



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

DECLARACION JURADA DE REVÁLIDA

DISPOSICIÓN ANMAT N° 9688/2019

N° rev: 1706-6#0001

En nombre y representación de la firma TELVIDEO DIVISION MEDITEL SRL , 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: 1706-6

Disposición autorizante N° DC 00 de fecha 15 marzo 2018
Disposiciones modificatorias y reválidas N°: N/A

Datos Característicos del Producto Médico:

Nombre descriptivo: PUNTAS PARA DESVASTADO ENDOSCOPICO-ARTROSCOPICO

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
17-918 SISTEMA PARA DESVASTADO ARTROSCOPICO

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

Clase de Riesgo: II

Indicación/es autorizada/s: Las puntas endoscópicas/artroscópicas son dispositivos de corte giratorio que se utilizan en aplicaciones quirúrgicas endoscópicas artroscópicas para el afeitado y resección de tejidos blandos y huesos. Se utilizan conjuntamente con un equipo de afeitado/desvastado (Shaver para artroscopia)

Modelos: 1400, Aggressive Meniscus Cutter ø3,5mm, -- 1401, Aggressive Meniscus Cutter ø4,2mm, -- 1402, Aggressive Meniscus Cutter ø5,5mm, -- 1403, Aggressive Meniscus Cutter Plus ø4,2mm, -- 1404, Full Radius Resector ø3,5mm, -- 1405, Full Radius Resector ø4,2mm, -- 1406, Full Radius Resector ø5,5mm, -- 1407, Aggressive Full Radius ø3,5mm, -- 1408, Aggressive Full Radius ø4,2mm, -- 1409, Aggressive Full Radius ø5,5mm, -- 1410, Oval Burr ø5,5mm, -- 1411, Oval Burr ø6,5mm, -- 1412, Round Burr ø4,2mm, -- 1413, Round Burr ø5,5mm, -- 1414, Round Burr ø6,5mm, -- 1415, Tapered Burr ø5,5mm, -- 1416, Tapered Burr ø6,5mm, -- 1418, Double Aggressive Full Radius ø4,2mm, -- 1419, Double Aggressive Full Radius ø5,5mm, -- 1420, Full

Radius Resector Sharp Cut ø4,2mm, -- 1422, Full Radius Resector Small Window ø4,2mm, -- 1423, Meniscus Cutter ø3,5mm, -- 1424, Meniscus Cutter ø4,2mm, -- 1425, Meniscus Cutter ø5,5mm, -- 1426, Aggressive Meniscus Side Cutter ø3,5mm, -- 1427, Aggressive Meniscus Side Cutter ø4,2mm, -- 1428, Aggressive Meniscus Side Cutter ø5,5mm, -- 1429, Trimmer ø3,5mm, -- 1430, Trimmer ø4,2mm, -- 1431, Trimmer ø5,5mm, -- 1433, Aggressive Open End Cutter ø4,2mm, -- 1434, Full Radius Resector ø4,2mm, -- 1435, Full Radius Resector ø5,5mm, -- 1436, Aggressive Full Radius ø4,2mm, -- 1437, Aggressive Full Radius ø5,5mm, -- 1438, Aggressive Meniscus Side Cutter ø4,2mm, -- 1439, Aggressive Meniscus Side Cutter ø5,5mm, -- 1440, Full Radius Resector Small Window ø5,5mm, -- 1441, Double Full Radius ø4,2mm, -- 1442, Double Full Radius ø5,5mm, -- 1444, Double Meniscus Cutter ø4,2mm, -- 1445, Double Meniscus Cutter ø5,5mm, -- 1446, Aggressive Full Radius Plus ø4,2mm, -- 1447, Aggressive Meniscus Cutter Plus ø4,2mm, -- 1448, Aggressive Oval Burr ø5,5mm, -- 1449, Aggressive Oval Burr ø6,5mm, -- 1450, Conical Double Full Radius ø4,2mm, -- 31025, Round Burr ø2,5mm, -- 31035, Round Burr ø3,5mm, -- 31042, Round Burr ø4,2mm, -- 31055, Round Burr ø5,5mm, -- 31065, Round Burr ø6,5mm, -- 31120, Full Radius Resector ø2,0mm, -- 31125, Full Radius Resector ø2,5mm, -- 31135, Full Radius Resector ø3,5mm, -- 31142, Full Radius Resector ø4,2mm, -- 31155, Full Radius Resector ø5,5mm, -- 31235, Meniscus Cutter ø3,5mm, -- 31242, Meniscus Cutter ø4,2mm, -- 31255, Meniscus Cutter ø5,5mm, -- 31320, Aggressive Full Radius ø2,0mm, -- 31325, Aggressive Full Radius ø2,5mm, -- 31335, Aggressive Full Radius ø3,5mm, -- 31342, Aggressive Full Radius ø4,2mm, -- 31355, Aggressive Full Radius ø5,5mm, -- 31435, Aggressive Meniscus Side Cutter ø3,5mm, -- 31442, Aggressive Meniscus Side Cutter ø4,2mm, -- 31455, Aggressive Meniscus Side Cutter ø5,5mm, -- 31535, Aggressive Meniscus Cutter ø3,5mm, -- 31542, Aggressive Meniscus Cutter ø4,2mm, -- 31555, Aggressive Meniscus Cutter ø5,5mm, -- 31742, Aggressive Open End Cutter ø4,2mm, -- 31855, Tapered Burr ø5,5mm, -- 31865, Tapered Burr ø6,5mm, -- 31955, Oval Burr ø5,5mm, -- 31965, Oval Burr ø6,5mm, -- 32035, Trimmer ø3,5mm, -- 32042, Trimmer ø4,2mm, -- 32055, Trimmer ø5,5mm, -- 32142, Aggressive Meniscus Cutter Plus ø4,2mm, -- 32242, Full Radius Resector Small Window ø4,2mm, -- 32255, Full Radius Resector Small Window ø5,5mm, -- 32342, Double Aggressive Full Radius ø4,2mm, -- 32355, Double Aggressive Full Radius ø5,5mm, -- 32442, Conical Double Full Radius ø4,2mm, -- 32542, Double Full Radius ø4,2mm, -- 32555, Double Full Radius ø5,5mm, -- 32642, Double Meniscus Cutter ø4,2mm, -- 32655, Double Meniscus Cutter ø5,5mm, -- 32742, Full Radius Resector Sharp Cut ø4,2mm, -- 33042, Full Radius Resector ø4,2mm, -- 33055, Full Radius Resector ø5,5mm, -- 33142, Aggressive Meniscus Side Cutter ø4,2mm, -- 33155, Aggressive Meniscus Side Cutter ø5,5mm, -- 33242, Aggressive Full Radius ø4,2mm, -- 33255, Aggressive Full Radius ø5,5mm, -- 33855, Aggressive Oval Burr ø5,5mm, -- 33865, Aggressive Oval Burr ø6,5mm, -- 41055, Round Burr ø5,5mm, -- 41135, Full Radius Resector ø3,5mm, -- 41335, Aggressive Full Radius ø3,5mm, -- 41342, Aggressive Full Radius ø4,2mm, -- 41355, Aggressive Full Radius ø5,5mm, -- 41955, Oval Burr ø5,5mm, -- 41965, Oval Burr ø6,5mm, -- 42142, Aggressive Meniscus Cutter Plus ø4,2mm, -- 42542, Double Full Radius ø4,2mm, -- 42555, Double Full Radius ø5,5mm, -- 42642, Double Meniscus Cutter ø4,2mm, -- 42655, Double Meniscus Cutter ø5,5mm, -- 42742, Full Radius Resector Sharp Cut ø4,2mm, -- 43855, Aggressive Oval Burr ø5,5mm, -- 43865, Aggressive Oval Burr ø6,5mm, -- 900092, Saw Blade 27x6x0,4 Cutting Strength 0,6mm, -- 900116, Saw Blade 22x8x0,3 Cutting Strength 0,4mm, -- 900117, Saw Blade 31x10x0,3 Cutting Strength 0,4mm, -- 900119, Saw Blade 50x14x0,4 Cutting Strength 0,7mm, -- 900123, Drill ø10mm 2,2x180mm cannulated, -- 900124, Drill ø9mm 2,2x180mm cannulated, -- 900125, Drill ø8mm 2,2x180mm cannulated, -- 900126, Drill ø7mm 2,2x180mm cannulated, -- 9131025, Round Burr ø2,5mm, -- 9131035, Round Burr ø3,5mm, -- 9131042, Round Burr ø4,2mm, -- 9131055, Round Burr ø5,5mm, -- 9131065, Round Burr ø6,5mm, -- 9131120, Full Radius Resector ø2,0mm, -- 9131125, Full Radius Resector ø2,5mm, -- 9131134, Full Radius Resector ø3,5mm, -- 9131135, Full Radius Resector ø3,5mm, -- 9131142, Full Radius Resector ø4,2mm, -- 9131148, Full

Radius Resector \varnothing 4,8mm, -- 9131155, Full Radius Resector \varnothing 5,5mm, -- 9131235, Meniscus Cutter \varnothing 3,5mm, -- 9131242, Meniscus Cutter \varnothing 4,2mm, -- 9131255, Meniscus Cutter \varnothing 5,5mm, -- 9131320, Aggressive Full Radius \varnothing 2,0mm, -- 9131325, Aggressive Full Radius \varnothing 2,5mm, -- 9131334, Aggressive Full Radius \varnothing 3,5mm, -- 9131335, Aggressive Full Radius \varnothing 3,5mm, -- 9131342, Aggressive Full Radius \varnothing 4,2mm, -- 9131348, Aggressive Full Radius \varnothing 4,8mm, -- 9131355, Aggressive Full Radius \varnothing 5,5mm, -- 9131435, Aggressive Meniscus Side Cutter \varnothing 3,5mm, -- 9131442, Aggressive Meniscus Side Cutter \varnothing 4,2mm, -- 9131455, Aggressive Meniscus Side Cutter \varnothing 5,5mm, -- 9131535, Aggressive Meniscus Cutter \varnothing 3,5mm, -- 9131542, Aggressive Meniscus Cutter \varnothing 4,2mm, -- 9131548, Aggressive Meniscus Cutter \varnothing 4,8mm, -- 9131555, Aggressive Meniscus Cutter \varnothing 5,5mm, -- 9131742, Aggressive Open End Cutter \varnothing 4,2mm, -- 9131855, Tapered Burr \varnothing 5,5mm, -- 9131865, Tapered Burr \varnothing 6,5mm, -- 9131955, Oval Burr \varnothing 5,5mm, -- 9131965, Oval Burr \varnothing 6,5mm, -- 9132035, Trimmer \varnothing 3,5mm, -- 9132042, Trimmer \varnothing 4,2mm, -- 9132055, Trimmer \varnothing 5,5mm, -- 9132142, Aggressive Meniscus Cutter Plus \varnothing 4,2mm, -- 9132242, Full Radius Resector Small Window \varnothing 4,2mm, -- 9132255, Full Radius Resector Small Window \varnothing 5,5mm, -- 9132342, Double Aggressive Full Radius \varnothing 4,2mm, -- 9132355, Double Aggressive Full Radius \varnothing 5,5mm, -- 9132442, Conical Double Full Radius \varnothing 4,2mm, -- 9132542, Double Full Radius \varnothing 4,2mm, -- 9132555, Double Full Radius \varnothing 5,5mm, -- 9132642, Double Meniscus Cutter \varnothing 4,2mm, -- 9132655, Double Meniscus Cutter \varnothing 5,5mm, -- 9132742, Full Radius Resector Sharp Cut \varnothing 4,2mm, -- 9133042, Full Radius Resector \varnothing 4,2mm, -- 9133055, Full Radius Resector \varnothing 5,5mm, -- 9133142, Aggressive Meniscus Side Cutter \varnothing 4,2mm, -- 9133155, Aggressive Meniscus Side Cutter \varnothing 5,5mm, -- 9133242, Aggressive Full Radius \varnothing 4,2mm, -- 9133255, Aggressive Full Radius \varnothing 5,5mm, -- 9133442, Aggressive Full Radius Plus \varnothing 4,2mm, -- 9133855, Aggressive Oval Burr \varnothing 5,5mm, -- 9133865, Aggressive Oval Burr \varnothing 6,5mm, -- 01401H, Aggressive Meniscus Cutter \varnothing 4,2mm, -- 01402H, Aggressive Meniscus Cutter \varnothing 5,5mm, -- 01403H, Aggressive Meniscus Cutter Plus \varnothing 4,2mm, -- 01408H, Aggressive Full Radius \varnothing 4,2mm, -- 01410H, Oval Burr \varnothing 5,5mm, -- 01413H, Round Burr \varnothing 5,5mm, -- 01420H, Full Radius Resector Sharp Cut \varnothing 4,2mm, -- 01424H, Meniscus Cutter \varnothing 4,2mm, -- 01436H, Aggressive Full Radius \varnothing 4,2mm, -- 01437H, Aggressive Full Radius \varnothing 5,5mm, -- 01448H, Aggressive Oval Burr \varnothing 5,5mm, -- 01449H, Aggressive Oval Burr \varnothing 6,5mm, -- 021025S, Round Burr \varnothing 2,5mm, -- 021035S, Round Burr \varnothing 3,5mm, -- 021042S, Round Burr \varnothing 4,2mm, -- 021055HS, Round Burr \varnothing 5,5mm, -- 021055S, Round Burr \varnothing 5,5mm, -- 021065S, Round Burr \varnothing 6,5mm, -- 021120S, Full Radius Resector \varnothing 2,0mm, -- 021125S, Full Radius Resector \varnothing 2,5mm, -- 021135S, Full Radius Resector \varnothing 3,5mm, -- 021142S, Full Radius Resector \varnothing 4,2mm, -- 021148S, Full Radius Resector \varnothing 4,8mm, -- 021155S, Full Radius Resector \varnothing 5,5mm, -- 021235S, Meniscus Cutter \varnothing 3,5mm, -- 021242HS, Meniscus Cutter \varnothing 4,2mm, -- 021242S, Meniscus Cutter \varnothing 4,2mm, -- 021255S, Meniscus Cutter \varnothing 5,5mm, -- 021320S, Aggressive Full Radius \varnothing 2,0mm, -- 021325S, Aggressive Full Radius \varnothing 2,5mm, -- 021335S, Aggressive Full Radius \varnothing 3,5mm, -- 021342HS, Aggressive Full Radius \varnothing 4,2mm, -- 021342S, Aggressive Full Radius \varnothing 4,2mm, -- 021348HS, Aggressive Full Radius \varnothing 4,8mm, -- 021348S, Aggressive Full Radius \varnothing 4,8mm, -- 021355HS, Aggressive Full Radius \varnothing 5,5mm, -- 021355S, Aggressive Full Radius \varnothing 5,5mm, -- 021435S, Aggressive Meniscus Side Cutter \varnothing 3,5mm, -- 021442S, Aggressive Meniscus Side Cutter \varnothing 4,2mm, -- 021455S, Aggressive Meniscus Side Cutter \varnothing 5,5mm, -- 021535S, Aggressive Meniscus Cutter \varnothing 3,5mm, -- 021542HS, Aggressive Meniscus Cutter \varnothing 4,2mm, -- 021542S, Aggressive Meniscus Cutter \varnothing 4,2mm, -- 021548HS, Aggressive Meniscus Cutter \varnothing 4,8mm, -- 021548S, Aggressive Meniscus Cutter \varnothing 4,8mm, -- 021555HS, Aggressive Meniscus Cutter \varnothing 5,5mm, -- 021555S, Aggressive Meniscus Cutter \varnothing 5,5mm, -- 021742S, Aggressive Open End Cutter \varnothing 4,2mm, -- 021855S, Tapered Burr \varnothing 5,5mm, -- 021955HS, Oval Burr \varnothing 5,5mm, -- 021955S, Oval Burr \varnothing 5,5mm, -- 021965S, Oval Burr \varnothing 6,5mm, -- 022042S, Trimmer \varnothing 4,2mm, -- 022142HS, Aggressive Meniscus Cutter Plus \varnothing 4,2mm, -- 022142S, Aggressive Meniscus Cutter Plus \varnothing 4,2mm, -- 022242S, Full Radius Resector Small

Window ø4,2mm, -- 022255S, Full Radius Resector Small Window ø5,5mm, -- 022342S, Double Aggressive Full Radius ø4,2mm, -- 022355S, Double Aggressive Full Radius ø5,5mm, -- 022542S, Double Full Radius ø4,2mm, -- 022555S, Double Full Radius ø5,5mm, -- 022642S, Double Meniscus Cutter ø4,2mm, -- 022655S, Double Meniscus Cutter ø5,5mm, -- 022742HS, Full Radius Resector Sharp Cut ø4,2mm, -- 022742S, Full Radius Resector Sharp Cut ø4,2mm, -- 023042S, Full Radius Resector ø4,2mm, -- 023055S, Full Radius Resector ø5,5mm, -- 023142S, Aggressive Meniscus Side Cutter ø4,2mm, -- 023155S, Aggressive Meniscus Side Cutter ø5,5mm, -- 023242HS, Aggressive Full Radius ø4,2mm, -- 023242S, Aggressive Full Radius ø4,2mm, -- 023255HS, Aggressive Full Radius ø5,5mm, -- 023255S, Aggressive Full Radius ø5,5mm, -- 023442S, Aggressive Full Radius Plus ø4,2mm, -- 023855HS, Aggressive Oval Burr ø5,5mm, -- 023855S, Aggressive Oval Burr ø5,5mm, -- 023865HS, Aggressive Oval Burr ø6,5mm, -- 023865S, Aggressive Oval Burr ø6,5mm, -- 031055H, Round Burr ø5,5mm, -- 031242H, Meniscus Cutter ø4,2mm, -- 031342H, Aggressive Full Radius ø4,2mm, -- 031542H, Aggressive Meniscus Cutter ø4,2mm, -- 031555H, Aggressive Meniscus Cutter ø5,5mm, -- 031955H, Oval Burr ø5,5mm, -- 032142H, Aggressive Meniscus Cutter Plus ø4,2mm, -- 032742H, Full Radius Resector Sharp Cut ø4,2mm, -- 033242H, Aggressive Full Radius ø4,2mm, -- 033255H, Aggressive Full Radius ø5,5mm, -- 033855H, Aggressive Oval Burr ø5,5mm, -- 033865H, Aggressive Oval Burr ø6,5mm, -- 9131055H, Round Burr ø5,5mm, -- 9131065H, Round Burr ø6,5mm, -- 9131242H, Meniscus Cutter ø4,2mm, -- 9131255H, Meniscus Cutter ø5,5mm, -- 9131342H, Aggressive Full Radius ø4,2mm, -- 9131348H, Aggressive Full Radius ø4,8mm, -- 9131355H, Aggressive Full Radius ø4,8mm, -- 9131542H, Aggressive Meniscus Cutter ø4,2mm, -- 9131548H, Aggressive Meniscus Cutter ø4,8mm, -- 9131555H, Aggressive Meniscus Cutter ø5,5mm, -- 9131955H, Oval Burr ø5,5mm, -- 9131965H, Oval Burr ø6,5mm, -- 9132142H, Aggressive Meniscus Cutter Plus ø4,2mm, -- 9132742H, Full Radius Resector Sharp Cut ø4,2mm, -- 9133242H, Aggressive Full Radius ø4,2mm, -- 9133255H, Aggressive Full Radius ø5,5mm, -- 9133855H, Aggressive Oval Burr ø5,5mm, -- 9133865H, Aggressive Oval Burr ø6,5mm

Período de vida útil: No aplica

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 individual

Método de esterilización: No aplica

Nombre del fabricante: EBERLE GMBH & Co. KG

Lugar de elaboración: Glasbronnenstrasse 6 75449 WURMBERG ALEMANIA

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 TELVIDEO DIVISION MEDITEL SRL bajo el número PM 1706-6 siendo su nueva vigencia hasta el 15 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: 27 febrero 2023



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

N° Identificadorio Trámite: 46361

Tramitada por Expediente N°: 1-0047-3110-001178-23-2