



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

ANEXO II

DECLARACIÓN DE CONFORMIDAD INICIAL – PM CLASE I- II

Número de revisión: 2396-17#0001

Número de PM:

2396-17

Nombre Descriptivo del producto:

Set de infusión intravenosa y líneas de extensión

Código de identificación y nombre técnico UMDNS:

12-157 Juegos para administración intravenosa

Clase de Riesgo:

Clase II

Marca de (los) producto(s) médico(s):

Kapsam

Modelos (en caso de clase II y equipos):

KS-IV101 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV101-PF 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV102 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV102-PF 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR

WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV103 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV103-PF 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV104 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 1-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV104-PF 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 1-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV105 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 1-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV105-PF 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 1-WAY CONNECTOR WITH CHECK-VALVE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV106 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING, MLL 2xDRIP CHAMBER

KS-IV106-PF 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING, MLL 2xDRIP CHAMBER

KS-IV107 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING MLL 2xDRIP CHAMBER

KS-IV107-PF 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING MLL 2xDRIP CHAMBER

KS-IV108 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING MLL 2xDRIP CHAMBER

KS-IV108-PF 1 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 1-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING MLL 2xDRIP CHAMBER

KS-IV201 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV201-PF 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV202 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV202-PF 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV203 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV203-PF 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV204 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 2-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV204-PF 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 2-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV205 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 2-WAY CONNECTOR WITH CHECK-VALVE, TRANSDUCER LINE, STOPCOCK, T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV205-PF 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 2-WAY CONNECTOR WITH CHECK-VALVE, TRANSDUCER LINE, STOPCOCK, T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV206 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING, MLL, 2XDRIP CHAMBER

KS-IV206-PF 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING, MLL, 2XDRIP CHAMBER

KS-IV207 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING, MLL, 2XDRIP CHAMBER

KS-IV207-PF 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING, MLL, 2XDRIP CHAMBER

KS-IV208 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2 WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING, MLL 2xDRIP CHAMBER

KS-IV208-PF 2 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 2-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING, MLL 2xDRIP CHAMBER

KS-IV201A 2 WAY IV INFUSION MULTIPLEXER SET, Spike, Clamp, 4 Way Y Connector, Check Valve, Needle Free, Twist Off

KS-IV201A-PF 2 WAY IV INFUSION MULTIPLEXER SET, Spike, Clamp, 4 Way Y Connector, Check Valve, Needle Free, Twist Off

KS-IV202A 2 WAY IV INFUSION MULTIPLEXER SET, Spike, Clamp 4 Way Y Connector, Needle Free, Twist Off

KS-IV202A-PF 2 WAY IV INFUSION MULTIPLEXER SET, Spike, Clamp 4 Way Y Connector, Needle Free, Twist Off

KS-IV203A 2 WAY IV INFUSION MULTIPLEXER SET, Spike Clamp, 4 Way Y Connector, Check Valve, Needle Free, Twist Off

KS-IV203A-PF 2 WAY IV INFUSION MULTIPLEXER SET, Spike Clamp, 4 Way Y Connector, Check Valve, Needle Free, Twist Off

KS-IV401 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET 4-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV401-PF 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV402 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV402-PF 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV403 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV403-PF 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV404 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 4-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV404-PF 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 4-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV405 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 4-WAY CONNECTOR WITH CHECK-VALVE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV405-PF 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, SAFETY CHECK-VALVE ON-LINE, 4-WAY CONNECTOR WITH CHECK-VALVE, TRANSDUCER LINE, STOPCOCK T-CONNECTOR PORT WITH NEEDLE-FREE, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV406 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING, MLL 2xDRIP CHAMBER

KS-IV406-PF 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH CHECK-VALVE AND NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING, MLL 2xDRIP CHAMBER

KS-IV407 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING MLL 2xDRIP CHAMBER

KS-IV407-PF 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH NEEDLE FREE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING MLL 2xDRIP CHAMBER

KS-IV408 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4 WAY CONNECTOR WITH

CHECK-VALVE, NEEDLE FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING MLL 2xDRIP CHAMBER
KS-IV408-PF 4 WAY IV CHEMOTHERAPY ADMINISTRATION SET, 4-WAY CONNECTOR WITH CHECK-VALVE, NEEDLE FREE Y- CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING MLL 2xDRIP CHAMBER
KS-IV401A 4 WAY IV INFUSION MULTIPLEXER SET, Spike Clamp, 4 Way Y Connector, Check Valve Needle Free, Twist Off
KS-IV401A-PF 4 WAY IV INFUSION MULTIPLEXER SET, Spike Clamp, 4 Way Y Connector, Check Valve Needle Free, Twist Off
KS-IV402A 4 WAY IV INFUSION MULTIPLEXER SET, Spike, Clamp, 4 Way Y Connector, Needle Free, Twist Off
KS-IV402A-PF 4 WAY IV INFUSION MULTIPLEXER SET, Spike, Clamp, 4 Way Y Connector, Needle Free, Twist Off
KS-IV403A 4 WAY IV INFUSION MULTIPLEXER SET, Spike, Clamp, 4 Way Y Connector, Check Valve, Twist Off
KS-IV403A-PF 4 WAY IV INFUSION MULTIPLEXER SET, Spike, Clamp, 4 Way Y Connector, Check Valve, Twist Off
KS-225 Extension line, LARGE-BORE (3X4.1mm)/26cm LIGHT-PROTECTED DEHP-FREE TUBING WITH CHECK-VALVE, MLL/MLL END
KS-226 Extension line, LARGE-BORE (3X4.1mm)/29cm LIGHT-PROTECTED DEHP-FREE TUBING, NEEDLE-FREE Y-CONNECTION PORT, TWO-WAY SPIKE/CHECK-VALVE, MLL END
KS-226CV Extension line, LARGE-BORE (3X4.1mm)/29cm LIGHT-PROTECTED DEHP-FREE TUBING, NEEDLE-FREE Y-CONNECTION PORT, TWO-WAY SPIKE/CHECK-VALVE, MLL END
KS-227 Extension line, 0.2 micron I.V. FILTER AND NEEDLE-FREE Y-CONNECTION PORT, LARGE-BORE(3X4.1mm)/29cm LIGHT-PROTECTED DEHP-FREE TUBING, TWO-WAY SPIKE/MLL END
KS-227CV Extension line, 0.2-micron I.V. FILTER AND NEEDLE-FREE Y-CONNECTION PORT, LARGE-BORE (3X4.1mm)/29cm LIGHT-PROTECTED DEHP-FREE TUBING, TWO-WAY SPIKE/MLL END
KS-228 Extension line, 1.2 micron BABY I.V. FILTER, SMALL-BORE (1x2.5mm)/15cm LIGHT-PROTECTED DEHP-FREE TUBING, MLL/FLL END
KS-229 Extension line, SMALL-BORE (1x2.5mm)/15cm LIGHT-PROTECTED DEHP-FREE TUBING MLL/FLL END
KS-229T Extension line, SMALL-BORE (1x2.5mm)/15cm TRANSPARENT DEHP-FREE TUBING, MLL/FLL END
KS-230 Extension line, TRIPLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 3 NEEDLE-FREE CONNECTOR, MLL/FLL END
KS-231 Extension line, TRIPLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 3 NEEDLE-FREE CONNECTOR, MLL/FLL END
KS-232 Extension line, TRIPLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 3 NEEDLE-FREE CONNECTOR AND 3 CHECK-VALVE, MLL/FLL END
KS-233 Extension line, TRIPLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 3 NEEDLE-FREE CONNECTOR AND 2 CHECK-VALVE MLL/FLL END
KS-234 Extension line, TRIPLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 3 NEEDLE-FREE CONNECTOR AND 1 CHECK-VALVE, MLL/FLL END
KS-235 Extension line, TRIPLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 0.2-micron BABY I.V. FILTER, 3 NEEDLE-FREE VEN VALVE AND 3 CHECK-VALVE, MLL/FLL
KS-236 Extension line, TRIPLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 0.2-micron BABY I.V. FILTER, 3 NEEDLE-FREE VEN VALVE AND 2 CHECK-VALVE, MLL/FLL END

KS-237 Extension line, 3-WAY STOPCOCK
KS-238 Extension line, 0.2-micron I.V. FILTER POSITIVE BABY TYPE, RMLL/FLL END
KS-239 Extension line, 0.2 micron I.V. FILTER, POSITIVE, PEDIATRIC-TYPE, RMLL/FLL END
KS-240 Extension line, 1.2 micron I.V. FILTER ADULT-TYPE, RMLL/FLL END
KS-241 Extension line, LARGE-BORE (3x4,1mm) LIGHT-PROTECTED DEHP-FREE TUBING, MLL/FLL END
KS-242 Extension line, CHECK-VALVE CONNECTOR, MLL/FLL END
KS-243 Extension line, NEEDLE-FREE CONNECTOR, MLL/FLL END
KS-244 Extension line, SYRINGE ADAPTOR MLL/FLL
KS-245 Extension line, 0.2 micron I.V. FILTER, LARGE-BORE (3X4.1mm)/15cm LIGHT-PROTECTED DEHP-FREE TUBING, MLL/MLL END
KS-246 Extension line, 0.2 micron I.V. FILTER, LARGE-BORE (3X4.1mm)/15cm LIGHT-PROTECTED DEHP-FREE TUBING, MLL/FLL END
KS-247 Extension line, 1.2-micron BABY I.V. FILTER, SMALL-BORE (1x2.5mm)/10cm LIGHT-PROTECTED DEHP-FREE TUBING, MLL/FLL END
KS-248 Extension line, 0,2-micron BABY I.V. FILTER, SMALL-BORE (1x2.5mm)/10cm LIGHT-PROTECTED DEHP-FREE TUBING, MLL/FLL END
KS-249 Extension line, TRIPLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 0.2-micron - 1.2-micron BABY I.V. FILTER AND 3 NEEDLE-FREE VEN VALVE, MLL/FLL
KS-250 Extension line, DOUBLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 2 NEEDLE-FREE CONNECTOR, MLL/FLL END
KS-251 Extension line, DOUBLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 2 CHECK-VALVE, MLL/FLL END
KS-252-02 Extension line, DOUBLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 0.2-micron BABY I.V. FILTER AND 2 NEEDLE-FREE CONNECTOR, MLL/FLL END
KS-252-12 Extension line, DOUBLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 1.2-micron BABY I.V. FILTER AND 2 NEEDLE-FREE CONNECTOR, MLL/FLL END
KS-253 Extension line, TWO-WAY SPIKE ADAPTOR WITH NEEDLE-FREE CONNECTOR
KS-254 Extension line, TWO-WAY MICRO SPIKE ADAPTOR WITH NEEDLE-FREE CONNECTOR
KS-254-1314 Extension line, TWO-WAY MICRO SPIKE ADAPTOR FOR 13-14 mm, NEEDLE-FREE CONNECTOR
KS-254-2021 Extension line, TWO-WAY MICRO SPIKE ADAPTOR FOR 20-21 mm, NEEDLE-FREE CONNECTOR
KS-255 Extension line, ONE-WAY SPIKE ADAPTOR FOR BAG ACCESS WITH NEEDLE-FREE CONNECTOR
KS-256 Extension line, ONE-WAY SPIKE ADAPTOR FOR BAG ACCESS WITH NEEDLE-FREE CONNECTOR AND CHECK-VALVE
KS-257A Extension line, 0.2-micron POSITIVE I.V. FILTER, RMLL/FLL END
KS-258K Extension line, 1.2-micron I.V. FILTER PEDIATRIC-TYPE, RMLL/FLL END
KS-259B Extension line, 1.2-micron I.V. FILTER BABY-TYPE, RMLL/FLL END
KS-250CV Extension line, DOUBLE LUMEN SMALL-BORE (1x2.5mm) LIGHT-PROTECTED DEHP-FREE TUBING WITH 2 NEEDLE-FREE CONNECTOR, 2 CHECK-VALVE, MLL/FLL END
KS-260FR Extension line, FLOW REGULATOR, TRANSPARENT LARGE-BORE (3X4.1mm)/50cm DEHP-FREE TUBING MLL/FLL END
KS-260FR-PF Extension line, FLOW REGULATOR, TRANSPARENT LARGE-BORE (3X4.1mm)/50cm PVC-FREE TUBING, MLL/FLL END
KS-261FR Extension line, FLOW REGULATOR AND Y-SITE INJECTION PORT, LARGE-BORE

(3X4.1mm)/46cm TRANSPARENT DEHP-FREE TUBING, MLL/FLL END

KS-261FR-PF Extension line, FLOW REGULATOR AND Y-SITE INJECTION PORT, LARGE-BORE (3X4.1mm)/46cm TRANSPARENT PVC-FREE TUBING, MLL/FLL END

KS-262FR Extension line, FLOW REGULATOR AND NEEDLE-FREE Y-CONNECTION PORT, LARGE-BORE (3X4.1mm)/46cm TRANSPARENT 3 DEHP-FREE TUBING, MLL/FLL END

KS-262FR-PF Extension line, FLOW REGULATOR AND NEEDLE-FREE Y-CONNECTION PORT, LARGE-BORE (3X4.1mm)/46cm TRANSPARENT PVC-FREE TUBING, MLL/FLL END

KS-263 Extension line, 1.2-micron I.V. FILTER, LARGE-BORE (3X4.1mm)/15cm LIGHT-PROTECTED DEHP-FREE TUBING, MLL/FLL END

KS-264 Extension line, SMALL-BORE (1X2.5mm)/10cm LIGHT-PROTECTED DEHP-FREE TUBING WITH NEEDLE-FREE CONNECTOR, MLL/FLL END

KS-264-CV Extension line, SMALL-BORE (1x2.5mm)/10cm LIGHT-PROTECTED DEHP-FREE TUBING WITH NEEDLE-FREE CONNECTOR, CHECK-VALVE, MLL/FLL END

KS-265 Extension line, SMALL-BORE (1x2.5mm)/10cm LIGHT-PROTECTED DEHP-FREE TUBING WITH CHECK-VALVE, MLL/FLL END

KS-266 Extension line, INTEGRATED WITH PHARMASCOPE HIGH-VOLUME TRANSFER SET (HYBRID SET)

KS-267 Extension line, STOPCOCK WITH NEEDLE FREE VALVE AND MALE LUER ACTIVATED

KS-IV301 FLOW REGULATOR IV INFUSION SET, DRIP CHAMBER W VENTED SPIKE, Y-SITE INJECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV301-PF FLOW REGULATOR IV INFUSION SET, DRIP CHAMBER W VENTED SPIKE, Y-SITE INJECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) PUR-FREE TUBING

KS-IV302-02 IV INFUSION SET WITH FLOW REGULATOR AND 0.2 MICRON FILTER, 0.2 MICRON I. V. FILTER, DRIP CHAMBER W VENTED SPIKE, Y-SITE INJECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV302-PF-02 IV INFUSION SET WITH FLOW REGULATOR AND 0.2 MICRON FILTER, 0.2 MICRON I.V. FILTER, DRIP CHAMBER W VENTED SPIKE, Y-SITE INJECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) PURE TUBING

KS-IV303-12 IV INFUSION SET WITH FLOW REGULATOR AND 1.2 MICRON FILTER, 1.2 Micron I.V. FILTER, DRIP CHAMBER W VENTED SPIKE, Y-SITE INJECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV303-PF-12 IV INFUSION SET WITH FLOW REGULATOR AND 1.2 MICRON FILTER, 1.2 Micron I.V. FILTER, DRIP CHAMBER w VENTED SPIKE, Y-SITE INJECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV501 IV INFUSION SET, DRIP CHAMBER W VENTED SPIKE, Y-SITE INJECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV501-PF IV INFUSION SET, DRIP CHAMBER W VENTED SPIKE, Y-SITE INJECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV502 IV INFUSION SET, DRIP CHAMBER W VENTED SPIKE, NEEDLE FREE Y-CONNECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV502-PF IV INFUSION SET, DRIP CHAMBER W VENTED SPIKE, NEEDLE FREE Y-CONNECTION PORT, TRANSPARENT LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV503 IV INFUSION SET, VENTED SPIKE, DRIP CHAMBER, ROLLER CLAMP, Y-SITE INJECTION PORT, LIGHT- PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV503-PF IV INFUSION SET, VENTED SPIKE, DRIP CHAMBER, ROLLER CLAMP, Y-SITE INJECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

KS-IV504 IV INFUSION SET, VENTED SPIKE, DRIP CHAMBER, ROLLER CLAMP, NEEDLE-FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) DEHP-FREE TUBING

KS-IV504-PF IV INFUSION SET, VENTED SPIKE, DRIP CHAMBER, ROLLER CLAMP,

NEEDLE-FREE Y-CONNECTION PORT, LIGHT-PROTECTED LARGE-BORE (3X4.1mm) PUR TUBING

Composición cuali-cuanti porcentual exacta (si corresponde):

No aplica.

Indicación/es autorizada/s:

Los productos están indicados para proporcionar una conexión y extensión seguras para la transferencia de fluidos entre una fuente de fluido intravenoso y el paciente.

Período de vida útil (si corresponde):

5 años.

Método de Esterilización (si corresponde):

ETO.

Forma de presentación:

Por unidad. Por 30, 50, 75, 100, 200 unidades.

Condición de uso:

Uso exclusivo a profesionales e instituciones sanitarias

Nombre del fabricante:

Kapsam Saglik Urunleri Ltd

Lugar/es de elaboración:

Cumhuriyet Mah. ismet Inonu Cd., No: 57 Cayirova, Kocaeli, 41420, Turquía.

En nombre y representación de la firma Inhar Ingeniería Hospitalaria S.A. , el responsable legal y el responsable técnico declaran bajo juramento que los productos médicos enumerados en el presente Anexo, satisfacen los Requisitos Esenciales de Seguridad y Desempeño de Productos Médicos por la Disposición ANMAT N° 11467/24, que cumplen y se encuentra a disposición de la Autoridad Sanitaria la documentación técnica que contenga los requerimientos solicitados en el Apéndice IV y V del Anexo del Reglamento Técnico aprobado por Disposición ANMAT N° 64/25 y Disposición ANMAT N° 9688/19.

CUMPLIMIENTO DE REQUISITOS ESENCIALES DE SEGURIDAD Y DESEMPEÑO.
DISPOSICIÓN ANMAT N° 11467/24 Y GESTIÓN DE RIESGO

ENSAYO/VALIDACION/GESTION DE RIESGO	LABORATORIO /N° DE PROTOCOLO	FECHA DE EMISIÓN
1. TS EN ISO 13485:2016 EN ISO 14971:2020 EN 62366-1:2015 MEDDEV 2.7/1 EN ISO 11607-1:2020 EN ISO 11607-2:2020 EN ISO 8536-4:2020 EN ISO 8536-8:2015 EN ISO 8536-9:2015 EN ISO 8536- 10:2015 EN ISO 8536- 11:2015 EN ISO 8536-12: 2021 EN ISO 8536-13:2016 EN ISO 8536-14:2018 EN ISO 8536-14:2018	No aplica.	No aplica.
2. TS EN ISO 13485:2016 EN ISO 14971:2020 EN 62366-1:2015 EN ISO 11607-1:2020 EN ISO 11607-2:2020 MEDDEV 2.7/1 EN ISO 8536-4:2020 EN ISO 8536-8:2015 EN ISO 8536-9:2015 EN ISO 8536- 10:2015 EN ISO 8536- 11:2015 EN ISO 8536-12: 2021 EN ISO 8536-13:2016 EN ISO 8536-14:2018 EN ISO 8536-14:2018 EN ISO 15223-1:2021	No aplica.	No aplica.
3. TS EN ISO 13485:2016 EN ISO 14971:2020 EN 62366-1:2015 EN ISO 11607-1:2020 EN ISO 11607-2:2020 MEDDEV 2.7/1 EN ISO 8536-4:2020 EN ISO 8536-8:2015 EN ISO 8536-9:2015	No aplica.	No aplica.

EN ISO 8536- 10:2015 EN ISO 8536- 11:2015 EN ISO 8536-12: 2021 EN ISO 8536-13:2016 EN ISO 8536-14:2018 EN ISO 8536-14:2018		
4. TS EN ISO 13485:2016 EN ISO 14971:2020 EN 62366-1:2015 MEDDEV 2.7/1 ASTM F1980 EN ISO 11607-1:2020 EN ISO 11607-2:20204	No aplica.	No aplica.
5. TS EN ISO 13485:2016 EN ISO 14971:2020 EN 62366-1:2015 ASTM F1980 EN ISO 11607-1:2020 EN ISO 11607-2:2020 EN ISO 15223:2021	No aplica.	No aplica.
6. TS EN ISO 13485:2016 EN ISO 14971:2020 EN 62366-1:2015 MEDDEV 2.7/1 EN ISO 11607-1:2020 EN ISO 11607-2:2020 EN ISO 10993-10:2014	No aplica.	No aplica.
7. TS EN ISO 13485:2016 EN ISO 14971:2020 EN 62366-1:2015 MEDDEV 2.7/1 EN ISO 10993-1:2021 EN ISO 10993-5:2021 EN ISO 10993-4:2020 EN ISO 10993-10:2014 EN ISO 10993-11:2018 EN 868-5:2019 EN ISO 11607-2:2020 EN ISO 10993-12:2021 EN ISO 10993-7:2010 ISO 10993-7:2008/AMD1:2019 EN ISO 8536-4:2020 EN ISO 8536-8:2015 EN ISO 8536-11:2015 EN ISO 8536-10:2015 EN ISO 8536-13:2016 EN ISO 8536-9:2015	No aplica.	No aplica.

EN ISO 8536-12:2021 EN ISO 11607-1:2020 EN ISO 8536-14:2018 EN ISO 11607-2:2020		
8. TS EN ISO 13485:2016 EN ISO 8536-4:2020 EN ISO 8536-8:2015 EN ISO 8536-10:2015 EN ISO 8536-11:2015 EN ISO 8536-12:2021 EN ISO 8536-13:2016 EN ISO 8536-9:2015 EN ISO 11607-1:2020 EN 868-5:2019 EN ISO 11607-2:2020 ASTM F1980-16 EN ISO 15223-1:2021 EN ISO 20417:2021 EN ISO 11135:2014 EN ISO 14937:2011 EN ISO 11138-1:2017 EN ISO 11138-2:2017 EN ISO 18472:2018 EN ISO 11737-1:2018 EN ISO 14644-1:2016 EN ISO 14644-2:2016 EN ISO 14644-3:2019 EN ISO 14644-4:2006 EN ISO 14644-8:2022	No aplica.	No aplica.
9. EN ISO 8536-4:2020 EN ISO 8536-8:2015 EN ISO 8536-10:2015 EN ISO 8536-11:2015 EN ISO 8536-12:2021 EN ISO 8536-13:2016 EN ISO 8536-9:2015 EN ISO 8536-14:2018 EN ISO 11607-1:2020 ASTM F1980-16 TS EN ISO 13485:2016 EN ISO 10993-12: 2021 EN ISO 14971:2020 EN 62366-1:2015	No aplica.	No aplica.
10. EN ISO 8536-4:2020 EN ISO 8536-9:2015	No aplica.	No aplica.
11. No aplica.	No aplica.	No aplica.
12.	No aplica.	No

EN ISO 14971:2020 EN 62366-1:2015 EN ISO 8536-4:2020 EN ISO 8536-8:2015 EN ISO 8536-10:2015 EN ISO 8536-11:2015 EN ISO 8536-12:2021 EN ISO 80369-7:2021 EN ISO 8536-13:2016 EN ISO 8536-9:2015 EN ISO 8536-14:2018 EN 868-5:2019		aplica.
13. EN ISO 15223-1 :2021 EN ISO 20417:2021 EN 62366-1:2015 EN ISO 8536-8:2015 EN ISO 8536-10:2015 EN ISO 8536-11:2015 EN ISO 8536-12:2021 EN ISO 8536-9:2015 EN ISO 11607-1:2020 EN 868-5:2019 EN ISO 8536-4:2020 EN 15986- 1:2011	No aplica.	No aplica.

El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento mantener en su establecimiento y a disposición de la autoridad sanitaria la documentación allí declarada y la que establece la Disposición 9688/19, bajo apercibimiento de lo que establece la Ley N° 16.463, el Decreto N° 341/92 y las que correspondan del Código Penal en caso de falsedad.

En caso de inexactitud o falsedad de la información o documentación, la Administración Nacional podrá suspender, cancelar, prohibir la comercialización y solicitar retiro del mercado de lo ya autorizado e iniciar los sumarios que pudieran corresponder.

LUGAR Y FECHA: Argentina, 06 abril 2026

Responsable Legal
Firma y Sello

Responsable Técnico
Firma y Sello



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 9688/19, quedando inscripta en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de **Inhar Ingeniería Hospitalaria S.A.** bajo el número PM **2396-17**

Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad en la Ciudad de Buenos Aires a los días 06 abril 2026 la cual tendrá una vigencia de cinco (5) años a contar de la fecha.

Dirección de Evaluación de Registro
Firma y Sello

Instituto Nacional de Productos Médicos
Firma y Sello



Código "N°rev legajo#version" vigente a partir de 07/02/22, reemplaza la anterior codificación.
La validez del presente documento deberá verificarse mediante el código QR.

Tramitada por Expediente N°: 1-0047-3110-002389-26-3