



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

ANEXO II

DECLARACIÓN DE CONFORMIDAD DE MODIFICACIÓN – PM CLASE I- II

Número de revisión: 2405-9#0002

Fecha de Emisión de la Declaración revisión 00-Disposición Autorizante o su reválida:
30/12/2020

Número de PM:

2405-9

Nombre Descriptivo del producto:

Laparoscopios

Código de identificación y nombre técnico UMDNS:

12-291: Laparoscopios

Clase de Riesgo:

Clase II

Marca de (los) producto(s) médico(s):

RUDOLF

Modelos (en caso de clase II y equipos):

AT127-030 ARTHROSCOPE, AUTOCLAVABLE 2.7 MM,30°,WL 110 MM
AT140-000 ARTHROSCOPE, AUTOCLAVABLE 4.0 MM,0°,WL 175 MM
AT140-030 ARTHROSCOPE, AUTOCLAVABLE 4,0 MM,30°,WL 175 MM
AT140-070 ARTHROSCOPE, AUTOCLAVABLE 4,0 MM,70°,WL 175 MM
EN127-000 OTOSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 0°,
EN127-030 OTOSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 30°,
EN127-100 SINUSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 0°,
EN127-130 SINUSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 30°,

EN127-170 SINUSCOPE,AUTOCLAVABLE, Ø 2.7 MM,DIRECTION OF VIEW 70°,
 EN140-000 SINUSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 0°,
 EN140-030 SINUSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 30°,
 EN140-045 SINUSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 45°,
 EN140-070 SINUSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 70°,
 EN140-100 OTOSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 0°,
 EN140-130 OTOSCOPE,AUTOCLAVABLE, Ø 4 MM,DIRECTION OF VIEW 30°,
 EP101 EASYPORT TROCAR SLEEVE STANDARD FOR INSTRUMENTS OF UP TO Ø 10MM,
 EP103 EASYPORT TROCAR SLEEVE STANDARD FOR INSTRUMENTS OF UP TO Ø 5 MM,
 EP111 EASYPORT TROCAR SLEEVE WITH THREAD FOR INSTRUMENTS OF UP TO Ø
 10MM,
 EP113 EASYPORT TROCAR SLEEVE WITH THREAD FOR INSTRUMENTS OF UP TO Ø
 5.5MM
 EP124-251 EASYPORT-TROCARSLEEVE WITH TRIANGULAR TROCAR FOR INSTRUMENTS
 EP150-262 TROCARSHEATH METAL STANDARD WL 100 MM, Ø 5.5 MM
 EP150-266 TROCARSHEATH METAL STANDARD WL 111,5 MM, Ø 11.0 MM
 EP150-267 TROCARSHEATH METAL STANDARD WL 107,5 MM, Ø 12.5 MM
 EP151-262 TROCARSHEATH METAL THREADED WL 100 MM, Ø 5.5 MM
 EP151-266 TROCARSHEATH METAL THREADED WL 111,5 MM, Ø 11.0 MM
 EP151-267 TROCARSHEATH METAL THREADED WL 107,5 MM, Ø 12.5 MM
 EP210 EASYPORT HOUSING WITH STOPCOCK FOR INSTRUMENTS OF UP TO Ø 10MM
 EP211 EASYPORT HOUSING FOR INSTRUMENTS OF UP TO Ø 10MM
 EP230 EASYPORT HOUSING WITH STOPCOCK FOR INSTRUMENTS OF UP TO Ø 5 MM
 EP400-404 EASYPORT DISPOSABLE SILICONE VALVE 5 PCS, Ø 3.0 - 12.5 MM
 EP400-405 EASYPORT SILICONE VALVE DISPOSABLE Ø 15,0 - 20,0 MM
 EP400-408 EASYPORT DISPOSABLE SILICON-VALVE(5 PCS) Ø 3 - 8 MM,
 EP400-412 EASYPORT DISPOSABLE SILICON-VALVE(5 PCS) Ø 10 - 12.5 MM
 EU107-012 URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID, Ø 6.0/7,5FR, WL 430MM,
 12°
 EU107-212 URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID, Ø 6.0/7,5FR, WL 430MM,
 12°
 EU109-012 URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID, 8/9,8FR,12°,WL430MM,
 EU109-212 URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID, 8/9,8FR,12°,WL430MM,
 EU111-012 URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID,8.5/11.5FR,12°,WL430MM,
 EU111-212 URETERO-RENOSCOPE,AUTOCLAVABLE SEMIRIGID,8.5 /11.5FR.
 ,12°,WL430MM,
 EU127-000 CYSTOSCOPE,AUTOCLAVABLE, 2.7 MM,0°,WORKING LENGTH 302 MM
 EU127-030 CYSTOSCOPE,AUTOCLAVABLE, 2.7 MM,30°,WORKING LENGTH 302 MM
 EU129-000 CYSTOSCOPE, AUTOCLAVABLE 2,9 MM,0°,WL 302 MM
 EU129-030 CYSTOSCOPE, AUTOCLAVABLE 2,9 MM,30°,WL 302 MM
 EU140-000 CYSTOSCOPE, AUTOCLAVABLE 4,0 MM,0°,WL 302 MM
 EU140-012 CYSTOSCOPE, AUTOCLAVABLE 4,0 MM,12°,WL 302 MM
 EU140-030 CYSTOSCOPE, AUTOCLAVABLE 4,0 MM,30°,WL 302 MM
 EU140-070 CYSTOSCOPE, AUTOCLAVABLE 4,0 MM,70°,WL 302 MM
 GY120-000 HYSTEROSCOPE, SEMIRIGID, AUTOCLAVABLE 2,0 MM,0°,WL 260 MM
 GY120-030 HYSTEROSCOPE, SEMIRIGID, AUTOCLAVABLE, 2,0 MM, 30°, WL 260 MM
 GY127-000 HYSTEROSCOPE, AUTOCLAVABLE 2,7 MM,0°,WL 302 MM
 GY127-030 HYSTEROSCOPE, AUTOCLAVABLE 2,7 MM, 30°,WL 302 MM
 GY127-070 HYSTEROSCOPE, AUTOCLAVABLE 2,7 MM,70°,WL 302 MM
 GY129-000 HYSTEROSCOPE, AUTOCLAVABLE 2,9 MM,0°,WL 302 MM
 GY129-030 HYSTEROSCOPE, AUTOCLAVABLE 2,9 MM,30°,WL 302 MM

GY140-000 HYSTEROSCOPE, AUTOCLAVABLE 4,0 MM,0°,WL 302 MM
 GY140-012 HYSTEROSCOPE, AUTOCLAVABLE 4,0 MM,12°,WL 302 MM
 GY140-030 HYSTEROSCOPE, AUTOCLAVABLE 4,0 MM,30°,WL 302 MM
 GY140-070 HYSTEROSCOPE, AUTOCLAVABLE 4,0 MM,70°,WL 302 MM
 LP100-000 LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,0°,WL 340 MM, 4K READY
 LP100-000-ICG LAPAROSCOPE, AUTOCLAVABLE; ICG Ø 10.0 MM,0°,WL 325 MM, 4K
 LP100-030 LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,30°,WL 340 MM, 4K READY
 LP100-030-ICG LAPAROSCOPE, AUTOCLAVABLE; ICG Ø 10.0 MM,30°,WL 325 MM, 4K
 LP100-045 LAPAROSCOPE, AUTOCLAVABLE Ø 10,0 MM,45°,WL 340 MM, 4K READY
 LP105-000 LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,0°,WL 425 MM
 LP105-030 LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,30°,WL 425 MM
 LP105-045 LAPAROSCOPE, AUTOCLAVABLE Ø 10.0 MM,45°,WL 425 MM
 LP150-000 LAPAROSCOPE, AUTOCLAVABLE Ø 5.0 MM,0°,WL 300 MM, 4K READY
 LP150-030 LAPAROSCOPE, AUTOCLAVABLE Ø 5.0 MM,30°,WL 300 MM, 4K READY
 LP250-100 ENDOSCOPE HOLDER, STANDARD
 LP250-101 INSULATED RAILS CLAMPING BASE FOR ENDOSCOPE HOLDER
 LP250-110 ENDOSCOPE HOLDER, L-COLUMN
 LP300-020 APPLICATOR F. ENDO-LIGATURE WL 180 MM, Ø 5-4 MM
 LP305-100 INSUFFLATION NEEDLE, VERES WL 100 MM, Ø 2 MM
 LP305-120 INSUFFLATION NEEDLE, VERESS NL 120 MM, Ø 2 MM
 LP305-150 INSUFFLATION NEEDLE, VERESS WL 150 MM, Ø 2 MM
 LP305-200 INSUFFLATION NEEDLE, VERESS WL 200 MM, Ø 2 MM
 LP305-610 HIGH FLOW VERESS CANNULA WITH LUER-LOCK-CONNECTOR
 LP305-617 HIGH FLOW VERESS CANNULA WITH LUER-LOCK-CONNECTOR
 LP310-021 SUCTION-IRRIG.TUBE WITH SLIDING VALVE WL 330 MM, Ø 5 MM
 LP310-031 SUCTION & IRRIG.TUBE, WITH TRUMPET VALVE WITH LASER TUBE, WL 340
 MM, Ø 5 MM
 LP310-032 SUCTION & IRRIG.TUBE,WITH TRUMPET VALVE WITHOUT LASER TUBE, WL
 340 MM, Ø 5 MM
 LP310-200 SUCTION-IRRIGATION HANDLE WITH TRUMPET VALVE AND TUBE/LUER-LOCK
 CONNECTION,
 LP310-201 TUBE ONLY WL 330 MM, Ø 5 MM
 LP310-202 TUBE ONLY WL 330 MM, Ø 10 MM
 LP310-205 SUCTION/IRRIGATION HANDLE, WITH TRUMPET VALVE AND TUBE/LUER-LOCK
 CONNECTION,
 LP310-501 HANDLE ONLY, WITH TRUMPET VALVE AND LUER-LOCK CONNECTION
 LP310-502 HANDLE ONLY, WITH TRUMPET VALVE AND TUBING CONNECTION
 LP310-503 HANDLE WITH SLIDING VALVE AND TUBING CONNECTION, ONLY
 LP310-510 STANDARD SUCTION TUBE WL 330 MM, Ø 5 MM, DRILLING 4
 LP310-511 STANDARD SUCTION TUBE WL 500 MM ,Ø 5 MM, DRILLING 4
 LP310-512 SUC.TUBE WITH MULTIPLE HOLES WL 330 MM, Ø 5 MM, DRILLING 48
 LP310-513 BLUNT SUCTION TUBE WL 330 MM, Ø 5 MM, DRILLING 48
 LP310-514 BLUNT SUCTION TUBE WL 500 MM, Ø 5 MM, DRILLING 48
 LP310-515 PUNCTION NEEDLE SUCTION TUBE WL 330 MM, Ø 5 MM
 LP310-516 AQUA DISSECTOR CANNULA WL 330 MM, Ø 5 MM
 LP310-517 BLUNT SUCTION TUBE WL 330 MM, Ø 5 MM, DRILLING 12
 LP310-518 STANDARD SUCTION TUBE WL 330 MM, Ø 5 MM, DRILLING 16
 LP310-547 BLUNT SUCTION TUBE WL 250 MM, Ø 2.8 MM, DRILLINGS 8
 LP310-548 BLUNT SUCTION TUBE WL 330 MM, Ø 2.8 MM, DRILLINGS 8
 LP312-100 PISTOL HANDLE WITH SLIDING VALVE, ONLY
 LP312-125 TUBE, ONLY WL 340 MM, Ø 5 MM

LP312-130 TUBE, ONLY, WL 340 MM, Ø 10 MM
 LP312-140 PUNCTION CANNULA, ONLY WL 330 MM, Ø 5 MM
 LP313-012 INJECTION AND PUNCTION NEEDLE WITH LUER-LOCK CONNECTION, WL 330 MM, Ø 5 MM
 LP313-013 INJECTION AND PUNCTION NEEDLE WITH LUER-LOCK CONNECTION, WL 450 MM, Ø 5 MM
 LP313-014 INJECTION AND PUNCTION NEEDLE WL 250 MM, Ø 2.8 MM
 LP313-015 INJECTION AND PUNCTION NEEDLE WL 330 MM, Ø 2.8 MM
 LP314-002 INSERTION TROCAR F.STER.SOLUTION,23,5CM WL 235 MM 1,0 L, Ø 6 MM
 LP315-105 PALPATION PROBE WL 250, Ø 2.8 MM
 LP315-111 PALPATION PROBE WL 330 MM, Ø 5 MM
 LP315-112 PALPATION PROBE WL 400 MM, Ø 5 MM
 LP315-113 PALPATION PROBE WL 450 MM, Ø 5 MM
 LP315-501 KNOT GUIDE WL 330 MM, Ø 4 MM
 LP315-502 KNOT GUIDE WL 330 MM, Ø 4,5 MM
 LP315-510 FASCIA-SUTURE ASSISTING DEVICE Ø 2,3 MM, NL 140MM
 LP323-000 HANDLE, ONLY FOR LP323-015 + RS005-000
 LP323-002 HANDLE, ONLY FOR LP 323-040
 LP323-015 INSERT,ONLY WL 355 MM, Ø 5 MM
 LP323-020 INSERT, ONLY WL 390 MM, Ø 10 MM
 LP323-025 LIVER-ELEVATOR, Ø5MM TRIANGLE 60MM, WL 38CM
 LP323-040 INSERT,ONLY WL 330 MM, Ø 10 MM
 LP323-205 ABDOMINAL SPECULUM, 90°, LENGTH OF BLADE 55 MM, 19.5CM
 LP325-010 CHOLANGIOGRAM CLAMP, WITH RATCHET F.T.PLACEM. OF A CATH. WITH CHANNEL 7 FR
 LP325-020 SPOON FORCEPS WITH IRRIGATION CHANNEL WL 330 MM, Ø 10 MM
 LP325-025 CLAW GRASPING FOCPS W IRRIGATION CHANNEL 2X3 TEETH, WL 330 MM, Ø10 MM
 LP371-010 ETHICON CLIPS, MEDIUM, INSERT, ONLY WL 330 MM, Ø 10 MM
 LP371-020 ETHICON CLIPS, MEDIUM-LARGE, INSERT, ONLY, WL 330 MM, Ø 10 MM
 LP371-030 ETHICON CLIPS, LARGE, INSERT, ONLY WL 330MM, Ø 10 MM
 LP371-100 HANDLE, ONLY
 LP371-101 TUBE FOR CLIP APPLYING FORCEPS, ONLY WL 330 MM, Ø 10 MM
 LP371-210 ETHIC.LIGATURCLIP FOR CLIP APPLY.FORCEPS TITANIUM; COLOUR CODE:BLUE; CLIP SIZE:
 LP371-211 ETHIC.LIGATURCLIP FOR CLIP APPLY.FORCEPS TITANIUM; COLOUR CODE:BLUE; CLIP SIZE:
 LP371-212 ETHIC.LIGATURCLIP FOR CLIP APPLY.FORCEPS TITANIUM;COLOUR CODE:WHITE;CLIP SIZE:
 LP371-213 ETHIC.LIGATURCLIP FOR CLIP APPLY.FORCEPS TITANIUM;COLOUR CODE:WHITE;CLIP SIZE:
 LP371-214 ETHIC.LIGATURCLIP FOR CLIP APPLY.FORCEPS TI;COLOUR CODE:GREEN;CLIP SIZE:MEDIUM-
 LP371-215 ETHIC.LIGATURCLIP FOR CLIP APPLY.FORCEPS TITANIUM;COLOUR CODE:YELLOW;CLIP SIZE
 LP372-010 INSERT ONLY F. CLIP-APPLYING FCPS. SMALL WL 330 MM, Ø 5,5 MM
 LP372-020 INSERT ONLY F. CLIP APPLYING FCPS.,MED. WL 330 MM, Ø 6,5 MM
 LP372-100 HANDLE, ONLY CLIP-APPLYING FORCEPS Ø 5.5 + 6.5 MM
 RU 8865-51 CLEANING BRUSH WL 380 MM, Ø 2,5 MM
 RU 8865-52 CLEANING BRUSH WL 500 MM, Ø 2,5 MM
 RU 8865-55 CLEANING BRUSH WL 380 MM, Ø 7 MM

RU 8865-56 CLEANING BRUSH WL 500 MM, Ø 7 MM
RU 8865-59 CLEANING BRUSH WL 380 MM, Ø 11 MM
RU 8865-60 CLEANING BRUSH WL 500 MM; Ø 11 MM
RU 8867-05 SPRAY GUN ONLY
RU 8867-06 SPRAY GUN WITH 1,5 M PVC TUBING AND CONUS
RU 8867-11 SPRAY GUN STD.SET, 8 ATTACHMENTS, 1/2"
RU 8867-12 SPRAY GUN STD.SET, 8 ATTACHMENTS, 3/4"
RU 8867-45 ATTACHMENT F: FOR SYRINGES AND CANNULAE WITH LUER CONE FOR THE
RU 8870-11HP NAIL NIPPER,STAINLESS,HIGH POLISHED 11,0CM
RU 8870-13HP NAIL NIPPER,STAINLESS, HIGH POLISHED 13,0CM
RU 8871-14HP NAIL NIPPER,STAINLESS, HIGH POLISHED 14,0 CM
RU 8872-12HP NAIL NIPPER,CONCAVE,STAINL.STEEL,HIGH P. 12,0 CM
RU 8874-13HP NAIL NIPPER,STAINLESS,HIGH POLISHED 13,0 CM
RU 8875-15 NAIL NIPPER,STAINLESS,15CM
RU 8878-10HP NAIL NIPPER,STAINLESS STEEL,HIGH POLISHD 10,0 CM
RU 8879-10 NAIL FILE,10CM
RU 8879-16 NAIL FILE,16CM
RU 8880-18 INSTRUMENT OIL, 18 ML
RU 8880-25 INSTRUMENT GREASE FOR STOPCOCKS, 10ML
RU 8900-51 WIRE BASKET 500 X 250 X 75 MM
RU 8901-50 WIRE BASKET,240X258X50MM
RU 8905-11/15 STERILIZATION TUBE, FOR DRILL WIRES UP TO (L) 160 MM - 6 1/4"
RU 8905-11/18 STERILIZATION TUBE, FOR DRILL WIRES UP TO (L) 230 MM - 9"
RU 8905-11/31 STERILIZATION TUBE, FOR DRILL WIRES UP TO (L) 310 MM - 12 1/4"
RU 8906-01 KARABINER
RU 8908-01 WIRE BASK.F.ENDOSC.,290X80X52MM Ø 1 -10 MM
RU 8908-02 WIRE BASK.F.ENDOSC.,670X80X55MM FOR 1 SCOPE Ø 1 -10 MM
RU 8908-11 WIRE BASK.F.ENDOSC.,460X80X55MM SINGLE SCOPE Ø 1 -10 MM
RU 8908-18 STORING RACK F.ENDOSC.INSTR.
RU 8910-65 NEEDLE CASE,65X42X8MM
RU 8916-01 NEEDLE CASE,65X16MM
RU 8916-11 INNER CASE FOR NEEDLE CASE
RU 8941-55 SAUERBRUCH WASTE FCPS.55CM
RU 8947-27 CHEATLE STERILIZING FCPS.27CM
RU 8948-20 UNIVERSAL GRASP.FCPS.STR.20CM
RU 8950-01 BUNT SAFETY PIN,10,5CM
RU 8950-02 MAYO SAFETY PIN,14CM
RU 8950-03 MAYO SAFETY PIN,14CM
RU 8964-02 MEASURING JUG.0,25L
RU 8964-05 MEASURING JUG.0,5L
RU 8964-10 MEASURING JUG.1,0L
RU 8964-20 MEASURING JUG.2,0L
RU 8970-01 KIDNEY BOWL STAINLESS STEEL,0.25 L., L 170 MM X H 36 MM
RU 8970-02 KIDNEY BOWL STAINLESS STEEL,0.5 L., L 250 MM X H 36 MM
RU 8970-03 KIDNEY BOWL STAINLESS STEEL,0.75 L., L 275 MM X H 45 MM
RU 8972-02 COTTON DISPENSER 100X100MM
RU 8972-03 COTTON DISPENSER 120X120MM
RU 8972-04 COTTON DISPENSER 150X150MM
RU 8975-05 MEDICINE CUP, 25CC
RU 8975-10 MEDICINE CUP, 50CC
RU 8975-10/10 MEDICINE CUP, 100CC

RU 8975-10/25 MEDICINE CUP, 250CC
RU 8975-20 MEDICINE SPOON,110X20MM
RU 8977-03 INSTRUMENT STORING TRAY 280X210X10MM
RU 8977-04 INSTRUMENT STORING TRAY 300X160X10MM
RU 8977-05 INSTRUMENT STORING TRAY 310X210X10MM
RU 8978-02 INSTRUMENT BOWL 350 X 245 X 35 MM
RU 8980-01 INSTR.BOX W.LID,165X90X35MM
RU 8980-02 INSTR.BOX W.LID,200X100X50MM
RU 8980-03 INSTR.BOX W.LID,220X150X50MM
RU 8980-04 INSTR.BOX W.LID,260X150X50MM
RU 8980-05 INSTR.BOX W.LID,305X205X50MM
RU 8984-02 JAR 55X120MM
RU 8984-03 JAR 55X125MM
RU 8984-04 JAR 50X180MM
RU 8984-05 JAR 85X135MM
RU 8984-06 JAR 85X175MM
RU 8984-07 JAR 100X200MM
RU 8985-01 BOWL 80X40MM
RU 8985-02 BOWL 116X50MM
RU 8985-03 BOWL 128X55MM
RU 8985-04 BOWL 147X65MM
RU 8985-05 BOWL 167X75MM
RU 8985-06 BOWL 187X85MM
RU 8985-10 BOWL 40X19MM
RU 8985-11 BOWL 61X30MM
RU 8986-12 BOWL 120X35MM
RU 8986-14 BOWL 140X35MM
RU 8986-16 BOWL 160X35MM
RU 8987-01 ROUND BOWL, 0,02 L
RU 8987-02 ROUND BOWL, 0,06 L
RU 8987-03 ROUND BOWL, 0,16 L
RU 8987-04 ROUND BOWL, 0,4 L
RU 8987-05 ROUND BOWL, 1 L
RU 8987-06 ROUND BOWL, 2,5 L
RU 8988-01 BOWL, ,150X75MM,0,75L
RU 8988-02 BOWL, 160X75MM,1,0L
RU 8988-03 BOWL, 220X70MM,2,0L
RU 8988-04 BOWL, 240X95MM, 3L
RU 8988-05 BOWL, 260X125MM,4,5L
RU 8988-06 BOWL, 300X115MM, 6L
RU 8988-07 BOWL, 320X140MM, 8,0 L
RU 8988-08 TRAY,380X130MM, 11,0 L
RU 8988-09 BOWL, 400X155MM,14,0L
RU 8989-00 BOWL, 235X190X40MM
RZ100-000 ENDOSCOPE ADAPTOR STORZ
RZ100-010 ENDOSCOPE-ADAPTOR WOLF
RZ200-000 RUBBER CAP FOR INSTRUMENT CHANNEL
RZ200-202 SPARE PART PART VALVE HOLDER FOR AXIAL WORKING CHANNEL ON URS
RZ310-205-1 SPARE PART: SUCTION SHAFT FOR LP310-205 AND LP310-200 SUCTION
IRRIGATION HANDLE
RZ310-205-2 SPARE PART: IRRIGATION SHAFT F.LP310-205 AND LP310-200 SUCTION

IRRIGATION HANDLE

RZ310-205-3 SPARE PART: SPRING FOR LP310-205 AND LP310-200 SUCTION IRRIGATION HANDLE

RZ310-205-4 SPARE PART: O-RING, SILICON, RED, LP310-205,LP310-200 SUCTION IRRIGATION

RZ310-205-5 SPARE PART: KNURLED RING CLOSED FOR LP310-205 & LP310-200SUCTION IRRIGAT.

RZ310-205-6 CAP ONLY, GREEN, SUCTION FOR LP310-200 AND LP310-205

RZ310-205-8 CAP ONLY, GREEN, IRRIGATION FOR LP310-200 AND LP310-205

RZ310-205-9 CAP ONLY, BLUE, IRRIGATION FOR LP310-200 AND LP310-205

RZ310-502-2 SPARE PART: SUCTION SHAFT FOR HANDEL LP310-502

RZ310-502-4 SPARE PART: SPRING FOR HANDEL LP310-502

RZ310-502-5 SPARE PART: KNURLED RING CLOSED FOR HANDEL LP310-502

RZ310-502-6 SPARE PART:

RZ310-502-7 SPARE PART: O-RING FOR HANDLE LP310-502

RZ310-502-8 SPARE PART: KNURLED RING OPEN FOR HANDLE ONLY LP310-502

RZ310-503 SPRING CAP FOR LP310-503

RZ310-503-00001 SPARE PART VALVE PIECE FOR LP310-503

RZ325-025 CAP FOR STANDARD LUER LOCK

RZ350-001 SHARP SLEEVE FOR SECURITY TROCAR TR350-055

RZ350-002 OBTURATOR FOR SECURITY TROCAR TR350-055

RZ350-003 LOCKING RATCHET FOR SECURITY TROCAR TR350-055/ TR350-110/ TR350-125

RZ350-004 SERRATED CAP FOR SECURITY TROCAR TR350-055/ TR350-110/ TR350-125

RZ350-005 SHARP SLEEVE FOR SECURITY TROCAR TR350-110

RZ350-006 OBTURATOR FOR SECURITY TROCAR TR350-110

RZ350-007 SHARP SLEEVE FOR SECURITY TROCAR TR350-125

RZ350-008 OBTURATOR FOR SECURITY TROCAR TR350-125

RZ350-110 SCREW COMPLETE FOR TR350-110

RZ352-001 SEALING CAP, FOR LAP-NEEDLE HOLDERS AND HANDLES WITH LUER-LOCK CONNECTION,

RZ4853-33 KNOB FOR HANDLE RU 4853-33 SPARE PART

RZ500-000 SPRING FOR UTERUS MANIPULATOR HY500-000

RZ500-100-00001 CLAMP SCREW FOR UTERUSMANIPULATOR, M10

RZ500-100-00002 SET SCREW FOR UTERUSMANIPULATOR

RZ500-110-1 SPRING FOR PUSHER, UTERUS MANIPULATOR SPARE PART FOR HY500-110

RZ500-110-2 SPRING FOR HANDLE, UTERUS MANIPULATOR SPARE PART FOR HY500-110

RZ6220-02 OPEN END WRENCHES, 11 MM, FOR PLASTER FOR PLASTER SAW RU 6220-20

RZ6220-03 RETAINING SREW, FOR PLASTER SAWS RU 6220-20 AND RU 6220-24

RZ6220-04 FIXATION RING, FOR PLASTER SAWS RU 6220-20 AND RU 6220-24

RZ6220-06 TORX-WRENCH WITH T-HANDLE

RZ6220-11 FIXATION RING WITH DRIVING PINS, FOR PLASTER SAW RU 6220-20

RZ6220-12 FLEECE FILTER ECO, PACKAGE OF 3 PCS.

RZ6220-13 FLEECE FILTER ECO, HEPA

RZ6220-14 FLEECE FILTER BAG, PACKAGE OF 5 PCS.

RZ6220-15 ENGINE GUARD FILTER

RZ6220-61 UPGRADE SET FOR RU 6220-20

RZ6220-62 TUBE COMPLETE, 2 METRES, FOR VACUUM CLEANER RU 6220-60

RZ6220-63 PAPER FILTER BAGS 5 EACH, FOR RU 6220-60

RZ6220-64 WET FILTER BAGS 5 EACH

RZ6220-65 ECO-FLAT FOLDING FILTER

RZ6220-66 ECO-FLAT FOLDING FILTER, HEPA, FOR RU 6220-20
RZ6220-67 HANGING KIT FOR OSCILLATION SAWS WITH HANDLE, HIGHT ADJUSTABLE
RZ6220-68 DUST REMOVAL UNIT TO VACUUM CLEANER
RZ6220-69 SUSPENSION WITH HANDLE, HEIGHT ADJUST. FOR RU 6220-20 + RU 6220-60
RZ6220-70 HOSE CLAMP, FOR RU 6220-60
RZ6220-71 PIN TYPE SOCKET WRENCH WITH T-HANDLE 11MM
RZ6220-72 MAGNETIC PLACEMENT FOR SAW BLADES AND TOOLS, FOR VACUUM CLEANER RU 6220-60
RZ6220-73 ADAPTER CABLE, FOR CONNECTION PLASTER- SAW TO VACUUM CLEANER
RZ630-008 USB-STICK 32GB - HIGH SPEED 2.0
RZ8406-12 SILICONE INSERTS FOR MOUTH GAG DENHART RU 8406-12
TR240-055 DOUBLE FUNCT.TROCAR WITH FLAPPING VALVE AND OPENING LEVER, WITH STOPCOCK
TR240-110 DOUBLE FUNCT.TROCAR WITH FLAPPING VALVE AND OPENING LEVER, WITH STOPCOCK
TR240-125 DOUBLE FUNCT.TROCAR WITH FLAPPING VALVE AND OPENING LEVER, WITH STOPCOCK
TR240-255 SPIRAL TUBE, METAL WL 95 MM, Ø 5.5 MM
TR240-311 SPIRAL TUBE, METAL WL 101 MM, Ø 11 MM
TR240-325 SPIRAL TUBE, METAL WL 98 MM, Ø 12.5 MM
TR300-055 TROCAR, CONICAL POINT Ø 5.5 MM
TR300-110 TROCAR, CONICAL POINT FOR TROKARSLEEVE WITH CANNULATION Ø 10MM
TR300-125 TROCAR, CONICAL POINT Ø 12.5 MM
TR310-054 TROCAR, WITH TRIANGULAR POINT Ø 5.5 MM
TR310-055 TROCAR, WITH TRIANGULAR POINT Ø 5.5 MM
TR310-110 TROCAR, WITH TRIANGULAR POINT FOR TROKARSLEEVE WITH CANNULATION Ø 10MM
TR310-125 TROCAR, WITH TRIANGULAR POINT Ø 12.5 MM
TR330-055 TROCAR FOR HASSON, CONICAL BLUNT Ø 5.5 MM
TR330-110 TROCAR FÜR HASSON, CONICAL BLUNT FOR TROKARSLEEVE WITH CANNULATION Ø 10MM
TR330-125 TROCAR FÜR HASSON, CONICAL BLUNT Ø 12,5 MM
TR350-055 SECURITY TROCAR SPIKE, Ø 5.5 MM
TR350-110 SECURITY TROCAR SPIKE, Ø 11 MM
TR350-125 SECURITY TROCAR SPIKE, Ø 12.5 MM
TR405-002 APPENDIX-EXTRACTOR A. REDUCER SLEEVE FOR ALL TROCAR SHEATS
TR410-002 REDUCER SLEEVES, WITHOUT LOOP Ø 11 MM TO 5,5 MM
TR411-002 REDUCER SLEEVES, WITH LOOP Ø 10 MM TO 5 MM
TR420-001 REDUCER, Ø 10MM-5 MM
TR420-003 REDUCER, Ø 12 MM-5 MM
TR421-001 DOUBLE REDUCER Ø 12 MM/ 10MM AND 5 MM
TR422-001 SLIDE REDUCER Ø 12,5 MM TO 5,5 MM

Composición cuali-cuanti porcentual exacta (si corresponde):

NA

Indicación/es autorizada/s:

Endoscopios e instrumental asociado diseñados para procedimientos laparoscópicos diagnósticos y terapéuticos.

Los ópticas de Rudolf se utilizan para visualizar el campo operatorio durante las intervenciones endoscópicas diagnósticas y quirúrgicas. El instrumental se utiliza en conjunto con las ópticas, con el fin de llevar a cabo las distintas intervenciones.

Período de vida útil (si corresponde):

5 AÑOS

Método de Esterilización (si corresponde):

NA

Forma de presentación:

POR UNIDAD

Condición de uso:

Uso exclusivo a profesionales e instituciones sanitarias

Nombre del fabricante:

Rudolf Medical GmbH + Co. KG

Lugar/es de elaboración:

Zollerstrasse 1, 78567 Fridingen, Alemania

En nombre y representación de la firma GEDOX SA , 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 EMISIÓ
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		N
1. ISO/TS 18339 ISO 15223-1 C2.7 ISO 14971 C2.2 ISO 13485 ISO 10993-23 C2.6.5 ISO 10993-18 C2.6.5 ISO 10993-12 C2.6.5 ISO 10993-11 C2.6.5 ISO 10993-10 C2.6.5 ISO 10993-5 C2.6.5 ISO 10993-1 C2.6.5 IEC 62366-1 IEC 60601-2-18 IEC 60601-1-6 IEC 60601-1 3.1 3.2 ISO 20417 C2.7	NA	NA
2. ISO 14971, Capítulo 1.2, 2017/745 MDR ISO 14971 C2.2 ISO 13485 ISO 14971 C2.2 ISO 13485 IEC 60601-1	NA	NA
3. ISO 14971 C2.2 ISO 13485 ISO 13485 ISO 14971 ISO 14155 ISO 14971 C2.2 ISO 13485 IEC 60601-1 ISO 14971 C2.2 ISO 13485	NA	NA
4. ISO 14971 C2.2 ISO 13485 IEC 60601-1 ISO 14971 C2.2 ISO 13485 ISO 15223-1 C2.7 ISO 14971 C2.2 IEC 62366-1 IEC 60601-1-6 IEC 60601-1 ISO 20417 C2.7 ISO 15223-1 C2.7 ISO 14971 C2.2 ISO 13485 ISO 20417 C2.7	NA	NA
5. ISO 14971 C2.2 IEC 62366-1 IEC 60601-1-6 ISO 14971 C2.2 IEC 62366-1 IEC 60601-1-6	NA	NA
7. 7.1 ISO 15223-1 C2.7 ISO 14971 C2.2 ISO 13485 ISO 10993-23 C2.6.5 ISO 10993-18 C2.6.5 ISO 10993-12 C2.6.5 7.2 ISO 15223-1 C2.7 ISO 14971 C2.2 ISO 13485 ISO 10993-23 C2.6.5 ISO 10993-18 C2.6.5 ISO 10993-12 C2.6.5 7.3 ISO 10993-11 C2.6.5 ISO 10993-10 C2.6.5 ISO 10993-5 C2.6.5 ISO 10993-1 C2.6.5 IEC 62366-1 IEC 60601-1-6 ISO 20417 C2.7 7.4 NA	NA	NA
8. 8.1 ISO 14971 C2.2 ISO 13485 IEC 60601-1 8.2 - 8.4 NA 8.5 - 8.6 ISO 13485 8.7 NA	NA	NA
9. 9.1 ISO 14971 IEC 60601-1, IEC 60601-2-2 EN 1041 9.2 ISO 13485 ISO 14971 IEC 60601-1, IEC 60601-2-2 IEC 62366, IEC 60601-1-6 IEC 60601-1-2 9.3 ISO 13485 ISO 14971 IEC 60601-1, IEC 60601-2-2	NA	NA
10. 10.1 ISO 14971 C2.2 ISO 13485 ISO 10993-23 C2.6.5 ISO 10993-18 C2.6.5 ISO 10993-12 C2.6.5 ISO 10993-11 C2.6.5 ISO 10993-10 C2.6.5 ISO 10993-5 C2.6.5 ISO 10993-1 C2.6.5 ISO 7153-1 IEC 60601-1 10.2 ISO 17665-1 C2.6.1 ISO 17664-1 ISO 14971 C2.2 ISO 13485 ISO 10993-23 C2.6.5 ISO 10993-18 C2.6.5 ISO 10993-12 C2.6.5 ISO 10993-11 C2.6.5 ISO 10993-10 C2.6.5 ISO 10993-5 C2.6.5 ISO 10993-1	NA	NA
11. 11.1 - 11.2 ISO 17665-1 C2.6.1 ISO 17664-1 ISO 14971 C2.2 ISO 13485 IEC 62366-1 IEC 60601-1-6 11.2.2 NA 11.3 11.3.1 ISO 14971 C2.2 ISO 13485 IEC 62366-1 IEC 60601-1-6 11.4 11.4.1 NA 11.5 NA	NA	NA
12.1 ISO 14971 IEC 60601-1, IEC 60601-2-2 12.2 - 12.4 NA 12.5 ISO 13485 IEC 60601-2-2 12.6 ISO 14971 IEC 60601-1, IEC 60601-2-2 12.7 12.7.1 ISO 14971 IEC 60601-1, IEC	NA	NA

60601-2-2 12.7.2 - 12.7.3 NA 12.7.4 ISO 14971 IEC 60601-1, IEC 60601-2-2 12.7.5 ISO 14971 IEC 60601-1, IEC 60601-2-2 12.8 ISO 14971 IEC 60601-1, IEC 60601-2-2 12.9 ISO 14971 IEC 60601-1, IEC 60601-2-2 NA NA		
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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 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, 19 junio 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 la modificación en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de **GEDOX SA** bajo el número PM **2405-9** en la Ciudad de Buenos Aires a los días 19 junio 2026

Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad, la cual mantendrá la vigencia que consta en la Declaración inicial revisión 00 o Disposición Autorizante o su reválida.

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°: 1-0047-3110-004790-26-1