



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

DECLARACION JURADA DE REVÁLIDA

DISPOSICIÓN ANMAT N° 9688/2019

N° rev: 1136-65#0001

En nombre y representación de la firma Electromedik S.A. , el responsable legal y el responsable técnico declaran bajo juramento cumplir con la Disposición 9688/19 I Anexo V para el producto médico inscripto bajo el Número de PM: 1136-65

Disposición autorizante N° DC N°00 de fecha 12 marzo 2018
Disposiciones modificatorias y reválidas N°: No aplica.

Datos Característicos del Producto Médico:

Nombre descriptivo: Circuito paciente de anestesia

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
10-139 Circuitos Respiratorios Externos Anestesia

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

Clase de Riesgo: II

Indicación/es autorizada/s: Los circuitos respiratorios de anestesia se emplean para la conducción de gases anestésicos en pacientes adultos, niños y lactantes. Están diseñados para pacientes en prácticas anestésicas de emergencia y estándar. El usuario debe estar familiarizado y haber recibido formación en cuanto a la selección del sistema y sobre el uso y el mantenimiento del producto.

Modelos: o Mapleson

038-01-255 Mapleson C Bagging System (1.6m) 10mm lightweight corrugated tube with 2L Reservoir Bag and Adult APL Valve + 15F/6-9mm adapter

038-01-256 Mapleson A Magill System (1.6m) 22mm lightweight corrugated tube with 2L Reservoir Bag and Adult APL Valve

038-01-257 Mapleson A Parallel Lack System (1.6m) 22mm lightweight corrugated tubes with 2L Reservoir Bag and Adult APL Valve

038-01-258 Mapleson C Bagging System (2.1m) Star Lumen tube with 2L Reservoir Bag and

Adult APL Valve + 22mm Female adapter

038-01-258A Mapleson C Bagging System (4m) Star Lumen tube with 2L Reservoir Bag and Adult APL Valve + 22mm Female adapter

038-01-251 Mapleson D Bain System (1.6m) 22mm lightweight corrugated tube with 2L Reservoir Bag and Adult APL Valve

038-01-251Ag Argentic Mapleson D Bain System (1.6m) 22mm lightweight corrugated tube with 2L Reservoir Bag and Adult APL Valve

038-01-253 Mapleson D Bain System (2.4m) 22mm lightweight corrugated tube with 2L Reservoir Bag and Adult APL Valve

038-01-254 Mapleson D Bain System (5.4m) 22mm lightweight corrugated tube with 2L Reservoir Bag and Adult APL Valve

038-01-200 Basic Bain Coaxial System (1.6m) 22mm lightweight, flexible corrugated tube with 22mm M swivel connector + low profile elbow

038-01-200B Basic Bain Coaxial System (1.6m) with limb 22mm lightweight, flexible corrugated tube with 22mm M / 15mm F swivel connector + 2L Reservoir Bag + low profile elbow + two spare M/M connectors + 1.6m limb

038-01-210 Basic Bain Coaxial System (2.4m) 22mm lightweight, flexible corrugated tube with 22mm M swivel connector + low profile elbow

038-02-270 Mapleson C Direct System (1.6m) 10mm corrugated tube with 0.5L reservoir bag and paediatric APL valve with spare 15F/6-9mm connector

038-02-271 Mapleson C Paediatric Bagging System (1.6m) 10mm corrugated tube with 0.5L reservoir bag and paediatric APL valve with spare 15F/6-9mm connector

038-02-272 Mapleson C Direct System (1.6m) 10mm corrugated tube with 1L reservoir bag and paediatric APL valve with spare 15F/6-9mm connector

038-02-273 Mapleson F Ayres T-Piece with APL Valve (1.6m) 10mm corrugated tube fresh gas line with 15mm M connector and spare 15F/6-9mm flexible connector with 0.5L closed tail reservoir bag and paediatric APL valve

038-02-190 Mapleson F Infant T-Piece (2.1m) Star lumen tubing with 22mm F spare connector, 0.5L open tail reservoir bag

038-02-191 Mapleson F Infant T-Piece (1.6m) 10mm corrugated tube fresh gas line with 15mm M connector and spare 15F/6-9mm flexible connector with 0.5L open tail reservoir bag

038-02-195 Mapleson F Ayres T-Piece (2.1m) Star lumen tube with 22mm F spare connector, 0.5L open tail reservoir bag and double swivel elbow with elastomeric cap

038-02-196 Mapleson F Ayres T-Piece (1.6m) 10mm corrugated tube, fresh gas line with 22mm F connector with 0.5L open tail reservoir bag and double swivel elbow

038-02-196C Mapleson F Ayres T-Piece (1.6m) 10mm corrugated tube, fresh gas line with 22mm F connector with 0.5L open tail reservoir bag and double swivel elbow + monitoring line

038-02-198 Mapleson F Ayres T-Piece (2.1m) Star lumen tube with 22mm F spare connector, 1L reservoir bag and double swivel elbow with elastomeric cap

o Paralelo básico

038-01-100 Basic Parallel (1.6m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + spare M/M connector

038-01-100Ag Argentic Basic Parallel (1.6m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + spare M/M connector

038-01-102 Basic Parallel with Swivel Y (1.6m) 22mm lightweight, flexible corrugated tube with Swivel Y piece and 22mm F connectors + spare M/M connector

038-01-103 Basic Parallel with Swivel Y (2.4m) 22mm lightweight, flexible corrugated tube with Swivel Y piece and 22mm F connectors + spare M/M connector

038-01-105 Basic Parallel (2.4m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + spare M/M connector

038-01-105Ag Argentic Basic Parallel (2.4m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + spare M/M connector

038-01-120 Basic Parallel (1.6m) with limb 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + 0.8m F/F limb + spare M/M connector

038-01-120Ag Argentic Basic Parallel (1.6m) with limb 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + 0.8m F/F limb + spare M/M connector

038-01-125 Basic Parallel (2.4m) with limb 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + 0.8m F/F limb + spare M/M connector

038-01-122 Basic Parallel (1.6m) with Swivel Y + limb 22mm lightweight, flexible corrugated tube with Swivel Y piece and 22mm F connectors + 0.8m F/F limb + spare M/M connector

038-01-110 Basic Parallel (1.6m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + 0.8m F/F limb + Low Profile Elbow + 2L Reservoir Bag + spare M/M connector

038-01-110Ag Argentic Basic Parallel (1.6m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + 0.8m F/F limb + Low Profile Elbow + 2L Reservoir Bag + spare M/M connector

038-01-110GE Basic Parallel (1.6m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + 0.8m F/F limb + Low Profile Elbow + 2L Reservoir Bag + spare M/M connector with fixed angled elbow bag connector compatible with Advanced Breathing System (ABS) Technology

038-01-110LX Basic Parallel (2.4m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + 0.8m F/F limb + Low Profile Elbow + 2L Reservoir Bag + spare M/M connector

038-01-110LXGE Basic Parallel (2.4m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + 0.8m F/F limb + Low Profile Elbow + 2L Reservoir Bag + spare M/M connector with fixed angled elbow bag connector compatible with Advanced Breathing System (ABS) Technology

038-01-110LXXY Basic Parallel (4.5m) 22mm lightweight, flexible corrugated tube with parallel Y piece and 22mm F connectors + 1.6m F/F limb + Low Profile Elbow + 2L Reservoir Bag + spare M/M connector

o Paralelo Flexi-Lock

038-01-106 Flexi-Lock Parallel (2.0m expanded) with Y piece and 22mm F connectors + 0.8m F/F limb + spare M/M connector + Low Profile Elbow

o Interior liso

038-01-104 Adult Smooth Bore Circuit (1.6m) 22mm lightweight smooth bore tubing with parallel Y piece and flexible 22mm F connectors + spare 22mm M/M connector

038-01-107 Adult Smooth Bore Circuit (2.4m) 22mm lightweight smooth bore tubing with parallel Y piece and flexible 22mm F connectors + spare 22mm M/M connector

038-01-108 Adult Smooth Bore Circuit (1.6m) 22mm lightweight smooth bore tubing with detachable parallel Y piece and flexible 22mm F connectors + spare 22mm M/M connector

038-01-109 Adult Smooth Bore Circuit (2.4m) 22mm lightweight smooth bore tubing with detachable parallel Y piece and flexible 22mm F connectors + spare 22mm M/M connector

038-01-123 Adult Smooth Bore Circuit (1.6m) with limb 22mm lightweight smooth bore tubing with detachable parallel swivel Y piece and flexible 22mm F connectors + 0.8m F/F limb + spare 22mm M/M connector

038-01-124 Adult Smooth Bore Circuit (1.6m) 22mm lightweight smooth bore tubing with parallel Y piece and flexible 22mm F connectors + 0.8m F/F limb + spare 22mm M/M connector

038-01-127 Adult Smooth Bore Circuit with limb (2.4m) 22mm lightweight smooth bore tubing with parallel Y piece and flexible 22mm F connectors + 0.8m F/F limb + spare 22mm M/M connector

038-01-128 Adult Smooth Bore Circuit (1.6m) with limb 22mm lightweight smooth bore tubing with detachable parallel Y piece and flexible 22mm F connectors + 0.8m F/F limb + spare 22mm M/M connector

038-02-163 Paediatric Smooth Bore Circuit (1.5m) 15mm lightweight smooth bore tubing with detachable Y piece and flexible 22mm F connectors + spare 22mm M/M connector

038-02-164 Paediatric Smooth Bore Circuit (1.5m) 15mm lightweight smooth bore tubing with low dead space Y piece + Monitoring Ports and flexible 22mm F connectors + spare 22mm M/M connector

038-02-166 Paediatric Smooth Bore Circuit (1.5m) 15mm lightweight smooth bore tubing with parallel Y piece and flexible 22mm F connectors + spare 22mm M/M connector

038-02-162 Paediatric Smooth Bore Circuit (1.5m) 15mm lightweight smooth bore tubing with bifurcated Y piece with monitoring ports and flexible 22mm F connectors + spare 22mm M/M connector

o Ventiflow

038-01-500 Ventiflow (1.6m) Circuit with Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-500Ag Argentic Ventiflow (1.6m) Circuit with Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-501 Ventiflow Basic (1.6m) Circuit with 2L Reservoir Bag, Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-505 Ventiflow (2.4m) Circuit with Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-506 Ventiflow Basic (2.4m) Circuit with 2L Reservoir Bag, Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-506Ag Argentic Ventiflow Basic (2.4m) Circuit with 2L Reservoir Bag, Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-510 Ventiflow Standard (1.6m) Circuit with Monitoring Line, Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-510Ag Argentic Ventiflow Standard (1.6m) Circuit with Monitoring Line, Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-515 Ventiflow Standard (2.4m) Circuit with Monitoring Line, Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-520 Ventiflow Plus (1.6m) Circuit with Adult APL Valve, 2L Reservoir Bag, Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-520Ag Argentic Ventiflow Plus (1.6m) Circuit with Adult APL Valve, 2L Reservoir Bag, Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-525 Ventiflow Plus (2.4m) Circuit with Adult APL Valve, 2L Reservoir Bag, Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-530 Ventiflow Max (1.6m) Circuit with Adult APL Valve, 2L Reservoir Bag, integral Monitoring Line and Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-530Ag Argentic Ventiflow Max (1.6m) Circuit with Adult APL Valve, 2L Reservoir Bag, integral Monitoring Line and Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

038-01-535Ag Argentic Ventiflow Max (2.4m) Circuit with Adult APL Valve, 2L Reservoir Bag, integral Monitoring Line and Flexi-lock expandable limb + spare 22mm M/M connector + Elbow

o Entonox

038-01-176 Entonox Circuit with Mouth Piece (2.4m) Low resistance corrugated tube with 22mm F connector, one way valve and mouth piece

038-01-177 Entonox Circuit with Mask (2.4m) Low resistance 22mm corrugated tube with 22mm F connector, one way valve and face mask

038-01-178 Entonox Circuit with Mouth Piece and Mask (2.4m) Low resistance 22mm corrugated tube with 22mm F connector, one way valve, mouth piece and face mask

o Circulares paralelos

038-02-180 Paediatric Flexi-Lock Parallel (1.5m Expandable) 15mm corrugated tube, parallel Y piece, 22mm F connectors + spare 22mm M/M connector

038-02-165 Basic Parallel (1.6m) Low resistance 15mm corrugated tube, parallel Y piece, 22mm F connectors + spare 22mm M/M connector

o Inteliflo

038-01-900 Inteliflo Plus Adult Kit 1 - 1.0m

038-01-901 Inteliflo Plus Adult Kit 1 - 1.5m

038-01-902 Inteliflo Plus Adult Kit 1 - 1.8m

038-01-903 Inteliflo Plus Adult Kit 1 - 2.7m

038-01-904 Inteliflo Plus Adult Kit 2 - 1.0m

038-01-905 Inteliflo Plus Adult Kit 2 - 1.5m

038-01-906 Inteliflo Plus Adult Kit 2 - 1.8m

038-01-907 Inteliflo Plus Adult Kit 2 - 2.7m

038-01-910 Inteliflo Standard Adult Kit 1 - 1.0m

038-01-911 Inteliflo Standard Adult Kit 1 - 1.5m

038-01-912 Inteliflo Standard Adult Kit 1 - 1.8m

038-01-913 Inteliflo Standard Adult Kit 1 - 2.7m

038-01-914 Inteliflo Standard Adult Kit 2 - 1.0m

038-01-915 Inteliflo Standard Adult Kit 2 - 1.5m

038-01-916 Inteliflo Standard Adult Kit 2 - 1.8m

038-01-917 Inteliflo Standard Adult Kit 2 - 2.7m

038-01-920 Inteliflo Basic Kit 1 - 1.0m

038-01-921 Inteliflo Basic Kit 1 - 1.5m

038-01-922 Inteliflo Basic Kit 1 - 1.8m

038-01-923 Inteliflo Basic Kit 1 - 2.7m

038-01-950 Inteliflo Plus Adult Kit 3 - 1.0m

038-01-951 Inteliflo Plus Adult Kit 3 - 1.5m

038-01-952 Inteliflo Plus Adult Kit 3 - 1.8m

038-01-953 Inteliflo Plus Adult Kit 3 - 2.7m

038-01-954 Inteliflo Plus Adult Kit 4 - 1.0m

038-01-955 Inteliflo Plus Adult Kit 4 - 1.5m

038-01-956 Inteliflo Plus Adult Kit 4 - 1.8m

038-01-957 Inteliflo Plus Adult Kit 4 - 2.7m

038-01-960 Inteliflo Standard Adult Kit 3 - 1.0m

038-01-961 Inteliflo Standard Adult Kit 3 - 1.5m

038-01-962 Inteliflo Standard Adult Kit 3 - 1.8m

038-01-963 Inteliflo Standard Adult Kit 3 - 2.7m

038-01-964 Inteliflo Standard Adult Kit 4 - 1.0m

038-01-965 Inteliflo Standard Adult Kit 4 - 1.5m

038-01-966 Inteliflo Standard Adult Kit 4 - 1.8m

038-01-967 Inteliflo Standard Adult Kit 4 - 2.7m

038-01-970 Inteliflo Basic Kit 2 - 1.0m

038-01-971 Inteliflo Basic Kit 2 - 1.5m

038-01-972 Inteliflo Basic Kit 2 - 1.8m

038-01-973 Inteliflo Basic Kit 2 - 2.7m

Período de vida útil: 5 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biológico: No aplica.

Forma de presentación: Por unidad.

Método de esterilización: No aplica.

Nombre del fabricante: Flexicare Medical Limited

Lugar de elaboración: Cynon Valley Business Park, Mountain Ash, CF45 4ER, Reino Unido.

El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento que el producto médico no ha sufrido modificaciones según Artículo 11° Disposición 9688/19, que cumple y satisface los Requisitos Esenciales de Seguridad y Eficacia (R.E.S.E.) previstos por la Disposición ANMAT N° 4306/99.

La empresa mantiene en su establecimiento y a disposición de la autoridad sanitaria la documentación requerida por disposición ANMAT N° 2318/02 y 9688/19

Responsable Legal
Firma y Sello

Responsable Técnico
Firma y Sello

La presente DECLARACIÓN JURADA ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 9688/19, quedando inscripta la reválida en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de Electromedik S.A. bajo el número PM 1136-65 siendo su nueva vigencia hasta el 12 marzo 2028

Instituto Nacional de Productos Médicos ANMAT
Firma y Sello

El presente certificado será válido únicamente cuando se presente junto con las Disposiciones previas del PM enunciadas anteriormente y sea verificado con su código QR a través de la página

de ANMAT.

Fecha de emisión: 02 junio 2023



La validez del presente documento deberá verificarse mediante el código QR.

N° Identificador Trámite: 46462

Tramitada por Expediente N°: 1-0047-3110-001296-23-1