



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

DECLARACION JURADA DE REVÁLIDA

DISPOSICIÓN ANMAT N° 9688/2019

N° rev: 1136-67#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: 1136-67

Disposición autorizante N° DDC Rev 00, expediente 1-0047-3110-001716-18-7 de fecha 19 marzo 2018

Disposiciones modificatorias y reválidas N°: DDC Rev 01, modificación, expediente 1-0047-3110-004032-18-2

Datos Característicos del Producto Médico:

Nombre descriptivo: Accesorios para circuitos respiratorios

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
15-562 Circuitos Respiratorios Externos

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

Clase de Riesgo: II

Indicación/es autorizada/s: Los accesorios se emplean en circuitos respiratorios dedicados a la conducción de gases en pacientes adultos, niños y lactantes.

Modelos: 038-41-340 Adult Angled Viral / Bacterial Filter

038-41-360 Adult Viral / Bacterial Filter

038-41-365 Adult Viral / Bacterial Filter with Tethered Cap Port

038-41-345 Adult Angled Viral / Bacterial Filter with Tethered Cap Port

038-41-365LS Luersafe Adult Viral / Bacterial Filter with Self-Sealing Port

038-41-366 Adult Viral / Bacterial Filter with Tethered Cap Port + Low Profile Elbow

038-42-360 Mini Viral / Bacterial Filter

038-42-365 Mini Viral / Bacterial Filter with Tethered Cap Port

038-42-365LS Luersafe Mini Viral / Bacterial Filter with Self-Sealing Port

038-42-366 Mini Viral / Bacterial Filter with Tethered Cap Port + Low Profile Elbow
 038-41-330 Adult Angle Viral / Bacterial Filter + HME
 038-41-350 Adult Viral / Bacterial Filter + HME
 038-41-355 Adult Viral / Bacterial Filter + HME with Tethered Cap Port
 038-41-355LS Luersafe Adult Viral / Bacterial Filter + HME with Self-Sealing Port
 038-41-335 Adult Angled Viral / Bacterial Filter + HME with Tethered Cap Port
 038-41-335LS Luersafe Adult Angled Viral / Bacterial Filter + HME with Self-Sealing Port
 038-41-356 Adult Viral / Bacterial Filter + HME with Tethered Cap Port + Low Profile Elbow
 038-41-357 Adult Viral / Bacterial Filter with HME Tethered Cap Port + 15mm Tube + Low Profile Elbow
 038-41-359 Adult Viral / Bacterial Filter with Tethered Cap Port + Expandable Catheter Mount + Double Swivel Elbow + Elastomeric Cap
 038-42-350 Mini Viral / Bacterial Filter
 038-42-355 Mini Viral / Bacterial Filter with Tethered Cap Port
 038-42-355LS Luersafe Mini Viral / Bacterial Filter with Self-Sealing Port
 038-42-356 Mini Viral / Bacterial Filter with Tethered Cap Port + Low Profile Elbow
 038-42-357 Mini Viral / Bacterial Filter with Tethered Cap Port + Expandable Catheter Mount + Double Swivel Elbow + Elastomeric Cap
 038-41-370 Adult Pleated Hydrophobic Bacterial / Viral Filter
 038-41-375 Adult Pleated Hydrophobic Bacterial / Viral Filter with Tethered Cap Port
 038-41-376 Adult Pleated Hydrophobic Bacterial / Viral Filter with Tethered Cap Port + Expandable Catheter Mount + Double Swivel Elbow + Elastomeric Cap
 038-42-380 Paediatric Pleated Hydrophobic Bacterial / Viral Filter
 038-42-385 Paediatric Pleated Hydrophobic Bacterial / Viral Filter with Tethered Cap Port
 038-42-386 Paediatric Pleated Hydrophobic Bacterial / Viral Filter with Tethered Cap Port + Catheter Mount + Plain Elbow
 038-42-365STR Sterile Mini Viral / Bacterial Filter with Tethered Cap Port
 038-41-360STR Sterile Adult Viral / Bacterial Filter
 038-41-365STR Sterile Adult Viral / Bacterial Filter with Tethered Cap Port
 038-41-340STR Sterile Adult Angled Viral / Bacterial Filter
 038-41-345STR Sterile Adult Angled Viral / Bacterial Filter with Tethered Cap Port
 038-42-385STR Sterile Paediatric Pleated Hydrophobic Bacterial / Viral Filter with Tethered Cap Port
 038-41-370STR Sterile Adult Pleated Hydrophobic Bacterial / Viral Filter
 038-41-375STR Sterile Adult Pleated Hydrophobic Bacterial / Viral Filter with Tethered Cap Port
 038-41-376STR Sterile Adult Pleated Hydrophobic Bacterial / Viral Filter with Tethered Cap Port + Expandable Catheter Mount + Double Swivel Elbow + Elastomeric Cap
 038-42-355STR Sterile Mini Viral / Bacterial Filter + HME with Tethered Cap Port
 038-41-350STR Sterile Adult Viral / Bacterial Filter + HME
 038-41-330STR Sterile Adult Angled Viral / Bacterial Filter + HME
 038-41-335STR Sterile Adult Angled Viral / Bacterial Filter + HME with Tethered Cap Port
 038-41-335LSSTR Sterile Luersafe Adult Angled Viral / Bacterial Filter + HME with Self-Sealing Port
 038-41-355LSSTR Sterile Luersafe Adult Viral / Bacterial Filter + HME with Self-Sealing Port
 038-41-355STR Sterile Adult Viral / Bacterial Filter + HME with Tethered Cap Port
 038-41-357STR Sterile Adult Viral / Bacterial Filter with HME Tethered Cap Port + 15mm Tube + Low Profile Elbow
 038-41-345LS Luersafe Adult Angled Viral / Bacterial Filter with Self-Sealing Port
 038-01-226 22mm Corrugated Tubing with 45cm repeat, 50m coil in dispensing box
 038-01-228 22mm Corrugated Tubing with 15cm repeat, 50m coil in dispensing box
 038-01-230 22mm Corrugated Tubing 2m with two 22mm female connectors

032-10-066 Entonox Mouth Piece

038-61-301 Catheter Mount Standard 15mm Tube, 22mm F and 15mm F Connectors

038-61-301/640 Catheter Mount Standard 15mm Tube with Detachable Low Profile Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-301/641 Catheter Mount Standard 15mm Tube with Detachable Luer Lock Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-301/645 Catheter Mount Standard 15mm Tube with Detachable Double Swivel Elbow, Elastomeric Cap, 22mm F and 15mm F/22mm M Connectors

038-61-302 Catheter Mount Standard 15mm Tube with Low Profile Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-303 Catheter Mount Standard 15mm Tube with Luer Lock Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-304 Catheter Mount Standard 15mm Tube with Low Profile Elbow, Elastomeric Cap, 22mm F and 15mm F/22mm

038-61-305 Catheter Mount Standard 15mm Tube with Double Swivel Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-306 Catheter Mount Standard 15mm Tube with Double Swivel Elbow, Elastomeric Cap, 22mm F and 15mm F/22mm M Connectors

038-61-310 Catheter Mount Flexi-Lock Tube, 15mm M and 15mm F Connectors

038-61-310/640 Catheter Mount Flexi-Lock Tube with Detachable Low Profile Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-310/643 Catheter Mount Flexi-Lock Tube with Detachable Double Swivel Elbow, 22mm F and 15mm F/15mm M Connectors

038-61-310/645 Catheter Mount Flexi-Lock Tube with Detachable Double Swivel Elbow, Elastomeric Cap, 22mm F and 15mm F/15mm M Connectors

038-61-311 Catheter Mount Flexi-Lock Tube, 22mm F and 15mm F Connectors

038-61-312 Catheter Mount Flexi-Lock Tube with Low Profile Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-313 Catheter Mount Flexi-Lock Tube with Luer Lock Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-314 Catheter Mount Flexi-Lock Tube with Elbow, Elastomeric Cap, 22mm F and 15mm F/22mm M Connectors

038-61-315 Catheter Mount Flexi-Lock Tube with Double Swivel Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-316 Catheter Mount Flexi-Lock Tube with Double Swivel Elbow, Elastomeric Cap, 22mm F and 15mm F/22mm M Connectors

038-61-321 Catheter Mount Smooth Bore, 22mm F and 15mm F Connectors

038-61-322 Catheter Mount Smooth Bore with Low Profile Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-323 Catheter Mount Smooth Bore with Luer Lock Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-324 Catheter Mount Smooth Bore with Elbow, Elastomeric Cap, 22mm F and 15mm F/22mm M Connectors

038-61-325 Catheter Mount Smooth Bore with Double Swivel Elbow, 22mm F and 15mm F/22mm M Connectors

038-61-326 Catheter Mount Smooth Bore with Double Swivel Elbow, Elastomeric Cap, 22mm F and 15mm F/22mm M Connectors

010-650 Adult – Self-Sealing Water Trap

020-650 Paediatric - Self-Sealing Water Trap

030-650 Neonatal - Self-Sealing Water Trap

010-610 22mm M / F Serrated Connector

010-611 22mm M / 22mm M / 15mm F Connector
 010-612 22mm F / 15mm M Connector
 010-613 15mm M / M Connector
 010-614 15mm M / F Connector
 010-617 22mm M / 30F Scavenging Connector
 010-601 22mm M / F with Barbed Right Angled Connector
 010-602 22mm M / F with Luer Right Angled Connector
 010-603 22mm F / F with Luer Right Angled Connector
 010-604 22F / F Connector with Port and Plug
 010-605 22mm M / F Connector with Port and Plug
 010-630 22M / M / M T-piece
 010-631 22M / M / F T-piece
 010-633 22mm M / M / M T-piece with port
 010-634 22mm M / M / F T-piece with port
 010-638 15mm M / 22mm M / 15mm F with Luer Right Angled Connector
 010-639 15mm M / 22mm M / 15mm F with Barbed Right Angled Connector
 010-620 22mm Plain Parallel Y-Piece
 010-621 22mm Plain Parallel Y-Piece + Monitoring Ports
 010-622 22mm Parallel Y-Piece with CO2 Luer Lock Port
 010-623 22mm Swivel Y-Piece
 010-623LS 22mm Swivel Y-Piece with LuerSafe Connector
 020-620 15mm Plain Parallel Y-Piece
 020-621 15mm Y-Piece with Monitoring Ports
 010-640 Elbow Low Profile 22M / 15F
 010-641 Elbow with Luer Lock Port 22M / 15F
 010-642 Elbow with Elastomeric Cap for Suction 22M / 15F
 010-643 Double Swivel Elbow 22M / 15F
 010-645 Double Swivel Elbow with Suction Cap 22M / 15F
 010-700 Monitoring Line with M / M Connectors – 2m Tubing
 010-700X Monitoring Line with M / M Connectors – 3m Tubing
 010-705 Monitoring Line with F / F Connectors – 2m Tubing
 010-710 Monitoring Line with M / F Connectors – 2m Tubing
 010-720 Luersafe Monitoring Line with M / M Connectors – 2m Tubing
 010-725 Luersafe Monitoring Line with M / F Connectors – 2m Tubing
 038-81-820NL 2 Litre Reservoir Bag with 22mm Female Connector
 038-81-830NL 3 Litre Reservoir Bag with 22mm Female Connector
 038-82-805NL 0.5 Litre Reservoir Bag with 15 mm Female Connector – Open Tail
 038-82-810NL 1 Litre Reservoir Bag with 22mm Female Connector
 038-83-805NL 0.5 Litre Reservoir Bag with 22mm Female Connector – Closed Tail
 032-10-089 Bubble Humidifier with Fine Diffuser – 400ml, 4 PSI (recommended for hospital)
 032-10-090 Bubble Humidifier with PVC Diffuser – 300ml, 6 PSI (recommended for home use)
 038-01-225 22mm Corrugated tube. 45cm repeat in dispensing box. 50m
 038-01-227 22mm Blue Corrugated tube. 45cm repeat in dispensing box. Low Compliance
 038-02-225 15mm Corrugated tube. 45cm repeat in dispensing box
 038-35-291 Corrugated Tube (1.6m) Breathing System with Exhaust Port
 010-740 Luer Lock Disc Filter (Female – Male)
 010-741 Luer Slip Disc Filter (Female – Luer Slip)
 010-742 Luer Lock Disc Filter (Male – Female)
 032-10-003 Nebuliser
 032-10-004 Nebuliser with T-piece and Mouthpiece
 032-10-005 Nebuliser with T-piece, Mouthpiece and Tubing

032-10-007 Nebuliser, Adult Aerosol Mask and Tubing
032-10-007NC Nebuliser, Adult Aerosol Mask, Nose Clip and Tubing
032-10-011 Nebuliser, Paediatric Aerosol Mask and Tubing
032-10-015 Nebuliser
032-10-016 Nebuliser, Adult Aerosol Mask and Tubing
032-10-017 Nebuliser, Paediatric Aerosol Mask and Tubing
032-10-064 22mm Mouthpiece
032-10-065 22mm Mouthpiece and T-piece
010-636 T-piece
032-10-120 In-line Valve for use with MaxiNeb Nebuliser

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



BORRUEL Julieta
CUIL 27221672696

Responsable Legal
Firma y Sello



BRAIDOT Gabriel Martin
CUIL 20266942754

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 1136-67 siendo su nueva vigencia hasta el 19 marzo 2028



TERRIZZANO Maria Lorena
CUIL 23242965604

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: 30 abril 2024



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

N° Identificadorio Trámite: 46773

Tramitada por Expediente N°: 1-0047-3110-001621-23-1