

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

RESOLUCIÓN No. 2018023770 DE 6 de Junio 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 AUTOMATICO 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 ARTICULO 57 DE LA LEY 962 DE 2005 EL INVIMA REALIZARA EL CONTROL POSTERIOR DENTRO DE LOS QUINCE (15) DIAS SIGUIENTES A SU EXPEDICIÓN.

RESUELVE

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

PRODUCTO: ESFIGMOMANÓMETROS
MARCA: WELCHALLYN
REGISTRO SANITARIO NO.: INVIMA 2018DM-0018127
TIPO DE REGISTRO: IMPORTAR Y VENDER
TITULAR(ES): WELCH ALLYN INC CON DOMICILIO EN ESTADOS UNIDOS DE AMÉRICA
FABRICANTE(S): WELCH ALLYN INC CON DOMICILIO EN ESTADOS UNIDOS DE AMÉRICA
WELCH ALLYN DE MEXICO S DE R.L. DE C.V. CON DOMICILIO EN MEXICO
IMPORTADOR(ES): A.T. MEDICAS S.A. CON DOMICILIO EN MEDELLIN - ANTIOQUIA
ALLERS S.A. CON DOMICILIO EN CALI - VALLE.
IMCOLMEDICA S.A. CON DOMICILIO EN BOGOTA - D.C.
LA MUELA S.A.S. CON DOMICILIO EN BUCARAMANGA – SANTANDER
TECNICA ELECTRO MEDICA S.A. CON DOMICILIO EN BOGOTA - D.C.
V.H.F LTDA CON DOMICILIO EN BOGOTA - D.C.
ACONDICIONADOR(ES): A.T. MEDICAS S.A. CON DOMICILIO EN MEDELLIN - ANTIOQUIA
ALLERS S.A. CON DOMICILIO EN CALI - VALLE.
IMCOLMEDICA S.A. CON DOMICILIO EN BOGOTA - D.C.
IMCOLMEDICA S.A. CON DOMICILIO EN COTA – CUNDINAMARCA
LA MUELA S.A.S. CON DOMICILIO EN GIRON – SANTANDER
TECNICA ELECTRO MEDICA S.A. CON DOMICILIO EN BOGOTA - D.C.
V.H.F LTDA CON DOMICILIO EN BOGOTA - D.C.
TIPO DE DISPOSITIVO NO INVASIVO
RIESGO: I
COMPOSICIÓN:

PARTES QUE COMPONEN EL DISPOSITIVO MÉDICO	COMPOSICIÓN CUALITATIVA
MANÓMETRO ANEROIDE	ABS PLASTIC
PERILLA DE INSUFLACIÓN CON VÁLVULA DE DESINFLADO METAL	GOMA (RUBBER)
TUBO CONECTOR	GOMA (RUBBER)
BRAZALETE ESTÁNDAR DOS PIEZAS	NYLON
BOLSA INFLABLE	NEOPRENE
BRAZALETE REUSABLE FLEXIPOINT DE UNA PIEZA	NYLON

USOS: SON DISPOSITIVOS DE MEDICIÓN DE LA PRESIÓN SANGUINEA NO INVASIVOS DISEÑADOS PARA DETERMINAR LA PRESIÓN SANGUINEA EN PACIENTES DESDE PEDIÁTRICOS HASTA ADULTOS. DURANTE EL PROCEDIMIENTO SE DETERMINAN LA PRESIÓN SISTÓLICA Y DIASTÓLICA.

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PRESENTACIÓN COMERCIAL: PRESENTACIÓN INDIVIDUAL
OBSERVACIONES: EL PRESENTE REGISTRO SANITARIO AMPARA LAS SIGUIENTES
REFERENCIAS:

901040 - 767 SERIES
7670-01 767 WALL ANEROID W/ ADULT CUFF
7670-01CB 767 WALL GAGE, ADULT 2-PC CUFF
7670-01W 767 WALL ANEROID W/ ADULT CUFF, IWS ONLY
7670-02 767 WALL ANEROID MANOMETER ONLY W/ 8' TUBING
7670-10 767 MOBILE ANEROID ON 5-LEG STAND W/ 1-PIECE ADULT CUFF
7670-10CB 767 MOBILE ANEROID ON 5-LEG STAND W/ 2-PIECE ADULT CUFF AND BLADDER
7670-16 767 DESK GAGE, ADULT CUFF
7670-06 767 MOBILE STAND & BASKET ASSEMB ONLY (BASE WEIGHT NOT INCLUDED)
7670-07 INF. SYS. BASKET (L/WHITE)
7670-09 RAIL MOUNT KIT
7670-12 767 ROLLING MOBILE STAND
901041 - DURASHOCK
DS58 DS58 HAND ANEROID ONLY
DS58-11 DS58 HAND ANEROID W/ ADULT CUFF AND CASE
DS58-11CB DS58 HAND ANEROID W/ ADULT CUFF AND BLADDER AND CASE
DS58-MC DS58 HAND ANEROID FAMILY PRACTICE KIT
DS58-MCCB DS58 HAND ANEROID FAMILY PRACTICE KIT W/ CUFF AND BLADDER
DS58-PD DS58 HAND ANEROID PEDIATRIC KIT
DS58-PDCB DS58 HAND ANEROID PEDIATRIC KIT
DS48 DS48 INTEG ANEROID ONLY
DS48-11 DS48 INTEG ANEROID W/ ADULT CUFF AND CASE
DS48-11CB DS48A POCKET ANEROID W/ ADULT CUFF AND CASE
DS48A DS48A POCKET ANEROID ONLY
5090-02 POCKET ANEROID W/ ADULT CUFF
5090-03 GAUGE ONLY
5090-41 POCKET ANEROID W/ L ADULT CUFF
5098-27 DS66 INTEG ANEROID SPHYG. W/ ADULT CUFF
5098-27CB DS66 TRIGGER ANEROID, ADULT 2-PC CUFF
5098-28 DS66 INTEG ANEROID SPHYG. W/ L ADULT CUFF
5098-28CB DS66 TRIGGER ANEROID, LG ADULT 2-PC CUFF
5098-29 DS66 INTEG ANEROID SPHYG. W/ CHILD CUFF
5098-30 DS66 INTEG ANEROID SPHYG. MULTI-CUFF KIT
5098-30CB DS66 TRIGGER ANEROID, 2-PC CUFF KIT
5098-31 DS66 GAUGE ONLY
5098-33 DS66 INTEG ANEROID SPHYG. W/ ADULT AND CHILD PRINT CUFF
DS45 MODEL DS45, GAUGE ONLY
DS45-09 DS45 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, CHILD

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DS45-10 DS45 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, SM ADULT
DS45-11 DS45 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, ADULT
DS45-11C DS45 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, ADULT - W/ CASE
DS45-11CB DS45 INTEG ANEROID SPHYG. W/ ADULT 2-PC CUFF
DS45-12 DS45 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, L ADULT
DS45-13CB DS45 INTEG ANEROID SPHYG. W/ THIGH 2-PC CUFF
DS45-MC DS45 MULTI CUFF KIT
DS45A MODEL DS45, GAUGE W/ INTEG ADAPTER
DS44 MODEL DS44, GAUGE ONLY
DS44-09 DS44 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, CHILD
DS44-09CB DS44 INTEG ANEROID SPHYG. WIT CHILD 2-PC CUFF
DS44-09P DS44 INTEG ANEROID SPHYG. W/ COLOR PRINT CUFF, CHILD
DS44-10 DS44 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, SM ADULT
DS44-11 DS44 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, ADULT
DS44-11C DS44 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, ADULT W/ CASE
DS44-11CB DS44 INTEG ANEROID SPHYG. W/ TWO-TONE (2 PIECE) GRAY CUFF, ADULT
DS44-11CBT DS44 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF W/ TYCOS DIAL, ADULT
DS44-11CV DS44 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, ADULT - W/ CASE
DS44-11V DS44 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, ADULT
DS44-12 DS44 INTEG ANEROID SPHYG. W/ TWO-TONE GRAY CUFF, L ADULT
DS44-13CB DS44 INTEG ANEROID SPHYG. W/ THIGH 2-PC CUFF
DS44A MODEL DS44, GAUGE W/ INTEG ADAPTER
DS44-DUR09 TWO-TONE GRAY CUFF W/ GRAY TUBE, CHILD
DS44-DUR11 TWO-TONE GRAY CUFF W/ GRAY TUBE, ADULT
DS44-DUR11F TWO-TONE GRAY CUFF, W/ GRAY TUBE, ADULT
DS44-DUR12 TWO-TONE GRAY CUFF W/ GRAY TUBE, L ADULT
DS44-DUR12F TWO-TONE GRAY CUFF, W/ GRAY TUBE, L ADULT
DS44-V BUMPER VARIETY PACK
DS45-DUR11 TWO-TONE GRAY CUFF W/ BLACK TUBE, ADULT
DS45-DUR11F TWO-TONE GRAY CUFF W/ BLACK TUBE, L-SIZE BULB, ADULT
DS45-DUR12F TWO-TONE GRAY CUFF W/ BLACK TUBE, L-SIZE BULB, L ADULT
ACCESORIOS
901043 - BRAZALETES FLEXIPOINT REUSABLES
REUSE-06 CUFF, SM INFANT, DUR, (EA)

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REUSE-07 CUFF, INFANT, DUR, (EA)
REUSE-08 CUFF, SM CHILD, DUR, (EA)
REUSE-09 CUFF, CHILD, DUR, (EA)
REUSE-10 CUFF, SM ADULT, DUR, (EA)
REUSE-11 CUFF, ADULT, DUR, (EA)
REUSE-11L CUFF, ADULT LONG, DUR, (EA)
REUSE-12 CUFF, L ADULT, DUR, (EA)
REUSE-12L CUFF, L ADULT LONG, DUR, (EA)
REUSE-13 CUFF, THIGH, DUR, (EA)
REUSE-MLT CUFF, DUR, ASSORTED CONNECTORS (8 PACK)
5082-159 WASH CAP, FLEXIPOINT BP CUFF, (EA)
REUSE-06-1HP CUFF, SM INFANT, DUR, 1-TUBE, HP (EA)
REUSE-06-1MQ CUFF, SM INFANT, DUR, 1-TUBE, LOCK (EA)
REUSE-06-1SC CUFF, SM INFANT, DUR, 1-TUBE, SCREW (EA)
REUSE-06-1TP CUFF, SM INFANT, DUR, 1-TUBE, TRI-PUR (EA)
REUSE-07-1HP CUFF, INFANT, DUR, 1-TUBE, HP (EA)
REUSE-07-1MQ CUFF, INFANT, DUR, 1-TUBE, LOCK (EA)
REUSE-07-1SC CUFF, INFANT, DUR, 1-TUBE, SCREW (EA)
REUSE-07-1TP CUFF, INFANT, DUR, 1-TUBE, TRI-PUR (EA)
REUSE-07-2BV INF. SYS., INFANT, DUR, 2-TUBE, BULB AND VALVE (EA)
REUSE-07-2MF CUFF, REUS, INFANT, 2-TUBE, MF
REUSE-07-2MQ CUFF, INFANT, DUR, 2-TUBE, LOCK (EA)
REUSE-07-2SC CUFF, INFANT, DUR, 2-TUBE, SCREW (EA)
REUSE-07-2TP CUFF, INFANT, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-07-2TPE CUFF, INFANT, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-08-1HP CUFF, SM CHILD, DUR, 1-TUBE, HP (EA)
REUSE-08-1MQ CUFF, SM CHILD, DUR, 1-TUBE, LOCK (EA)
REUSE-08-1SC CUFF, SM CHILD, DUR, 1-TUBE, SCREW (EA)
REUSE-08-1TP CUFF, SM CHILD, DUR, 1-TUBE, TRI-PUR (EA)
REUSE-08-2BV INF. SYS., SM CHILD, DUR, 2-TUBE, BULB AND VALVE (EA)
REUSE-08-2MF CUFF, REUS SM CHILD 2-TUBE MF
REUSE-08-2MQ CUFF, SM CHILD, DUR, 2-TUBE, LOCK (EA)
REUSE-08-2SC CUFF, SM CHILD, DUR, 2-TUBE, SCREW (EA)
REUSE-08-2TP CUFF, SM CHILD, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-08-2TPE CUFF, SM CHILD, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-09-1HP CUFF, CHILD, DUR, 1-TUBE, HP (EA)
REUSE-09-1MQ CUFF, CHILD, DUR, 1-TUBE, LOCK (EA)
REUSE-09-1SC CUFF, CHILD, DUR, 1-TUBE, SCREW (EA)
REUSE-09-1TP CUFF, CHILD, DUR, 1-TUBE, TRI-PUR (EA)
REUSE-09-2BV INF. SYS., CHILD, DUR, 2-TUBE, BULB AND VALVE (EA)
REUSE-09-2MF CUFF, REUS, CHILD, 2-TUBE MF
REUSE-09-2MQ CUFF, CHILD, DUR, 2-TUBE, LOCK (EA)
REUSE-09-2SC CUFF, CHILD, DUR, 2-TUBE, SCREW (EA)
REUSE-09-2TP CUFF, CHILD, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-09-2TPE CUFF, CHILD, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-10-1HP CUFF, SM ADULT, DUR, 1-TUBE, HP (EA)
REUSE-10-1MQ CUFF, SM ADULT, DUR, 1-TUBE, LOCK (EA)
REUSE-10-1SC CUFF, SM ADULT, DUR, 1-TUBE, SCREW (EA)

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REUSE-10-1TP CUFF, SM ADULT, DUR, 1-TUBE, TRI-PUR (EA)
REUSE-10-2BV INF. SYS., SM ADULT, DUR, 2-TUBE, BULB AND VALVE (EA)
REUSE-10-2MF CUFF, REUS, SM AD, 2-TUBE, MF
REUSE-10-2MQ CUFF, SM ADULT, DUR, 2-TUBE, LOCK (EA)
REUSE-10-2SC CUFF, SM ADULT, DUR, 2-TUBE, SCREW (EA)
REUSE-10-2TP CUFF, SM ADULT, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-10-2TPE CUFF, SM ADULT, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-11-1HP CUFF, ADULT, DUR, 1-TUBE, HP (EA)
REUSE-11-1MQ CUFF, ADULT, DUR, 1-TUBE, LOCK (EA)
REUSE-11-1SC CUFF, ADULT, DUR, 1-TUBE, SCREW (EA)
REUSE-11-1TP CUFF, ADULT, DUR, 1-TUBE, TRI-PUR (EA)
REUSE-11-2BV INF. SYS., ADULT, DUR, 2-TUBE, BULB AND VALVE (EA)
REUSE-11-2MF CUFF, REUS, ADULT, 2-TUBE, MF
REUSE-11-2MQ CUFF, ADULT, DUR, 2-TUBE, LOCK (EA)
REUSE-11-2SC CUFF, ADULT, DUR, 2-TUBE, SCREW (EA)
REUSE-11-2TP CUFF, ADULT, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-11-2TPE CUFF, ADULT, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-11L-1HP CUFF, ADULT LONG, DUR, 1-TUBE, HP (EA)
REUSE-11L-1MQ CUFF, ADULT LONG, DUR, 1-TUBE, LOCK (EA)
REUSE-11L-1SC CUFF, ADULT LONG, DUR, 1-TUBE, SCREW (EA)
REUSE-11L-1TP CUFF, ADULT LONG, DUR, 1-TUBE, TRI-PUR (EA)
REUSE-11L-2BV INF. SYS., ADULT LONG, DUR, 2-TUBE, BULB AND VALVE (EA)
REUSE-11L-2MQ CUFF, ADULT LONG, DUR, 2-TUBE, LOCK (EA)
REUSE-11L-2SC CUFF, ADULT LONG, DUR, 2-TUBE, SCREW (EA)
REUSE-11L-2TP CUFF, ADULT LONG, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-12-1HP CUFF, L ADULT, DUR, 1-TUBE, HP (EA)
REUSE-12-1MQ CUFF, L ADULT, DUR, 1-TUBE, LOCK (EA)
REUSE-12-1SC CUFF, L ADULT, DUR, 1-TUBE, SCREW (EA)
REUSE-12-1TP CUFF, L ADULT, DUR, 1-TUBE, TRI-PUR (EA)
REUSE-12-2BV INF. SYS., L ADULT, DUR, 2-TUBE, BULB AND VALVE (EA)
REUSE-12-2MF CUFF, REUS, LG AD, 2-TUBE, MF
REUSE-12-2MQ CUFF, L ADULT, DUR, 2-TUBE, LOCK (EA)
REUSE-12-2SC CUFF, L ADULT, DUR, 2-TUBE, SCREW (EA)
REUSE-12-2TP CUFF, L ADULT, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-12-2TPE CUFF, L ADULT, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-12L-1HP CUFF, L ADULT LONG, DUR, 1-TUBE, HP (EA)
REUSE-12L-1MQ CUFF, L ADULT LONG, DUR, 1-TUBE, LOCK (EA)
REUSE-12L-1SC CUFF, L ADULT LONG, DUR, 1-TUBE, SCREW (EA)
REUSE-12L-1TP CUFF, L ADULT LONG, DUR, 1-TUBE, TRI-PUR (EA)
REUSE-12L-2BV INF. SYS., L ADULT LONG, DUR, 2-TUBE, BULB AND VALVE (EA)
REUSE-12L-2MQ CUFF, L ADULT LONG, DUR, 2-TUBE, LOCK (EA)
REUSE-12L-2SC CUFF, L ADULT LONG, DUR, 2-TUBE, SCREW (EA)
REUSE-12L-2TP CUFF, L ADULT LONG, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-13-1HP CUFF, THIGH, DUR, 1-TUBE, HP (EA)
REUSE-13-1MQ CUFF, THIGH, DUR, 1-TUBE, LOCK (EA)
REUSE-13-1SC CUFF, THIGH, DUR, 1-TUBE, SCREW (EA)
REUSE-13-1TP CUFF, THIGH, DUR, 1-TUBE, TRI-PUR (EA)

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REUSE-13-2BV INF. SYS., THIGH, DUR, 2-TUBE, BULB AND VALVE (EA)
REUSE-13-2MF CUFF, REUS, THIGH, 2-TUBE, MF
REUSE-13-2MQ CUFF, THIGH, DUR, 2-TUBE, LOCK (EA)
REUSE-13-2SC CUFF, THIGH, DUR, 2-TUBE, SCREW (EA)
REUSE-13-2TP CUFF, THIGH, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-13-2TPE CUFF, THIGH, DUR, 2-TUBE, TRI-PUR (EA)
REUSE-08 CUFF, SM CHILD, DUR, (EA)
REUSE-09 CUFF, CHILD, DUR, (EA)
REUSE-10 CUFF, SM ADULT, DUR, (EA)
REUSE-11 CUFF, ADULT, DUR, (EA)
REUSE-11L CUFF, ADULT LONG, DUR, (EA)
REUSE-12 CUFF, L ADULT, DUR, (EA)
REUSE-12L CUFF, L ADULT LONG, DUR, (EA)
REUSE-13 CUFF, THIGH, DUR, (EA)
901044 - BRAZALETES DESECHABLES
SOFT-09 CUFF, CHILD, DISP., SOFT, (20 PACK)
SOFT-10 CUFF, SM ADULT, DISP., SOFT, (20 PACK)
SOFT-11 CUFF, ADULT, DISP., SOFT, (20 PACK)
SOFT-11L CUFF, ADULT LONG, DISP., SOFT, (20 PACK)
SOFT-12 CUFF, L ADULT, DISP., SOFT, (20 PACK)
SOFT-12L CUFF, L ADULT LONG, DISP., SOFT, (20 PACK)
SOFT-13 CUFF, THIGH, DISP., SOFT, (20 PACK)
SOFT-MLT CUFF, , DISP. SOFT, ASSORTED CONNECTORS (8 PACK)
SOFT-06-1HP CUFF, SM INFANT, DISP., SOFT, 1-TUBE, HP (20 PACK)
SOFT-06-1MQ CUFF, SM INFANT, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-06-1SC CUFF, SM INFANT, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-06-1TP CUFF, SM INFANT, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)
SOFT-07-1HP CUFF, INFANT, DISP., SOFT, 1-TUBE, HP (20 PACK)
SOFT-07-1MQ CUFF, INFANT, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-07-1SC CUFF, INFANT, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-07-1TP CUFF, INFANT, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)
SOFT-07-2MQ CUFF, INFANT, DISP., SOFT, 2-TUBE, LOCK (20 PACK)
SOFT-07-2SC CUFF, INFANT, DISP., SOFT, 2-TUBE, SCREW (20 PACK)
SOFT-07-2TP CUFF, INFANT, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-07-2TPE CUFF, INFANT, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-08-1HP CUFF, SM CHILD, DISP., SOFT, 1-TUBE, HP (20 PACK)
SOFT-08-1MQ CUFF, SM CHILD, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-08-1SC CUFF, SM CHILD, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-08-1TP CUFF, SM CHILD, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)
SOFT-08-2MQ CUFF, SM CHILD, DISP., SOFT, 2-TUBE, LOCK (20 PACK)
SOFT-08-2SC CUFF, SM CHILD, DISP., SOFT, 2-TUBE, SCREW (20 PACK)
SOFT-08-2TP CUFF, SM CHILD, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-08-2TPE CUFF, SM CHILD, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-09-1HP CUFF, CHILD, DISP., SOFT, 1-TUBE, HP (20 PACK)
SOFT-09-1MQ CUFF, CHILD, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-09-1SC CUFF, CHILD, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-09-1TP CUFF, CHILD, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)

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SOFT-09-2MQ CUFF, CHILD, DISP., SOFT, 2-TUBE, LOCK (20 PACK)
SOFT-09-2SC CUFF, CHILD, DISP., SOFT, 2-TUBE, SCREW (20 PACK)
SOFT-09-2TP CUFF, CHILD, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-09-2TPE CUFF, CHILD, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-10-1HP CUFF, SM ADULT, DISP., SOFT, 1-TUBE, HP (20 PACK)
SOFT-10-1MQ CUFF, SM ADULT, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-10-1SC CUFF, SM ADULT, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-10-1TP CUFF, SM ADULT, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)
SOFT-10-2MQ CUFF, SM ADULT, DISP., SOFT, 2-TUBE, LOCK (20 PACK)
SOFT-10-2SC CUFF, SM ADULT, DISP., SOFT, 2-TUBE, SCREW (20 PACK)
SOFT-10-2TP CUFF, SM ADULT, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-10-2TPE CUFF, SM ADULT, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-11-1HP CUFF, ADULT, DISP., SOFT, 1-TUBE, HP (20 PACK)
SOFT-11-1MQ CUFF, ADULT, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-11-1SC CUFF, ADULT, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-11-1TP CUFF, ADULT, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)
SOFT-11-2MQ CUFF, ADULT, DISP., SOFT, 2-TUBE, LOCK (20 PACK)
SOFT-11-2SC CUFF, ADULT, DISP., SOFT, 2-TUBE, SCREW (20 PACK)
SOFT-11-2TP CUFF, ADULT, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-11-2TPE CUFF, ADULT, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-11L-1HP CUFF, ADULT LONG, DISP., SOFT, 1-TUBE, HP (20 PACK)
SOFT-11L-1MQ CUFF, ADULT LONG, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-11L-1SC CUFF, ADULT LONG, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-11L-1TP CUFF, ADULT LONG, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)
SOFT-11L-2MQ CUFF, ADULT LONG, DISP., SOFT, 2-TUBE, LOCK (20 PACK)
SOFT-11L-2SC CUFF, ADULT LONG, DISP., SOFT, 2-TUBE, SCREW (20 PACK)
SOFT-11L-2TP CUFF, ADULT LONG, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-12-1HP CUFF, L ADULT, DISP., SOFT, 1-TUBE, HP (20 PACK)
SOFT-12-1MQ CUFF, L ADULT, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-12-1SC CUFF, L ADULT, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-12-1TP CUFF, L ADULT, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)
SOFT-12-2MQ CUFF, L ADULT, DISP., SOFT, 2-TUBE, LOCK (20 PACK)
SOFT-12-2SC CUFF, L ADULT, DISP., SOFT, 2-TUBE, SCREW (20 PACK)
SOFT-12-2TP CUFF, L ADULT, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-12-2TPE CUFF, L ADULT, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-12L-1HP CUFF, L ADULT LONG, DISP., SOFT, 1-TUBE, HP (20 PACK)
SOFT-12L-1MQ CUFF, L ADULT LONG, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-12L-1SC CUFF, L ADULT LONG, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-12L-1TP CUFF, L ADULT LONG, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)
SOFT-12L-2MQ CUFF, L ADULT LONG, DISP., SOFT, 2-TUBE, LOCK (20 PACK)
SOFT-12L-2SC CUFF, L ADULT LONG, DISP., SOFT, 2-TUBE, SCREW (20 PACK)
SOFT-12L-2TP CUFF, L ADULT LONG, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-13-1HP CUFF, THIGH, DISP., SOFT, 1-TUBE, HP (20 PACK)

República de Colombia
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RESOLUCIÓN No. 2018023770 DE 6 de Junio 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

SOFT-13-1MQ CUFF, THIGH, DISP., SOFT, 1-TUBE, LOCK (20 PACK)
SOFT-13-1SC CUFF, THIGH, DISP., SOFT, 1-TUBE, SCREW (20 PACK)
SOFT-13-1TP CUFF, THIGH, DISP., SOFT, 1-TUBE, TRI-PUR (20 PACK)
SOFT-13-2MQ CUFF, THIGH, DISP., SOFT, 2-TUBE, LOCK (20 PACK)
SOFT-13-2SC CUFF, THIGH, DISP., SOFT, 2-TUBE, SCREW (20 PACK)
SOFT-13-2TP CUFF, THIGH, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-13-2TPE CUFF, THIGH, DISP., SOFT, 2-TUBE, TRI-PUR (20 PACK)
SOFT-07-2BV INF. SYS., INFANT, DISP., SOFT, 2-TUBE, BULB AND VALVE (20 PACK)
SOFT-08-2BV INF. SYS., SM CHILD, DISP., SOFT, 2-TUBE, BULB AND VALVE (20 PACK)
SOFT-09-2BV INF. SYS., CHILD, DISP., SOFT, 2-TUBE, BULB AND VALVE (20 PACK)
SOFT-10-2BV INF. SYS., SM ADULT, DISP., SOFT, 2-TUBE, BULB AND VALVE (20 PACK)
SOFT-11-2BV INF. SYS., ADULT, DISP., SOFT, 2-TUBE, BULB AND VALVE (20 PACK)
SOFT-11L-2BV INF. SYS., ADULT LONG, DISP., SOFT, 2-TUBE, BULB AND VALVE (20 PACK)
SOFT-12-2BV INF. SYS., L ADULT, DISP., SOFT, 2-TUBE, BULB AND VALVE (20 PACK)
SOFT-12L-2BV INF. SYS., L ADULT LONG, DISP., SOFT, 2-TUBE, BULB AND VALVE (20 PACK)
SOFT-13-2BV INF. SYS., THIGH, DISP., SOFT, 2-TUBE, BULB AND VALVE (20 PACK)
SOFT-08 CUFF, SM CHILD, DISP., SOFT, (20 PACK)
SOFT-09 CUFF, CHILD, DISP., SOFT, (20 PACK)
SOFT-10 CUFF, SM ADULT, DISP., SOFT, (20 PACK)
SOFT-11 CUFF, ADULT, DISP., SOFT, (20 PACK)
SOFT-11L CUFF, ADULT LONG, DISP., SOFT, (20 PACK)
SOFT-12 CUFF, L ADULT, DISP., SOFT, (20 PACK)
SOFT-12L CUFF, L ADULT LONG, DISP., SOFT, (20 PACK)
SOFT-13 CUFF, THIGH, DISP., SOFT, (20 PACK)
901045 - BLOOD PRESSURE CUFF, SINGLE PATIENT
ECOCUFF-09 FLEXIPOINT ECOCUFF, CHILD, 15-21CM
ECOCUFF-10 FLEXIPOINT ECOCUFF, SM ADULT 20-28CM
ECOCUFF-11 FLEXIPOINT ECOCUFF, ADULT 27-38CM
ECOCUFF-12 FLEXIPOINT ECOCUFF, L/ADULT 33-45CM
ECOCUFF MLT FLEXIPOINT ECOCUFF MULTI-PACK
PORT-1 BP FLEXIPOINT FITTING, 1-TUBE, (PACK OF 10)
PORT-2 BP FLEXIPOINT FITTING, 2-TUBE, (PACK OF 10)
PORT-KIT BP FLEXIPOINT CONNECTORS, BOX OF VARIOUS CONNECTORS
1-BARB BP PORT FITTING, 1-TUBE, BARBS, (PACK OF 10)
1-SC BP PORT FITTING, 1-TUBE, SCREW, (PACK OF 10)
1-MQ BP PORT FITTING, 1-TUBE, LOCK, (PACK OF 10)
1-HP BP PORT FITTING, 1-TUBE, BAYONET, (PACK OF 10)
1-TPS BP PORT FITTING, 1-TUBE, TRI-PUR, (PACK OF 10)

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1-TPSE BP PORT FITTING, 1-TUBE, SM TRI-PUR, (PACK OF 10)
1-TPL BP PORT FITTING, 1-TUBE, TRI-PUR, (PACK OF 10)
1-TPLE BP PORT FITTING, 1-TUBE, L TRI-PUR, (PACK OF 10)
2-BARB BP PORT FITTING, 2-TUBE, BARBS, (PACK OF 10)
2-SC BP PORT FITTING, 2-TUBE, SCREW, (PACK OF 10)
2-MF BP PORT FITTING, 2 TUBE, M/F LOCK, (PACK OF 10)
2-SCC BP PORT FITTING, 2-TUBE, SCREW & CLAMP, (PACK OF 10)
2-MQ BP PORT FITTING, 2-TUBE, LOCK, (PACK OF 10)
2-TP BP PORT FITTING, 2-TUBE, TRI-PUR, (PACK OF 10)
2-TPLE BP PORT FITTING, 2-TUBE, L TRI-PUR, (PACK OF 10)
2-TPSE BP PORT FITTING, 2-TUBE, SM TRI-PUR, (PACK OF 10)
2-SRC BP PORT FITTING, 2-TUBE, FOR SRC, (PACK OF 10)
2-BVL BP PORT FITTING, 2-TUBE, L BULB AND VALVE, (PACK OF 10)
2-BVLC BP PORT FITTING, 2-TUBE, L BULB, VALVE AND CLAMP, (PACK OF 10)
2-BVS BP PORT FITTING, 2-TUBE, SM BULB AND VALVE, (PACK OF 10)
2-BVSC BP PORT FITTING, 2-TUBE, SM BULB, VALVE AND CLAMP, (PACK OF 10)
2-BVD BP PORT FITTING, 2-TUBE, ECONOMIC BULB, (PACK OF 10)
2-BVDC BP PORT FITTING, 2-TUBE, ECONOMIC BULB AND CLAMP, (PACK OF 10)
5082-159 WASH CAP, FLEXIPOINT BP CUFF, (EA)
5082-03 INFANT CUFF W/ 1 TUBE BAG
5082-07 NEWBORN CUFF W/ 1 TUBE BAG
5082-42 CHILD CUFF W/ 1 TUBE BAG
5082-43 ADULT CUFF W/ 1 TUBE BAG
5082-44 L ADULT CUFF W/ 1 TUBE BAG
5082-62 CHILD PRINT CUFF W/ 1 TUBE BAG
5082-77 THIGH CUFF W/ 1 TUBE BAG
5089-03 ADULT W/ 1 TUBE BAG
5089-04 CHILD W/ 1 TUBE BAG
5089-18 THIGH W/ 1 TUBE BAG
5089-21 L ADULT W/ 1 TUBE BAG
5089-25 INFANT W/ 1 TUBE BAG
5089-37 NEWBORN W/ 1 TUBE BAG
5082-01H ADULT CUFF (12/BOX)
5082-08 INFANT CUFF W/ 2 TUBE BAG
5082-144 NEWBORN CUFF W/ 2 TUBE BAG
5082-24 CHILD CUFF W/ 2 TUBE BAG
5082-25 ADULT CUFF W/ 2 TUBE BAG
5082-26 L ADULT CUFF W/ 2 TUBE BAG
5082-78 THIGH CUFF W/ 2 TUBE BAG
5089-01 ADULT W/ 2 TUBES BAG
5089-02 CHILD W/ 2 TUBES BAG
5089-19 THIGH W/ 2 TUBES BAG
5089-22 L ADULT W/ 2 TUBES BAG
5089-26 INFANT W/ 2 TUBES BAG
5089-38 NEWBORN W/ 2 TUBE BAG

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5089-11 METAL TWIST FIT CONNECTOR SET
5089-12 TUBING (27" LENGTH)
5089-13 COIL TUBING-8' LENGTH
5089-13H COIL TUBING (12/BOX)
5089-39 COIL TUBING-4' LENGTH
5082-01 ADULT CUFF
5082-02 CHILD CUFF
5082-11 THIGH CUFF
5082-16 L ADULT CUFF
5082-18 CHILD PRINT CUFF
5086-01 PREM. BULB, MD (BLACK)
5086-01H LATEX INF. BULB (12/BOX)
5086-03H L INF. BULB (6/BOX)
5086-06 INF. BULB, RED NEOPRENE
5086-08 STANDARD BULB (GRAY)
5087-01 AIR RELEASE VALVE, PREM.
5087-01H AIR RELEASE VALVE (12/BOX)
5087-10 KNOB, DURASHOCK CLASSIC
5087-16 AIR RELEASE VALVE, STANDARD
5088-01 AIR RELEASE VALVE AND LATEX INF. BULB
5088-01H BULB AND VALVE COMBINATION (12/BOX)
5091-13 INF. SYS. BASKET (SM/STAINLESS)
5091-47 INF. SYS. BASKET (L/BLACK)
7670-07 INF. SYS. BASKET (L/WHITE)
5082-141 ADULT (BLUE) INF. SYS. W/ 2 TUBE BAG
5082-21 CHILD INF. SYS. W/ 2 TUBE BAG
5082-22 ADULT INF. SYS. W/ 2 TUBE BAG
5082-22H INF. SYS., ADULT (6/BOX)
5082-23 L ADULT INF. SYS. W/ 2 TUBE BAG
5082-23H INF. SYS., L ADULT (6/BOX)
5082-45 THIGH INF. SYS. W/ 2 TUBE BAG
5089-01H INF. BAG, ADULT (2 TUBES) (12/BOX)
5089-22H INF. BAG, L ADULT (2 TUBES) (6/BOX)

EXPEDIENTE NO.: 20145869
RADICACIÓN NO.: 20181108201
FECHA DE RADICACIÓN: 31 05 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

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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 6 DE JUNIO DE 2018
ESTE ESPACIO, HASTA LA FIRMA SE CONSIDERA EN BLANCO.



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