



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

DECLARACION JURADA DE REVÁLIDA

DISPOSICIÓN ANMAT N° 9688/2019

N° rev: 1882-32#0003

En nombre y representación de la firma Bio Lap 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: 1882-32

Disposición autorizante N° 7229/16 de fecha 05 julio 2016

Disposiciones modificatorias y reválidas N°: Reválida N° rev: 1882-32#0001

Modificación N° rev: 1882-32#0002

Datos Característicos del Producto Médico:

Nombre descriptivo: SISTEMA DE TORNILLOS Y PLACAS PARA OSTEOSÍNTESIS DE PERONÉ E INSTRUMENTAL ASOCIADO

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
13-050-Placas, para Huesos

Marca(s) de (los) producto(s) médico(s): NEWCLIP TECHNICIS

Clase de Riesgo: III

Indicación/es autorizada/s: El sistema de placas y tornillos para osteosíntesis de peroné (distal y diáfisis), está indicado para la fijación de fracturas simples y complejas, osteotomías y pseudoartrosis de la porción distal y diáfisis del peroné

Modelos: CT2.8L30 Ø2.8 mm non-locking screw - L30 mm
CT2.8L30-ST Ø2.8 mm non-locking screw - L30 mm - STERILE
CT2.8L32 Ø2.8 mm non-locking screw - L32 mm
CT2.8L32-ST Ø2.8 mm non-locking screw - L32 mm - STERILE
CT2.8L34 Ø2.8 mm non-locking screw - L34 mm
CT2.8L34-ST Ø2.8 mm non-locking screw - L34 mm - STERILE
CT2.8L36 Ø2.8 mm non-locking screw - L36 mm
CT2.8L36-ST Ø2.8 mm non-locking screw - L36 mm - STERILE

CT2.8L38 Ø2.8 mm non-locking screw - L38 mm
 CT2.8L38-ST Ø2.8 mm non-locking screw - L38 mm - STERILE
 CT2.8L40 Ø2.8 mm non-locking screw - L40 mm
 CT2.8L40-ST Ø2.8 mm non-locking screw - L40 mm - STERILE
 CT2.8L42 Ø2.8 mm non-locking screw - L42 mm
 CT2.8L42-ST Ø2.8 mm non-locking screw - L42 mm - STERILE
 CT2.8L44 Ø2.8 mm non-locking screw - L44 mm
 CT2.8L44-ST Ø2.8 mm non-locking screw - L44 mm - STERILE
 CT2.8L46 Ø2.8 mm non-locking screw - L46 mm
 CT2.8L46-ST Ø2.8 mm non-locking screw - L46 mm - STERILE
 CT2.8L48 Ø2.8 mm non-locking screw - L48 mm
 CT2.8L48-ST Ø2.8 mm non-locking screw - L48 mm - STERILE
 CT2.8L50 Ø2.8 mm non-locking screw - L50 mm
 CT2.8L50-ST Ø2.8 mm non-locking screw - L50 mm - STERILE
 CT2.8L55 Ø2.8 mm non-locking screw - L55 mm
 CT2.8L55-ST Ø2.8 mm non-locking screw - L55 mm - STERILE
 CT2.8L60 Ø2.8 mm non-locking screw - L60 mm
 CT2.8L60-ST Ø2.8 mm non-locking screw - L60 mm - STERILE
 CT3.5L10 Ø3.5 mm non-locking screw - L10 mm
 CT3.5L10-ST Ø3.5 mm non-locking screw - L10 mm - STERILE
 CT3.5L12 Ø3.5 mm non-locking screw - L12 mm
 CT3.5L12-ST Ø3.5 mm non-locking screw - L12 mm - STERILE
 CT3.5L14 Ø3.5 mm non-locking screw - L14 mm
 CT3.5L14-ST Ø3.5 mm non-locking screw - L14 mm - STERILE
 CT3.5L16 Ø3.5 mm non-locking screw - L16 mm
 CT3.5L16-ST Ø3.5 mm non-locking screw - L16 mm - STERILE
 CT3.5L18 Ø3.5 mm non-locking screw - L18 mm
 CT3.5L18-ST Ø3.5 mm non-locking screw - L18 mm - STERILE
 CT3.5L20 Ø3.5 mm non-locking screw - L20 mm
 CT3.5L20-ST Ø3.5 mm non-locking screw - L20 mm - STERILE
 CT3.5L22 Ø3.5 mm non-locking screw - L22 mm
 CT3.5L22-ST Ø3.5 mm non-locking screw - L22 mm - STERILE
 CT3.5L24 Ø3.5 mm non-locking screw - L24 mm
 CT3.5L24-ST Ø3.5 mm non-locking screw - L24 mm - STERILE
 CT3.5L26 Ø3.5 mm non-locking screw - L26 mm
 CT3.5L26-ST Ø3.5 mm non-locking screw - L26 mm - STERILE
 CT3.5L28 Ø3.5 mm non-locking screw - L28 mm
 CT3.5L28-ST Ø3.5 mm non-locking screw - L28 mm - STERILE
 CT3.5L30 Ø3.5 mm non-locking screw - L30 mm
 CT3.5L30-ST Ø3.5 mm non-locking screw - L30 mm - STERILE
 CT3.5L32 Ø3.5 mm non-locking screw - L32 mm
 CT3.5L32-ST Ø3.5 mm non-locking screw - L32 mm - STERILE
 CT3.5L40 Ø3.5 mm non-locking screw - L40 mm
 CT3.5L40-ST Ø3.5 mm non-locking screw - L40 mm - STERILE
 CT3.5L45 Ø3.5 mm non-locking screw - L45 mm
 CT3.5L45-ST Ø3.5 mm non-locking screw - L45 mm - STERILE
 CT3.5L50 Ø3.5 mm non-locking screw - L50 mm
 CT3.5L50-ST Ø3.5 mm non-locking screw - L50 mm - STERILE
 CT3.5L55 Ø3.5 mm non-locking screw - L55 mm
 CT3.5L55-ST Ø3.5 mm non-locking screw - L55 mm - STERILE
 CT3.5L60 Ø3.5 mm non-locking screw - L60 mm

CT3.5L60-ST Ø3.5 mm non-locking screw - L60 mm - STERILE
 CT3.5L65 Ø3.5 mm non-locking screw - L65 mm
 CT3.5L65-ST Ø3.5 mm non-locking screw - L65 mm - STERILE
 CT3.5L70 Ø3.5 mm non-locking screw - L70 mm
 CT3.5L70-ST Ø3.5 mm non-locking screw - L70 mm - STERILE
 FTS1 Straight plate - Diaphyseal fibula - Symmetrical - Size 1
 FTS1-ST Straight plate - Diaphyseal fibula - Symmetrical - Size 1 - STERILE
 H1.4QT4.0L40 Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L40 mm
 H1.4QT4.0L45 Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L45 mm
 H1.4QT4.0L50 Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L50 mm
 H1.4QT4.0L55 Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L55 mm
 H1.4QT4.0L60 Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L60 mm
 H1.4QT4.0L65 Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L65 mm
 H1.4QT4.0L70 Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L70 mm
 QDT2.8L10 Ø2.8 mm non-locking screw - L10 mm
 QDT2.8L10-ST Ø2.8 mm non-locking screw - L10 mm - STERILE
 QDT2.8L12 Ø2.8 mm non-locking screw - L12 mm
 QDT2.8L12-ST Ø2.8 mm non-locking screw - L12 mm - STERILE
 QDT2.8L14 Ø2.8 mm non-locking screw - L14 mm
 QDT2.8L14-ST Ø2.8 mm non-locking screw - L14 mm - STERILE
 QDT2.8L16 Ø2.8 mm non-locking screw - L16 mm
 QDT2.8L16-ST Ø2.8 mm non-locking screw - L16 mm - STERILE
 QDT2.8L18 Ø2.8 mm non-locking screw - L18 mm
 QDT2.8L18-ST Ø2.8 mm non-locking screw - L18 mm - STERILE
 QDT2.8L20 Ø2.8 mm non-locking screw - L20 mm
 QDT2.8L20-ST Ø2.8 mm non-locking screw - L20 mm - STERILE
 QDT2.8L22 Ø2.8 mm non-locking screw - L22 mm
 QDT2.8L22-ST Ø2.8 mm non-locking screw - L22 mm - STERILE
 QDT2.8L24 Ø2.8 mm non-locking screw - L24 mm
 QDT2.8L24-ST Ø2.8 mm non-locking screw - L24 mm - STERILE
 QOT3.5L10 Ø3.5 mm non-locking screw - L10 mm
 QOT3.5L10-ST Ø3.5 mm non-locking screw - L10 mm - STERILE
 QOT3.5L12 Ø3.5 mm non-locking screw - L12 mm
 QOT3.5L12-ST Ø3.5 mm non-locking screw - L12 mm - STERILE
 QOT3.5L14 Ø3.5 mm non-locking screw - L14 mm
 QOT3.5L14-ST Ø3.5 mm non-locking screw - L14 mm - STERILE
 QOT3.5L16 Ø3.5 mm non-locking screw - L16 mm
 QOT3.5L16-ST Ø3.5 mm non-locking screw - L16 mm - STERILE
 QOT3.5L18 Ø3.5 mm non-locking screw - L18 mm
 QOT3.5L18-ST Ø3.5 mm non-locking screw - L18 mm - STERILE
 QOT3.5L20 Ø3.5 mm non-locking screw - L20 mm
 QOT3.5L20-ST Ø3.5 mm non-locking screw - L20 mm - STERILE
 QOT3.5L22 Ø3.5 mm non-locking screw - L22 mm
 QOT3.5L22-ST Ø3.5 mm non-locking screw - L22 mm - STERILE
 QOT3.5L24 Ø3.5 mm non-locking screw - L24mm
 QOT3.5L24-ST Ø3.5 mm non-locking screw - L24 mm - STERILE
 QT4.0L40 Ø4.0 mm lag screw - L40 mm
 QT4.0L40-ST Ø4.0 mm lag screw - L40 mm - STERILE
 QT4.0L45 Ø4.0 mm lag screw - L45 mm
 QT4.0L45-ST Ø4.0 mm lag screw - L45 mm - STERILE
 QT4.0L50 Ø4.0 mm lag screw - L50 mm

QT4.0L50-ST Ø4.0 mm lag screw - L50 mm - STERILE
 QT4.0L55 Ø4.0 mm lag screw - L55 mm
 QT4.0L55-ST Ø4.0 mm lag screw - L55 mm - STERILE
 QT4.0L60 Ø4.0 mm lag screw - L60 mm
 QT4.0L60-ST Ø4.0 mm lag screw - L60 mm - STERILE
 QT4.0L65 Ø4.0 mm lag screw - L65 mm
 QT4.0L65-ST Ø4.0 mm lag screw - L65 mm - STERILE
 QT4.0L70 Ø4.0 mm lag screw - L70 mm
 QT4.0L70-ST Ø4.0 mm lag screw - L70 mm - STERILE
 RITSM0 Standard plate - Distal tibia - Symmetrical - Size 0
 RITSM0-ST Standard plate - Distal tibia - Symmetrical - Size 0 - STERILE
 RITSM1 Standard plate - Distal tibia - Symmetrical - Size 1
 RITSM1-ST Standard plate - Distal tibia - Symmetrical - Size 1 - STERILE
 RITSMH1 Hook plate - Distal tibia - Symmetrical - Size 1
 RITSMH1-ST Hook plate - Distal tibia - Symmetrical - Size 1 - STERILE
 RTDLS1 Lateral plate - Distal fibula - Standard - Right - Size 1
 RTDLS1-ST Lateral plate - Distal fibula - Standard - Right - Size 1 - STERILE
 RTDLS2 Lateral plate - Distal fibula - Standard - Right - Size 2
 RTDLS2-ST Lateral plate - Distal fibula - Standard - Right - Size 2 - STERILE
 RTDLS3 Lateral plate - Distal fibula - Standard - Right - Size 3
 RTDLS3-ST Lateral plate - Distal fibula - Standard - Right - Size 3 - STERILE
 RTDLS4 Lateral plate - Distal fibula - Standard - Right - Size 4
 RTDLS4-ST Lateral plate - Distal fibula - Standard - Right - Size 4 - STERILE
 RTDLS5 Lateral plate - Distal fibula - Standard - Right - Size 5
 RTDLS5-ST Lateral plate - Distal fibula - Standard - Right - Size 5 - STERILE
 RTDQ1 Posterolateral plate - Distal fibula - Right - Size 1
 RTDQ1-ST Posterolateral plate - Distal fibula - Right - Size 1 - STERILE
 RTDQ2 Posterolateral plate - Distal fibula - Right - Size 2
 RTDQ2-ST Posterolateral plate - Distal fibula - Right - Size 2 - STERILE
 RTDQ3 Posterolateral plate - Distal fibula - Right - Size 3
 RTDQ3-ST Posterolateral plate - Distal fibula - Right - Size 3 - STERILE
 RTGLS1 Lateral plate - Distal fibula - Standard - Left - Size 1
 RTGLS1-ST Lateral plate - Distal fibula - Standard - Left - Size 1 - STERILE
 RTGLS2 Lateral plate - Distal fibula - Standard - Left - Size 2
 RTGLS2-ST Lateral plate - Distal fibula - Standard - Left - Size 2 - STERILE
 RTGLS3 Lateral plate - Distal fibula - Standard - Left - Size 3
 RTGLS3-ST Lateral plate - Distal fibula - Standard - Left - Size 3 - STERILE
 RTGLS4 Lateral plate - Distal fibula - Standard - Left - Size 4
 RTGLS4-ST Lateral plate - Distal fibula - Standard - Left - Size 4 - STERILE
 RTGLS5 Lateral plate - Distal fibula - Standard - Left - Size 5
 RTGLS5-ST Lateral plate - Distal fibula - Standard - Left - Size 5 - STERILE
 RTGQ1 Posterolateral plate - Distal fibula - Left - Size 1
 RTGQ1-ST Posterolateral plate - Distal fibula - Left - Size 1 - STERILE
 RTGQ2 Posterolateral plate - Distal fibula - Left - Size 2
 RTGQ2-ST Posterolateral plate - Distal fibula - Left - Size 2 - STERILE
 RTGQ3 Posterolateral plate - Distal fibula - Left - Size 3
 RTGQ3-ST Posterolateral plate - Distal fibula - Left - Size 3 - STERILE
 RTSLN1 Lateral plate - Distal fibula - Narrow - Symmetrical - Size 1
 RTSLN1-ST Lateral plate - Distal fibula - Narrow - Symmetrical - Size 1 - STERILE
 RTSLN2 Lateral plate - Distal fibula - Narrow - Symmetrical - Size 2
 RTSLN2-ST Lateral plate - Distal fibula - Narrow - Symmetrical - Size 2 - STERILE

SDT2.8L10 Ø2.8 mm locking screw - L10 mm
 SDT2.8L10-STI Ø2.8 mm locking screw - L10 mm - STERILE
 SDT2.8L12 Ø2.8 mm locking screw - L12 mm
 SDT2.8L12-STI Ø2.8 mm locking screw - L12 mm - STERILE
 SDT2.8L14 Ø2.8 mm locking screw - L14 mm
 SDT2.8L14-STI Ø2.8 mm locking screw - L14 mm - STERILE
 SDT2.8L16 Ø2.8 mm locking screw - L16 mm
 SDT2.8L16-STI Ø2.8 mm locking screw - L16 mm - STERILE
 SDT2.8L18 Ø2.8 mm locking screw - L18 mm
 SDT2.8L18-STI Ø2.8 mm locking screw - L18 mm - STERILE
 SDT2.8L20 Ø2.8 mm locking screw - L20 mm
 SDT2.8L20-STI Ø2.8 mm locking screw - L20 mm - STERILE
 SDT2.8L22 Ø2.8 mm locking screw - L22 mm
 SDT2.8L22-STI Ø2.8 mm locking screw - L22 mm - STERILE
 SDT2.8L24 Ø2.8 mm locking screw - L24 mm
 SDT2.8L24-STI Ø2.8 mm locking screw - L24 mm - STERILE
 SDT2.8L30 Ø2.8 mm locking screw - L30 mm
 SDT2.8L30-STI Ø2.8 mm locking screw - L30 mm - STERILE
 SDT2.8L32 Ø2.8 mm locking screw - L32 mm
 SDT2.8L32-STI Ø2.8 mm locking screw - L32 mm - STERILE
 SDT2.8L34 Ø2.8 mm locking screw - L34 mm
 SDT2.8L34-STI Ø2.8 mm locking screw - L34 mm - STERILE
 SDT2.8L36 Ø2.8 mm locking screw - L36 mm
 SDT2.8L36-STI Ø2.8 mm locking screw - L36 mm - STERILE
 SDT2.8L38 Ø2.8 mm locking screw - L38 mm
 SDT2.8L38-STI Ø2.8 mm locking screw - L38 mm - STERILE
 SDT2.8L40 Ø2.8 mm locking screw - L40 mm
 SDT2.8L40-STI Ø2.8 mm locking screw - L40 mm - STERILE
 SDT2.8L42 Ø2.8 mm locking screw - L42 mm
 SDT2.8L42-STI Ø2.8 mm locking screw - L42 mm - STERILE
 SDT2.8L44 Ø2.8 mm locking screw - L44 mm
 SDT2.8L44-STI Ø2.8 mm locking screw - L44 mm - STERILE
 SDT2.8L46 Ø2.8 mm locking screw - L46 mm
 SDT2.8L46-STI Ø2.8 mm locking screw - L46 mm - STERILE
 SDT2.8L48 Ø2.8 mm locking screw - L48 mm
 SDT2.8L48-STI Ø2.8 mm locking screw - L48 mm - STERILE
 SDT2.8L50 Ø2.8 mm locking screw - L50 mm
 SDT2.8L50-STI Ø2.8 mm locking screw - L50 mm - STERILE
 SDT2.8L55 Ø2.8 mm locking screw - L55 mm
 SDT2.8L55-STI Ø2.8 mm locking screw - L55 mm - STERILE
 SDT2.8L60 Ø2.8 mm locking screw - L60 mm
 SDT2.8L60-STI Ø2.8 mm locking screw - L60 mm - STERILE
 SOT3.5L10 Ø3.5 mm locking screw - L10 mm
 SOT3.5L10-ST Ø3.5 mm locking screw - L10 mm - STERILE
 SOT3.5L12 Ø3.5 mm locking screw - L12 mm
 SOT3.5L12-ST Ø3.5 mm locking screw - L12 mm - STERILE
 SOT3.5L14 Ø3.5 mm locking screw - L14 mm
 SOT3.5L14-ST Ø3.5 mm locking screw - L14 mm - STERILE
 SOT3.5L16 Ø3.5 mm locking screw - L16 mm
 SOT3.5L16-ST Ø3.5 mm locking screw - L16 mm - STERILE
 SOT3.5L18 Ø3.5 mm locking screw - L18 mm

SOT3.5L18-ST Ø3.5 mm locking screw - L18 mm - STERILE
 SOT3.5L20 Ø3.5 mm locking screw - L20 mm
 SOT3.5L20-ST Ø3.5 mm locking screw - L20 mm - STERILE
 SOT3.5L22 Ø3.5 mm locking screw - L22 mm
 SOT3.5L22-ST Ø3.5 mm locking screw - L22 mm - STERILE
 SOT3.5L24 Ø3.5 mm locking screw - L24 mm
 SOT3.5L24-ST Ø3.5 mm locking screw - L24 mm - STERILE
 WASH-T4 Compression washer for Ø4.0 mm compressive screws
 WASH-T4-ST Compression washer for Ø4.0 mm compressive screws - STERILE
 Instrumental
 ANC016 2.5 mm hexagonal screwdriver
 ANC042 Mini set - Base
 ANC042/CB Mini set - Cambered lid
 ANC046C Ø2.0 mm non threaded guide gauge for Ø2.8 mm screws
 ANC082E 2.0 mm quick coupling hexagonal prehensor screwdriver
 ANC083C 2 in 1 : 2.5 mm hexagonal prehensor screwdriver - Ø3.5 mm countersink
 ANC084 Ø2.8 mm quick coupling countersink
 ANC088C Ø2.0 mm quick coupling drill bit - L125 mm
 ANC089C Ø2.7 mm quick coupling drill bit - L125 mm
 ANC102 Length gauge for Ø2.8 mm screws
 ANC103 2.0 mm hexagonal non prehensor screwdriver
 ANC107 2.5 mm quick coupling hexagonal non prehensor screwdriver
 ANC124 Length gauge for Ø3.5 mm screws
 ANC186 Ø2.7 mm threaded guide gauge for Ø3.5 mm screws
 ANC191 Ø2.7 mm non threaded bent guide gauge for Ø3.5 mm screws
 ANC252 Fast drilling guide for lateral plate - Distal fibula - Standard - Left (RTGLSx)
 ANC253 Fast drilling guide for lateral plate - Distal fibula - Standard - Right (RTDLSx)
 ANC254/B Activ Ankle set - Base
 ANC254/C Activ Ankle set - Lid
 ANC254/I1 Activ Ankle set - Insert 1 - Implants
 ANC254/I2 Activ Ankle set - Insert 2 - Instruments
 ANC254/I3 Activ Ankle set - Insert 3 - Syndesmosis / Medial malleolus
 ANC254/R Activ Ankle set - Screw rack
 ANC256M Ø2.7 mm quick coupling drill bit - L180 mm
 ANC261M Ø2.7 mm non threaded bent long guide gauge for Ø3.5 and Ø4.0 mm screws
 ANC268C Ø2.0 mm threaded guide gauge for Ø2.8 mm screws
 ANC349 15 cm verbrugge forceps
 ANC350 Ø4.5 mm AO quick coupling handle - Size 1
 ANC388 2.5 mm quick coupling hexagonal non prehensor screwdriver - cannula Ø1.4 mm
 ANC414M Quick coupling drill bit Ø2.9 mm - cannula 1.4 mm - L125 mm
 ANC452 Bending iron
 ANC454 Fast drilling guide for posterolateral plate - Distal fibula - Left (RTGQx)
 ANC455 Fast drilling guide for posterolateral plate - Distal fibula - Right (RTDQx)
 ANC456 Fast drilling guide for lateral plate - Distal fibula - Narrow - Symmetrical (RTSLNx)
 ANC463 Ø3.5 mm quick coupling countersink
 ANC503 150 mm reduction forceps
 ANC504 150 mm pointed reduction forceps
 ANC542 Ø3.5 mm quick coupling drill bit - L125 mm
 ANC689 Length gauge for Ø2.8 mm screws - Measures 10 - 60 mm
 ANC690 Ø2.0 mm quick coupling drill bit - L180 mm
 ANC691 Ø2.0 mm threaded long guide gauge for Ø2.8 mm screws

ANC692 Ø2.0 mm non threaded bent guide gauge for Ø2.8 mm screws
ANC1137 Ø4.5 mm cannulated AO quick coupling straight handle with ratchet - Size 2
330.213.120 Pin Ø1.3 - L120 mm
33.0214.120 Pin Ø1.4 - L120 mm

Período de vida útil: Producto estéril: 5 años
Producto No estéril: No corresponde

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: Envase unitario estéril
Envase unitario no estéril

Método de esterilización: Radiación gamma

Nombre del fabricante: NEWCLIP TECHNICS

Lugar de elaboración: 45 rue des Garottières- PA de la Lande Saint Martin-44115 Haute Goulaine. Francia.

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° 11467/24.

La empresa mantiene en su establecimiento y a disposición de la autoridad sanitaria la documentación requerida por disposición ANMAT N° 64/25 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 Bio Lap S.A bajo el número PM 1882-32 siendo su nueva vigencia hasta el 05 julio 2031

Firmado digitalmente por: TERRIZZANO Maria Lorena
Fecha y hora: 09.10.2026 13:06:45

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: 07 octubre 2026



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

N° Identificador Trámite: 79311

Tramitada por Expediente N°: 1-0047-3110-004824-26-8



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