



**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: 2990-1#0001

Número de PM:

2990-1

Nombre Descriptivo del producto:

Fresas dentales

Código de identificación y nombre técnico UMDNS:

10-521 - Fresas, dentales

Clase de Riesgo:

Clase II

Marca de (los) producto(s) médico(s):

G & Z

Modelos (en caso de clase II y equipos):

2879-104-014-N, 368-204-016-3.5, 368-204-020-4.6, 368-204-023-5, 368-314-010-3.5, 368-314-012-3.5, 368-314-014-3.5, 368-314-016-3.5, 368-314-018-4.5, 368-314-020-5, 368-314-021-5, 368-314-023-5, 369-314-025-5,5, 369-315-025-5,5, 369XXL-317-025-5,5, 371-314-023-4,5, 379-104-050-C, 379-204-023-4.3, 379-314-012-3, 379-314-014-3, 379-314-016-3, 379-314-018-3.4, 379-314-020-4.2, 379-314-021-4.2, 379-314-023-4.5, 379-314-023-5, 379-314-027-5, 379-314-029-5,5, 379L-314-012-F, 379L-314-012-XF, 379L-314-016-F, 379L-314-016-XF, 379L-314-023-C, 379L-315-014-3, 379L-315-014-3-C, 379L-315-023-4.3, 379XL-316-012-3,5, 379XL-316-016-3,5, 379XL-316-016-3,5-F, 379XL-316-016-6, 379XXL-314-023-F, 379XXL-314-023-N, 379XXL-317-012-3,5, 379XXL-317-016-3,5, 379XXL-317-016-6, 379XXL-317-016-6-C, 381L-314-016-UF, 381L-314-016-XF, 381XL-314-016-F, 381XL-314-016-UF, 381XL-314-016-XF, 390-314-014-3,

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Composición cuali-cuanti porcentual exacta (si corresponde):

no corresponde

Indicación/es autorizada/s:

Reducir, modificar y pulir piezas dentales y restauraciones.

Período de vida útil (si corresponde):

10 años

Método de Esterilización (si corresponde):

no corresponde

Forma de presentación:

Envase unitario, envase con 5 unidades, envase con 10 unidades

Condición de uso:

Uso exclusivo a profesionales e instituciones sanitarias

Nombre del fabricante:

G & Z Instrumente GmbH

Lugar/es de elaboración:

Montfortstrasse 1, 6890 Lustenau, Austria

En nombre y representación de la firma RUEDA CRISTIAN LUIS , 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
1. 2. 3. 4. 5. 6. APLICA - ISO 13485 / 7.1. 7.2. APLICA - ISO 13485 / 7.3. 7.4. NO APLICA / 8.1. APLICA - ISO 13485 / 8.2. 8.3. 8.4. 8.5. 8.6. 8.7. NO APLICA / 9.1. 9.2. 9.3. APLICA-ISO 13485 / 10. 11. 12. NO APLICA	NA	NA

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, 01 abril 2026**

Responsable Legal  
Firma y Sello

Responsable Técnico  
Firma y Sello



**Ministerio de Salud**  
Secretaria 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 **RUEDA CRISTIAN LUIS** bajo el número PM **2990-1**

Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad en la Ciudad de Buenos Aires a los días 01 abril 2026 la cual tendrá una vigencia de cinco (5) años a contar de la fecha.

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°: 1-0047-3110-000485-26-1