97973 HeartSave myPAD 671 (non-rechargeable/ CPR)
97974 HeartSave myPAD 671 (non-rechargeable/ WALN)
97975 HeartSave myPAD 671 (non-rechargeable/ WALN/ CPR)
97976 HeartSave myPAD 671 (non-rechargeable/ LTE)
97977 HeartSave myPAD 671 (non-rechargeable/ LTE/ CPR)
97978 HeartSave myPAD 671 (non-rechargeable/ WALN/ LTE)
97979 HeartSave myPAD 671 (non-rechargeable/ WALN/ LTE/ CPR)
97952 HeartSave myPAD 675 (non-rechargeable)
97980 HeartSave myPAD 675 (non-rechargeable/ CPR)
97981 HeartSave myPAD 675 (non-rechargeable/ WALN)
97982 HeartSave myPAD 675 (non-rechargeable/ WALN/ CPR)
97983 HeartSave myPAD 675 (non-rechargeable/ LTE)
97984 HeartSave myPAD 675 (non-rechargeable/ LTE/ CPR)
97985 HeartSave myPAD 675 (non-rechargeable/ WALN/ LTE)
97986 HeartSave myPAD 675 (non-rechargeable/ WALN/ LTE/ CPR)
97953 HeartSave myPAD 678 (non-rechargeable)
97987 HeartSave myPAD 678 (non-rechargeable/ CPR)
97988 HeartSave myPAD 678 (non-rechargeable/ WALN)
97989 HeartSave myPAD 678 (non-rechargeable/ WALN/ CPR)
97990 HeartSave myPAD 678 (non-rechargeable/ LTE)
97991 HeartSave myPAD 678 (non-rechargeable/ LTE/ CPR)
97992 HeartSave myPAD 678 (non-rechargeable/ WALN/ LTE)
97993 HeartSave myPAD 678 (non-rechargeable/ WALN/ LTE/ CPR)
97954 HeartSave myPAD 670A (non-rechargeable)
97994 HeartSave myPAD 670A (non-rechargeable/ CPR)
97995 HeartSave myPAD 670A (non-rechargeable/ WALN)
97996 HeartSave myPAD 670A (non-rechargeable/ WALN/ CPR)
97997 HeartSave myPAD 670A (non-rechargeable/ LTE)

97998 HeartSave myPAD 670A (non-rechargeable/ LTE/ CPR)
97999 HeartSave myPAD 670A (non-rechargeable/ WALN/ LTE)
98000 HeartSave myPAD 670A (non-rechargeable/ WALN/ LTE/ CPR)
97955 HeartSave myPAD 671A (non-rechargeable)
98002 HeartSave myPAD 671A (non-rechargeable/ CPR)
98003 HeartSave myPAD 671A (non-rechargeable/ WALN)
98004 HeartSave myPAD 671A (non-rechargeable/ WALN/ CPR)
98005 HeartSave myPAD 671A (non-rechargeable/ LTE)
98006 HeartSave myPAD 671A (non-rechargeable/ LTE/ CPR)
98007 HeartSave myPAD 671A (non-rechargeable/ WALN/ LTE)
98008 HeartSave myPAD 671A (non-rechargeable/ WALN/ LTE/ CPR)
97956 HeartSave myPAD 675A (non-rechargeable)
98009 HeartSave myPAD 675A (non-rechargeable/ CPR)
98010 HeartSave myPAD 675A (non-rechargeable/ WALN)
98011 HeartSave myPAD 675A (non-rechargeable/ WALN/ CPR)
98012 HeartSave myPAD 675A (non-rechargeable/ LTE)
98013 HeartSave myPAD 675A (non-rechargeable/ LTE/ CPR)
98014 HeartSave myPAD 675A (non-rechargeable/ WALN/ LTE)
98015 HeartSave myPAD 675A (non-rechargeable/ WALN/ LTE/ CPR)
97957 HeartSave myPAD 678A (non-rechargeable)
98016 HeartSave myPAD 678A (non-rechargeable/ CPR)
98017 HeartSave myPAD 678A (non-rechargeable/ WALN)
98018 HeartSave myPAD 678A (non-rechargeable/ WALN/ CPR)
98019 HeartSave myPAD 678A (non-rechargeable/ LTE)
98020 HeartSave myPAD 678A (non-rechargeable/ LTE/ CPR)
98021 HeartSave myPAD 678A (non-rechargeable/ WALN/ LTE)
98022 HeartSave myPAD 678A (non-rechargeable/ WALN/ LTE/ CPR)
98071 HeartSave myPAD 670 (rechargeable)
98072 HeartSave myPAD 670 (rechargeable/ CPR)
98073 HeartSave myPAD 670 (rechargeable/ WALN)
98074 HeartSave myPAD 670 (rechargeable/ WALN/ CPR)
98075 HeartSave myPAD 670 (rechargeable/ LTE)
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98095 HeartSave myPAD 678 (rechargeable)
98096 HeartSave myPAD 678 (rechargeable/ CPR)
98097 HeartSave myPAD 678 (rechargeable/ WALN)
98098 HeartSave myPAD 678 (rechargeable/ WALN/ CPR)
98099 HeartSave myPAD 678 (rechargeable/ LTE)
98100 HeartSave myPAD 678 (rechargeable/ LTE/ CPR)
98101 HeartSave myPAD 678 (rechargeable/ WALN/ LTE)
98102 HeartSave myPAD 678 (rechargeable/ WALN/ LTE/ CPR)
98103 HeartSave myPAD 670A (rechargeable)
98104 HeartSave myPAD 670A (rechargeable/ CPR)
98105 HeartSave myPAD 670A (rechargeable/ WALN)

98106 HeartSave myPAD 670A (rechargeable/ WALN/ CPR)
98107 HeartSave myPAD 670A (rechargeable/ LTE)
98108 HeartSave myPAD 670A (rechargeable/ LTE/ CPR)
98109 HeartSave myPAD 670A (rechargeable/ WALN/ LTE)
98110 HeartSave myPAD 670A (rechargeable/ WALN/ LTE/ CPR)
98111 HeartSave myPAD 671A (rechargeable)
98112 HeartSave myPAD 671A (rechargeable/ CPR)
98113 HeartSave myPAD 671A (rechargeable/ WALN)
98114 HeartSave myPAD 671A (rechargeable/ WALN/ CPR)
98115 HeartSave myPAD 671A (rechargeable/ LTE)
98116 HeartSave myPAD 671A (rechargeable/ LTE/ CPR)
98117 HeartSave myPAD 671A (rechargeable/ WALN/ LTE)
98118 HeartSave myPAD 671A (rechargeable/ WALN/ LTE/ CPR)
98119 HeartSave myPAD 675A (rechargeable)
98120 HeartSave myPAD 675A (rechargeable/ CPR)
98121 HeartSave myPAD 675A (rechargeable/ WALN)
98122 HeartSave myPAD 675A (rechargeable/ WALN/ CPR)
98123 HeartSave myPAD 675A (rechargeable/ LTE)
98124 HeartSave myPAD 675A (rechargeable/ LTE/ CPR)
98125 HeartSave myPAD 675A (rechargeable/ WALN/ LTE)
98126 HeartSave myPAD 675A (rechargeable/ WALN/ LTE/ CPR)
98127 HeartSave myPAD 678A (rechargeable)
98128 HeartSave myPAD 678A (rechargeable/ CPR)
98129 HeartSave myPAD 678A (rechargeable/ WALN)
98130 HeartSave myPAD 678A (rechargeable/ WALN/ CPR)
98131 HeartSave myPAD 678A (rechargeable/ LTE)
98132 HeartSave myPAD 678A (rechargeable/ LTE/ CPR)
98133 HeartSave myPAD 678A (rechargeable/ WALN/ LTE)
98134 HeartSave myPAD 678A (rechargeable/ WALN/ LTE/ CPR)

Clase de Riesgo: IV

Indicación/es autorizada/s:

Desfibriladores externos semiautomáticos modelos HeartSave Y, desfibriladores externos automáticos modelos HeartSave YA, desfibriladores externos automáticos y semiautomáticos modelos HeartSave myPAD.

Pueden detectar arritmias cardíacas potencialmente fatales y generan el choque eléctrico necesario para intentar reanimar al paciente (desfibrilación).

El perfil de usuario previsto por el fabricante comprende personas con formación en primeros auxilios y uso del desfibrilador externo automático (DEA), personas con formación en soporte vital básico o avanzado, y personal médico cualificado con formación en reanimación. Asimismo, deberán cumplirse los requisitos de capacitación y uso establecidos por la legislación nacional vigente aplicable.

Período de vida útil: 10 años.

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

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

Forma de presentación: Unitaria.

Método de esterilización: N/A

Nombre del fabricante:

Metrax GmbH

Lugar de elaboración:

Rheinwaldstr. 22,
78628 Rottweil,
Alemania.

Se extiende el presente Certificado de Autorización e Inscripción del PM 1608-118 , con una vigencia cinco (5) años a partir de la fecha de la Disposición autorizante.

1-0047-3110-007491-25-4

Nº Identificador Trámite: 72130

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Digitally signed by FONTANA Luis Eduardo
Date: 2026.10.13 15:51:55 ART
Location: Ciudad Autónoma de Buenos Aires

LUIS EDUARDO FONTANA

Administrador Nacional

Administración Nacional de Medicamentos, Alimentos y Tecnología
Médica