



Ministerio de Salud
Secretaría de Políticas, Regulación e Institutos
A.N.M.A.T.

ANEXO II

DECLARACIÓN DE CONFORMIDAD INICIAL – PM CLASE I- II

Número de revisión: 00

Número de PM:

1136-65

Nombre Descriptivo del producto:

Circuito paciente de anestesia

Código de identificación y nombre técnico UMDNS:

10-139 Circuitos Respiratorios Externos Anestesia

Clase de Riesgo:

Clase II

Marca de (los) producto(s) médico(s):

Flexicare

Modelos (en caso de clase II y equipos):

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

Composición cuali-cuanti porcentual exacta (si corresponde):

No aplica

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.

Período de vida útil (si corresponde):

5 años

Método de Esterilización (si corresponde):

No aplica

Forma de presentación:

Por unidad

Condición de venta:

Venta Exclusiva a Profesionales e Instituciones Sanitarias

Nombre del fabricante:

Flexicare Medical Limited

Lugar/es de elaboración:

Cynon Valley Business Park, Mountain Ash, CF454ER. Reino Unido.

En nombre y representación de la firma Electromedik 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 Eficacia (R.E.S.E.) previstos por la Disposición ANMAT N° 4306/99, que cumplen y se encuentra a disposición de la Autoridad Sanitaria la documentación técnica que contenga los requerimientos solicitados en los Anexos III.B y III.C del Reglamento Técnico aprobado por Disposición ANMAT N° 2318/02 (TO 2004) y Disposición ANMAT N° 727/13.

CUMPLIMIENTO DE R.E.S.E. DISPOSICIÓN ANMAT N° 4306/99 Y GESTIÓN DE RIESGO

ENSAYO/VALIDACION/GESTION DE RIESGO	LABORATORIO/N° DE PROTOCOLO	FECHA DE EMISIÓN
1. BS EN ISO 14971:2012 EN ISO 13845:2012 ISO 10993-1:2009 BS EN ISO 5356-1:2004	No aplica	No aplica

ISO 5367:2000		
2. BS EN ISO 14971:2012		
ISO 9001:2008		
ISO 13485:2012		
3. BS EN ISO 14971:2012		
BS EN ISO 5356-1:2004		
ISO 5367:2000		
ISO 9001:2008		
ISO 13485:2012		
EN 868-5:2009		
BS EN ISO 15223-1:2016		
BS EN 980:2008		
4. ISO 10993-1:2009		
BS EN ISO 14971:2012		
ISO 9001:2008		
ISO 13485:2012		
5. BS EN ISO 14971:2012		
BS EN ISO 15223-1:2016		
BS EN 980:2008		
EN 868-5:2009		
6. BS EN ISO 14971:2012		
BS EN ISO 15223-1:2016		
BS EN 980:2008		
MDD 93/42/EEC 2007		
7.1 BS EN ISO 14971:2012		
ISO 10993-1:2009		
7.2/7.3 BS EN ISO 14971:2012		
ISO 10993-1:2009		
ISO 14644-1:2015		
7.4 N/A		
7.5 BS EN ISO 14971:2012		
ISO 10993-1:2009		
BS EN ISO 15223-1:2016		
BS EN 980:2008		
BS EN 15986:2011		
7.6 NA		
8.1 BS EN ISO 14971:2012		
ISO 9001:2008		
ISO 13485:2012		
ISO 14644-1:2015		
8.2 NA		
8.3 BS EN ISO 14971:2012		
BS EN ISO 15223-1:2016		
BS EN 980:2008		
ISO 11135:2014		
ISO 14644-1:2015		
8.4 EN ISO 14971:2012		
ISO 13485:2012		
ISO 11135:2014		
ISO 14644-1:2015		
8.5 ISO 13485:2012		

BS EN ISO 15223-1:2016		
BS EN 980:2008		
ISO 11135:2014		
ISO 14644-1:2015		
8.6 ISO 13485:2012		
ISO 14644-1:2015		
BS EN ISO 5356-1:2004		
ISO 5367:2000		
8.7 BS EN ISO 15223-1:2016		
BS EN 980:2008		
BS EN 556-1:2001		
9.1 BS EN ISO 14971:2012		
BS EN ISO 5356-1:2004		
ISO 5367:2000		
9.2 BS EN ISO 14971:2012		
BS EN ISO 5356-1:2004		
ISO 5367:2000		
9.3 BS EN ISO 14971:2012		
ISO 13485:2012		
ISO 5367:2000		
10/11/12.1/12.2/12.3/12.4/12.5/12.6 NA		
12.7.1 BS EN ISO 14971:2012		
BS EN ISO 5356-1:2004		
ISO 5367:2000		
12.7.2/12.7.3 NA		
12.7.4 BS EN ISO 14971:2012		
BS EN ISO 5356-1:2004		
ISO 5367:2000		
12.7.5/12.8/12.9 NA		
13.1: BS EN ISO 15223-1:2016		
BS EN 980:2008		
13.2 BS EN ISO 15223-1:2016		
BS EN 980:2008		
13.3 a,b BS EN ISO 15223-1:2016		
BS EN 980:2008		
13.3 c,d,e,f BS EN 556-1:2001		
EN ISO 15223-1:2016		
BS EN 980:2008		
13.3 g,h,i,l,n NA		
13.3 j,k BS EN ISO 15223-1:2016		
BS EN 980:2008		
13.3 m ISO 11135-1:2014		
BS EN ISO 10993-7		
13.4 BS EN ISO 15223-1:2016		
BS EN 980:2008		
13.5 ISO 13485:2003		
BS EN ISO 15223-1:2016		
BS EN 980:2008		
13.6 a, d, g, h, k BS EN ISO 15223-1:2016		
BS EN 980:2008		
13.6 b,e,f,i,j,l,m,n,o,p,q NA		

13.6 c BS EN ISO 14971:2012 BS EN ISO 5356-1:2004 ISO 5367:2000		
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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 727/13, 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, 12 marzo 2018

Responsable Legal
Firma y Sello

Responsable Técnico
Firma y Sello



Ministerio de Salud
Secretaría de Políticas, Regulación e Institutos
A.N.M.A.T.

La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 727/13 y N°5706/17, quedando inscripta 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**

Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad en la Ciudad de Buenos Aires a los días 12 marzo 2018 la cual tendrá una vigencia de cinco (5) años a contar de la fecha.

Dirección de Evaluación de Registro
Firma y Sello

Dirección Nacional de Productos Médicos
Firma y Sello

Tramitada por Expediente N°: 1-0047-3110-001546-18-1