



Ministerio de Salud
República Argentina

2026 - AÑO DE LA GRANDEZA ARGENTINA

DECLARACION JURADA

DISPOSICIÓN ANMAT N° 236/2026
DECRETO 895/25

N° rev: 1920-14#0001

En nombre y representación de la firma TREE S.R.L. , el responsable legal y el responsable técnico declaran bajo juramento cumplir con la Disposición 236/26 para el producto médico declarado bajo el Número de PM: 1920-14

Datos Característicos del Producto Médico:

Nombre descriptivo: Instrumentos quirúrgicos cortantes no articulados II

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
13-180 Instrumentos para Implantación de Prótesis, Ortopédicos

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

Regla de clasificación Disposición ANMAT N° 64/25: Regla 6

Clase de Riesgo: I

Indicación/es de uso: 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.

Modelos: 05.5.1030.113; 05.5.1031.113; 05.5.1032.113; 05.5.1033.113; 05.5.1034.113;
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03.5.1109.160; 03.5.1110.160; 03.5.1111.160;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

Período de vida útil: Los instrumentos tienen una vida útil indefinida y pueden reprocesarse

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Contiene látex: NO

Forma de presentación: unidad

Método de esterilización: N/A

Condición de conservación/almacenamiento (SI CORRESPONDE): Transportar el producto con cuidado, evitando caídas y fricciones que puedan provocar pérdida de condición de esterilidad, defectos en el acabado superficial de la pieza y su funcionalidad. Conserve siempre el producto en el embalaje original, hasta el momento de su uso, bajo la responsabilidad del equipo médico/hospitalario designado para tal fin, recordando que siempre deben prestar atención a la integridad del embalaje. ? Transportar el producto en un lugar seco, limpio, protegido de la luz. Fecha de fabricación y n°. del lote: ver etiqueta

Nombre del fabricante: BIOMETAL INDUSTRIA E COMERCIO LTDA

Lugar de elaboración: V LUIZ VARGA 2010 GLEBA BEATRIZ 13486606 LIMEIRA SP, BRASIL

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 , que cumple y satisface con los Requisitos Esenciales de Seguridad y Desempeño (R.E.S.D.) 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°236/26, Disposición ANMAT N°64/25 y Disposición ANMAT N° 9688/19.

Firma del Responsable Legal

Firme Responsable Técnico

La presente DECLARACIÓN JURADA ha sido emitida de acuerdo con las previsiones del Decreto 892/25 y la Disposición ANMAT N° 236/26, quedando 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, siendo su vigencia hasta el 10 agosto de 2031

La presente DJ será válida cuando sea escaneado su código QR y verificada digitalmente a través de la página de ANMAT. Asimismo, deberá estar acompañada de las disposiciones o DJ de habilitación enunciadas anteriormente.



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

N° Identificador Trámite: 80418

Tramitada por Expediente N°: 1-0047-3110-005973-26-9