

República de Colombia
Ministerio de Salud y Protección Social
Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA

RESOLUCIÓN No. 2018035108 DE 14 de Agosto de 2018

Por la cual se concede un Registro Sanitario

El Director Técnico de Dispositivos Médicos y otras Tecnologías del Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, en ejercicio de las facultades Legales conferidas en el Decreto 2078 de 2012, decreto Reglamentario 4725 de 2005, ley 1437 de 2011 y ley 962 de 2005

CONSIDERANDO

QUE ANTE ESTE INSTITUTO SE HA SOLICITADO LA CONCESIÓN DE UN REGISTRO SANITARIO AUTOMÁTICO CON BASE EN LA VERIFICACIÓN DE LA DOCUMENTACIÓN TÉCNICO LEGAL ALLEGADA ANTE LA DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS, EMITIENDO CONCEPTO FAVORABLE PARA LA EXPEDICIÓN DE ESTE REGISTRO SANITARIO. EN CONSECUENCIA A LO ANTERIOR, DE CONFORMIDAD CON EL ARTÍCULO 57 DE LA LEY 962 DE 2005 EL INVIMA REALIZARÁ EL CONTROL POSTERIOR DENTRO DE LOS QUINCE (15) DÍAS SIGUIENTES A SU EXPEDICIÓN.

RESUELVE

ARTÍCULO PRIMERO.- CONCEDER REGISTRO SANITARIO POR EL TÉRMINO DE DIEZ (10) AÑOS A

PRODUCTO: CUBIERTAS DE PROTECCIÓN DESECHABLES ESTERIL ALSARO®
MARCA: ALSARO®, ALS-BED CARE, SOLUCIONES MEDICO HOSPITALARIAS®, INVERFARMA®, OTAI®.
REGISTRO SANITARIO NO.: INVIMA 2018DM-0018418
TIPO DE REGISTRO: FABRICAR Y VENDER
TITULAR(ES): DISTRIBUCIONES ALSARO SAS CON DOMICILIO EN BOGOTÁ - D.C.
FABRICANTE(S): DISTRIBUCIONES ALSARO SAS CON DOMICILIO EN BOGOTÁ - D.C.
LABORATORIOS MEGAMEDICAL CON DOMICILIO EN BOGOTÁ - D.C.
EMERGENCIAS CLÍNICAS S.A.S CON DOMICILIO EN BOGOTÁ - D.C.
TIPO DE DISPOSITIVO: NO INVASIVO
RIESGO: I
COMPOSICIÓN:

PARTES QUE COMPONEN EL DISPOSITIVO MÉDICO	COMPOSICIÓN CUALITATIVA
CUBIERTAS DE PROTECCIÓN DESECHABLES ESTERIL ALSARO®	POLIPROPILENO NO TEJIDO SMS VARIEDAD DE COLORES (SPUNBONDING-MELTBLOWN-SPUNBONDING) DE 13 A 150 GR / M2
	POLIPROPILENO NO TEJIDO SPP (SPUNBONDING) DE 13 A 72 GR / M2
	POLIPROPILENO NO TEJIDO SMS LAMINADO (ALTA PROTECCIÓN) (SPUNBONDING-MELTBLOWN-SPUNBONDING) DE 12 A 72 GR / M2
	POLIPROPILENO NO TEJIDO SS (SPUNBONDING-SPUNBONDING) DE 12 A 72 GR / M2
	POLIPROPILENO NO TEJIDO SMMS (SPUNBONDING-MELTBLOWN-MELTBLOWN-SPUNBONDING) DE 13 A 72 GR / M2
	CAUCHO, VELCRO, BROCHES PLÁSTICOS Y CORDONES
	REFUERZO - PLÁSTICO POLIETILENO (PE) ALTA DENSIDAD (HDPE) - BAJA DENSIDAD (LDPE)

USOS: LAS CUBIERTAS DE PROTECCIÓN DESECHABLES ESTERILES EN TELA NO TEJIDA SMS Y/O LAMINADA (ALTA PROTECCIÓN) DEBEN SER USADAS COMO PROTECCIÓN CONTRA FLUIDOS CORPORALES TANTO PARA ÁREAS, EQUIPOS E INSTRUMENTAL O ACCESORIOS, SE EMPLEARÁN DONDE SE REALICEN PROCEDIMIENTOS DE EXAMEN MÉDICO Y/O DIAGNÓSTICO Y QUIRÚRGICOS DE DIFERENTES ESPECIALIDADES PARA REDUCIR LA PROPAGACIÓN / TRANSFERENCIA DE AGENTES INFECCIOSOS / MICROORGANISMOS, CONTAMINANTES Y/O MATERIAL PARTICULADO.

PRESENTACIÓN COMERCIAL: PRODUCTOS ESTERILES: EMPAQUE PRIMARIO (PGM-PAPEL GRADO MÉDICO), DE DIFERENTES MEDIDAS, EMPACADOS DE FORMA INDIVIDUAL, PAQUETES PARA DIFERENTES ESPECIALIDADES MÉDICO QUIRÚRGICAS DE 1 A 100 UNIDADES ; EMPAQUE SECUNDARIO BOLSA DE PLÁSTICO QUE CUBRA TODAS LAS UNIDADES Y TERCIARIO CORRUGADO DE DIFERENTES DIMENSIONES PARA MANIPULACIÓN, TRANSPORTE Y ALMACENAMIENTO COMERCIALIZADO EN EMPAQUE DE 1 A 100 UNIDADES Y/O DE MANERA CONJUNTA Y MUESTRA COMERCIAL

OBSERVACIONES: EL PRESENTE REGISTRO SANITARIO AMPARA LAS SIGUIENTES REFERENCIAS:

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FAMILIA (SI APLICA)	CÓDIGO, MODELO O REFERENCIA (SI APLICA)	DESCRIPCIÓN (SI APLICA)
ALS-0001 BED CARE	90*200/70*200/90*210/90*220/90*230/90*240/90*250/70*200/70*210/70*220/70*230/70*240/70*250/70*300/90*300/145*200/100X100/100X90/100X95/100X85/100X75/100X65/100X55/100X45/100X35/100X80/100X70/100X60/100X50/100X40/100X30/101X101/102X102/103X103/104X104/105X105/106X106/107X107/108X108/109X109/110X110/110X100/110X95/110X90/110X80/110X85/110X75/110X65/110X55/110X45/110X35/110X20/110X10/110X5/110X40/110X30/111X111/112X112/113X113/114X114/115X115/116X116/117X117/118X118/119X119/120X120/120X115/120X105/120X95/120X85/120X75/120X65/120X55/120X45/120X35/120X20/120X10/120X5/120X40/120X30/121X121/122X122/123X123/124X124/125X125/126X126/127X127/128X128/129X129/130X130/130X120/130X115/130X105/130X95/130X85/130X75/130X65/130X55/130X45/130X35/130X20/130X10/130X5/130X40/130X30/130X20/130X10/131X131/132X132/133X133/134X134/135X135/136X136/137X137/138X138/139X139/140X140/140X130/140X120/140X115/140X105/140X95/140X85/140X75/140X65/140X55/140X45/140X35/140X20/140X10/140X5/140X40/140X30/141X141/142X142/143X143/144X144/145X145/145X200/146X146/147X147/148X148/149X149/150X150/150X145/150X140/150X135/150X130/150X125/150X120/150X115/150X110/150X95/150X90/150X85/150X80/150X75/150X70/150X65/150X60/150X55/150X50/145X45/150X40/150X30/151X151/152X152/153X153/154X154/155X155/156X156/157X157/158X158/159X159/160X160/160X155/165X165/160X150/160X145/160X140/160X135/160X130/160X125/160X120/160X115/160X110/160X105/160X100/160X95/160X90/160X85/160X80/160X75/160X70/160X65/160X60/160X55/160X50/160X45/160X40/160X35/160X30/165X165/170X170/170X165/170X160/170X155/170X150/170X145/170X140/170X135/170X130/170X125/170X120/170X115/170X110/170X105/170X100/170X95/170X90/170X85/170X80/170X75/170X70/170X65/170X60/170X55/170X50/170X45/170X40/170X35/170X30/175X175/180X180/180X175/180X170/180X165/180X160/180X155/180X150/180X145/180X140/180X135/180X130/180X125/180X120/180X115/180X110/180X105/180X100/180X95/180X90/180X85/180X80/180X75/180X70/180X65/180X60/180X55/180X50/180X45/180X40/180X35/180X30/185X185/190X190/195X195/190X185/190X180/190X175/190X170/190X165/190X160/190X155/190X150/190X145/190X140/190X135/190X130/190X125/190X120/190X115/190X110/190X105/190X100/190X95/190X90/190X85/190X80/190X75/190X70/190X65/190X60/190X55/190X50/190X45/190X40/190X35/190X30/200X200/205X205/200X205/200X195/200X190/200X185/200X180/200X175/200X170/200X165/200X160/200X155/200X150/200X145/200X140/200X135/200X130/200X125/200X120/200X115/200X110/200X105/200X100/200X95/200X90/200X85/200X80/200X75/200X70/200X65/200X60/200X55/200X50/200X45/200X40/200X35/200X30/200X25/200X20/200X15/200X10/200X5/200X40/200X30/210X210/215X215/210X200/210X195/210X190/210X185/210X180/210X175/210X170/210X165/210X160/210X155/210X150/210X145/210X140/210X135/210X130/210X125/210X120/210X115/210X110/210X105/210X100/210X95/210X90/210X85/210X80/210X75/210X70/210X65/210X60/210X55/210X50/210X45/210X40/210X35/210X30/220X220/225X220/220X230/220X235/220X240/220X245/220X250/220X255/220X260/220X265/220X270/220X275/220X280/220X285/220X290/220X295/220X300/305X220/220X310/220X315/220X320/220X325/220X330/220X335/220X340/220X345/220X350/220X360/220X370/220X380/220X390 /145X2,00 CM	SABANA PLANA O CUBIERTA PLANA/ SABANA FUELLE
ALS-0002 BED CARE	90*200/70*200/90*210/90*220/90*230/90*240/90*250/70*200/70*210/70*220/70*230/70*240/70*250/70*300/90*300/145*200/TIPO A/TIPO B/SABANA ENEMA LAMINADO//100X100/100X90/100X95/100X85/100X75/100X65/100X55/100X45/100X35/100X80/100X70/100X60/100X50/100X40/100X	SABANA RESORTADA O CUBIERTA RESORTADA/FORRO COLCHON

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República de Colombia
Ministerio de Salud y Protección Social
Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA

RESOLUCIÓN No. 2018035108 DE 14 de Agosto de 2018
Por la cual se concede un Registro Sanitario

El Director Técnico de Dispositivos Médicos y otras Tecnologías del Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, en ejercicio de las facultades Legales conferidas en el Decreto 2078 de 2012, decreto Reglamentario 4725 de 2005, ley 1437 de 2011 y ley 962 de 2005

	EQUIPOS	
	CUBIERTA DE PROTECCION PARA INSTRUMENTAL: 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República de Colombia
Ministerio de Salud y Protección Social
Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA

RESOLUCIÓN No. 2018035108 DE 14 de Agosto de 2018

Por la cual se concede un Registro Sanitario

El Director Técnico de Dispositivos Médicos y otras Tecnologías del Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, en ejercicio de las facultades Legales conferidas en el Decreto 2078 de 2012, decreto Reglamentario 4725 de 2005, ley 1437 de 2011 y ley 962 de 2005

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VIDA UTIL: 3 AÑOS
EXPEDIENTE NO.: 20148965
RADICACIÓN NO.: 20181156882
FECHA DE RADICACION: 06 08 2018

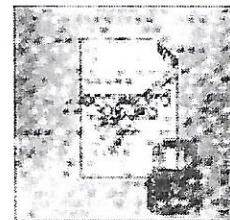
ARTICULO SEGUNDO. - CONTRA LA PRESENTE RESOLUCIÓN PROCEDE ÚNICAMENTE EL RECURSO DE REPOSICIÓN, QUE DEBERÁ INTERPONERSE ANTE EL DIRECTOR DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS, DENTRO DE LOS DIEZ (10) DÍAS SIGUIENTES A SU NOTIFICACIÓN, EN LOS TÉRMINOS SEÑALADOS EN EL CÓDIGO DE PROCEDIMIENTO ADMINISTRATIVO Y DE LO CONTENCIOSO ADMINISTRATIVO.

ARTICULO TERCERO. - LA PRESENTE RESOLUCIÓN RIGE A PARTIR DE LA FECHA DE SU EXPEDICIÓN.

ARTICULO CUARTO. - LOS DERECHOS QUE SE DERIVEN DE ESTA RESOLUCIÓN QUEDARAN SUJETAS AL CONTROL POSTERIOR QUE DEBE REALIZAR EL INSTITUTO NACIONAL DE VIGILANCIA DE MEDICAMENTOS Y ALIMENTOS INVIMA DE CONFORMIDAD CON LO PREVISTO POR EL ARTICULO 22 DEL DECRETO 4725 DE 2005.

COMUNIQUESE, NOTIFIQUESE Y CUMPLASE

DADA EN BOGOTÁ D.C. A LOS 14 DE AGOSTO DE 2018
ESTE ESPACIO, HASTA LA FIRMA SE CONSIDERA EN BLANCO.



(Handwritten signature)

ELKIN HERNAN OTALVARO CIFUENTES
DIRECTOR TECNICO DE DISPOSITIVOS MEDICOS Y OTRAS TECNOLOGIAS
Proyectó: Legal: jmarinc , Técnico: jparraa, Revisó: cordina_varios

Firma válida

Firmado digitalmente por
ELKIN HERNAN
OTALVARO CIFUENTES
Fecha: 2018.08.15
10:45:06 COT
Razón: Invima
Locación: BOGOTA D.C.,
Colombia

Apéndice

INSTITUTO NACIONAL DE VIGILANCIA DE MEDICAMENTOS Y ALIMENTOS	
INVIMA	
A la fecha notifíquese personalmente a _____	
Con identificación No. _____	_____ de _____
y T.P. No. _____	_____ de _____
de la Resolución No. _____	_____ de fecha _____
En Bogotá 23 ABO. 2010	Hora 10:48
Notificado _____	_____
Notificador _____	<i>[Signature]</i>