



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

ANEXO II
DECLARACIÓN DE CONFORMIDAD INICIAL – PM CLASE I- II

Número de revisión: 1920-14#0001

Número de PM:

1920-14

Nombre Descriptivo del producto:

Instrumentos quirúrgicos cortantes no articulados II

Código de identificación y nombre técnico UMDNS:

13-180 Instrumentos para Implantación de Prótesis, Ortopédicos

Clase de Riesgo:

Clase I

Marca de (los) producto(s) médico(s):

BIOMETAL

Modelos (en caso de clase II y equipos):

05.5.1030.113; 05.5.1031.113; 05.5.1032.113; 05.5.1033.113; 05.5.1034.113; 05.5.1035.113;
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11.5.0002.016 - BROCA Ø 1,60 X LONGITUD 93MM ER11.5.0020.020 - BROCA Ø 2,00 X
LONGITUD 110MM ER 11.5.0001.016 - BROCA Ø 1,60 X LONGITUD 38MM ER 11.5.0001.021 -
BROCA Ø 2,10 X LONGITUD 38MM ER

Composición cuali-cuanti porcentual exacta (si corresponde):

N/A

Indicación/es autorizada/s:

Están indicados para asistir en procedimientos quirúrgicos de colocación de
implantes para traumatología y artroplastia, que necesariamente deben ser realizados por un
profesional médico con conocimiento de la técnica quirúrgica y de los aspectos mecánicos de los
instrumentos.

Período de vida útil (si corresponde):

Los instrumentos tienen una vida útil indefinida y pueden reprocesarse

Método de Esterilización (si corresponde):

N/A

Forma de presentación:

Unidad

Condición de uso:

Uso exclusivo a profesionales e instituciones sanitarias

Nombre del fabricante:

BIOMETAL INDUSTRIA E COMERCIO LTDA

Lugar/es de elaboración:

V LUIZ VARGA 2010 GLEBA BEATRIZ 13486606, LIMEIRA SP, BRASIL

En nombre y representación de la firma TREE S.R.L. , 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 EMISIÓN
N/A	-	-

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, 22 septiembre 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 en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de **TREE S.R.L.** bajo el número PM

1920-14

Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad en la Ciudad de Buenos Aires a los días 22 septiembre 2026 la cual tendrá una vigencia de cinco (5) años a contar de la fecha.

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Veronica
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TERRIZZANO Maria Lorena
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Dirección de Evaluación de Registro
Firma y Sello

Instituto Nacional de Productos Médicos
Firma y Sello



ORTIZ Andrea Melina
CUIL 27367241522



ABRIOLA Leticia Adriana
CUIL 27323186494



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°: 1-0047-3110-006458-26-7

SANCHEZ
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n Anibal
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