



**Ministerio de Salud y Desarrollo Social**  
Secretaría de Gobierno de Salud  
A.N.M.A.T.

## ANEXO II

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

Número de revisión: 00

Número de PM:

2394-1

Nombre Descriptivo del producto:

Sistema de brackets y materiales para ortodoncia.

Código de identificación y nombre técnico UMDNS:

16-697 Materiales para ortodoncia

Clase de Riesgo:

Clase II

Marca de (los) producto(s) médico(s):

3B ORTHODONTIC

Modelos (en caso de clase II y equipos):

Brackets para ortodoncia Roth, MBT, Edgewise y lingual.

BR222-254, BR222-20114, BR222-20124, BR222-21134, BR222-21144, BR222-20214, BR222-20224, BR222-21234, BR222-21244, BR222-20314, BR222-20334, BR222-20344, BR222-20354, BR222-20434, BR222-20444, BR222-20454, BR222-20314H, BR222-20114H, BR222-20124H, BR222-21134H, BR222-20214H, BR222-20224H, BR222-21234H, BR812-107, BR812-137, BR812-157, BR812-10117, BR812-10127, BR812-11137, BR812-11147, BR812-10217, BR812-10227, BR812-11237, BR812-11247, BR812-10317, BR812-11337, BR812-11347, BR812-11357, BR812-11437, BR812-11447, BR812-11457, BR812-10137, BR812-10147, BR812-10237, BR812-10247, BR812-10337, BR812-10347, BR812-10357, BR812-10437, BR812-10447, BR812-10457, BR811-107, BR811-137, BR811-157, BR811-10117, BR811-

10127, BR811-11137, BR811-11147, BR811-10217, BR811-10227, BR811-11237, BR811-11247, BR811-10317, BR811-11337, BR811-11347, BR811-11357, BR811-11437, BR811-11447, BR811-11457, BR811-10137, BR811-10147, BR811-10237, BR811-10247, BR811-10337, BR811-10347, BR811-10357, BR811-10437, BR811-10447, BR811-10457, BR821-107, BR821-137, BR821-157, BR821-10117, BR821-10127, BR821-11137, BR821-11147, BR821-10217, BR821-10227, BR821-11237, BR821-11247, BR821-10317, BR821-11337, BR821-11347, BR821-11357, BR821-11437, BR821-11447, BR821-11457, BR821-10137, BR821-10147, BR821-10237, BR821-10247, BR821-10337, BR821-10347, BR821-10357, BR821-10437, BR821-10447, BR821-10457, BR822-107, BR822-137, BR822-157, BR822-10117, BR822-10127, BR822-11137, BR822-11147, BR822-10217, BR822-10227, BR822-11237, BR822-11247, BR822-10317, BR822-11337, BR822-11347, BR822-11357, BR822-11437, BR822-11447, BR822-11457, BR822-10137, BR822-10147, BR822-10237, BR822-10247, BR822-10337, BR822-10347, BR822-10357, BR822-10437, BR822-10447, BR822-10457, BR822-11137H, BR822-10127H, BR822-10117H, BR822-10217H, BR822-10227H, BR822-11237H, BR822-10317H, BR222-254H, BR822-137H, BR822-157H, BR822-11134H, BR822-10124H, BR822-10114H, BR822-10214H, BR822-10224H, BR822-11234H, BR822-10314H, BR822-134H, BR822-154H, BR822-11134L, BR822-10124L, BR822-10114L, BR822-10214L, BR822-10224L, BR822-11234L, BR822-10314L, BR822-134L, BR822-154L, BR822-11134L, BR822-10124L, BR822-10114L, BR822-10214L, BR822-10224L, BR822-11234L, BR822-10314L, BR822-134L, BR822-154L, BR822-104, BR822-134, BR822-154, BR822-10114, BR822-10124, BR822-11134, BR822-11144, BR822-10214, BR822-10224, BR822-11234, BR822-11244, BR822-10314, BR822-11334, BR822-11344, BR822-11354, BR822-11434, BR822-11444, BR822-11454, BR822-10134, BR822-10144, BR822-10234, BR822-10244, BR822-10334, BR822-10344, BR822-10354, BR822-10434, BR822-10444, BR822-10454, BR821-104, BR821-134, BR821-154, BR821-10114, BR821-10124, BR821-11134, BR821-11144, BR821-10214, BR821-10224, BR821-11234, BR821-11244, BR821-10314, BR821-11334, BR821-11344, BR821-11354, BR821-11434, BR821-11444, BR821-11454, BR821-10134, BR821-10144, BR821-10234, BR821-10244, BR821-10334, BR821-10344, BR821-10354, BR821-10434, BR821-10444, BR821-10454, BR812-104, BR812-134, BR812-154, BR812-10114, BR812-10124, BR812-11134, BR812-11144, BR812-10214, BR812-10224, BR812-11234, BR812-11244, BR812-10314, BR812-11334, BR812-11344, BR812-11354, BR812-11434, BR812-11444, BR812-11454, BR812-10134, BR812-10144, BR812-10234, BR812-10244, BR812-10334, BR812-10344, BR812-10354, BR812-10434, BR812-10444, BR812-10454, BR811-104, BR811-134, BR811-154, BR811-10114, BR811-10124, BR811-11134, BR811-11144, BR811-10214, BR811-10224, BR811-11234, BR811-11244, BR811-10314, BR811-11334, BR811-11344, BR811-11354, BR811-11434, BR811-11444, BR811-11454, BR811-10134, BR811-10144, BR811-10234, BR811-10244, BR811-10334, BR811-10344, BR811-10354, BR811-10434, BR811-10444, BR811-10454, BR811-102, BR811-132, BR811-152, BR811-10112, BR811-10122, BR811-11132, BR811-11142, BR811-10212, BR811-10222, BR811-11232, BR811-11242, BR811-10312, BR811-11332, BR811-11342, BR811-11352, BR811-11432, BR811-11442, BR811-11452, BR811-10132, BR811-10142, BR811-10232, BR811-10242, BR811-10332, BR811-10342, BR811-10352, BR811-10432, BR811-10442, BR811-10452, BR812-102, BR812-132, BR812-152, BR812-10112, BR812-10122, BR812-11132, BR812-11142, BR812-10212, BR812-10222, BR812-11232, BR812-11242, BR812-10312, BR812-11332, BR812-11342, BR812-11352, BR812-11432, BR812-11442, BR812-11452, BR812-10132, BR812-10142, BR812-10232, BR812-10242, BR812-10332, BR812-10342, BR812-10352, BR812-10432, BR812-10442, BR812-10452, BR821-102, BR821-132, BR821-152, BR821-10112, BR821-10122, BR821-11132, BR821-11142, BR821-10212, BR821-10222, BR821-11232, BR821-11242, BR821-10312, BR821-11332, BR821-11342, BR821-11352, BR821-11432, BR821-11442, BR821-11452, BR821-10132, BR821-10142, BR821-10232, BR821-10242, BR821-10332, BR821-10342, BR821-10352, BR821-10432, BR821-

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#### Tubos Bucales para ortodoncia Roth, MBT, Edgewise y Lingual

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#### Bandas para ortodoncia para caninos, pre molares y molares

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Botones linguales para cementar y soldar

IA09-301M, IA09-101M, IA09-102M, IA09-001M, IA10-001S, IA10-001, IA10-001L, IA04-051, IA04-059, IA04-081, IA04-151, IA04-101, IA10-151, IA10-051, IA04-601, IA04-602, IA04-603, IA04-304, IA17-002, IA17-001, IA17-201, IA04-604, IA17-101, IA17-101G, IA17-102, IA17-102G, IA04-303, IA04-305, IA04-306, IA12-002, IA16-002, IA06-208, IA06-012, IA06-020, IA06-208

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Hooks (ganchos) para deslizamiento

IA05-001, IA05-001L, IA05-103, IA05-103JQ, IA05-202, IA05-201, IA05-202JQ, IA05-201JQ, IA05-301, IA05-302, IA05-111, IA05-121, IA05-501, IA05-502, IA05-105, IA05-101, IA05-101L, IA05-401, IA05-401L, IA05-701, IA05-702, IA05-703, IA05-704, IA05-601, IA05-602, IA05-603, IA05-604.

Composición cuali-cuanti porcentual exacta (si corresponde):

NA

Indicación/es autorizada/s:

Tratamientos de ortodoncia y ortopedia maxilar para la prevención y/o corrección de la posición de las piezas dentarias, maloclusiones dentarias, deformidad dentofacial y anomalías de los maxilares óseos.

Período de vida útil (si corresponde):

NA

Método de Esterilización (si corresponde):

NA

Forma de presentación:

Brackets para ortodoncia: unidad; set x 20 piezas.

Tubos bucales para ortodoncia: envase x 4 unidades.

Bandas para ortodoncia: envase x 4 unidades.

Botones linguales: envase x 10 unidades.

Hooks (ganchos) para deslizamiento: envase x 10 unidades.

Condición de venta:

Venta Exclusiva a Profesionales e Instituciones Sanitarias

Nombre del fabricante:

Hangzhou Xingchen 3B Dental Instrument & Material Co., Ltd.

Lugar/es de elaboración:

Building 1, No 39 Kangxian Road, Gongshu district, 310015 Hangzhou, P.R. China.

En nombre y representación de la firma Orthodontika Argentina 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 Eficacia (R.E.S.E.) previstos por la Disposición ANMAT N° 4306/99, que cumplen y se encuentra a disposición de la Autoridad Sanitaria la documentación técnica que contenga los requerimientos solicitados en los Anexos III.B y III.C del Reglamento Técnico aprobado por Disposición ANMAT N° 2318/02 (TO 2004) y Disposición ANMAT N° 727/13.

**CUMPLIMIENTO DE R.E.S.E. DISPOSICIÓN ANMAT N° 4306/99 Y GESTIÓN DE RIESGO**

<b>ENSAYO/VALIDACION/GESTION DE RIESGO</b>	<b>LABORATORIO/ N° DE PROTOCOLO</b>	<b>FECHA DE EMISIÓN</b>
1. ISO13485:2012; ISO14971:2012; Directiva 93/42/ECC; EN62366:2009.-	NC	NC
2. ISO13485:2012; ISO14971:2012; Directiva 93/42/ECC; ISO10993-12:2009; EN62366:2009.-	NC	NC
3. ISO13485:2012; ISO14971:2012; Directiva 93/42/ECC; EN62366:2009; ISO7153-1:2001.-	NC	NC
4. ISO13485:2012; ISO14971:2012; Directiva 93/42/ECC; EN62366:2009; ISO15223-1:2016.-	NC	NC
5. ISO13485:2012; ISO14971:2012; Directiva 93/42/ECC; EN62366:2009.-	NC	NC
6. ISO13485:2012; ISO14971:2012; Directiva 93/42/ECC; EN62366:2009; MEDDEV 2.7.1.-	NC	NC
7. ISO13485:2012; ISO14971:2012; Directiva 93/42/ECC; EN62366:2009; ISO10993-1/3/5:2009; ISO7405:2009.-	NC	NC
8. ISO13485:2012; ISO14971:2012; Directiva 93/42/ECC; EN62366:2009; ISO7405:2009; ISO10993-11/12:2009; ISO15223-1:2016; EN980:2008.-	NC	NC
9. ISO14971:2012; Directiva 93/42/ECC; EN62366:2009; ISO15223-1:2016; EN980:2008; EN1041:2009.-	NC	NC
10. N/A.-	NC	NC
11. N/A.-	NC	NC
12. ISO14971:2012.-	NC	NC
13. ISO13485:2012; ISO14971:2012; Directiva 93/42/ECC; EN62366:2009; ISO7405:2009; ISO10993-11/12:2009; ISO15223-1:2016; EN 980:2008; EN1041:2009.-	NC	NC

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 727/13, 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, 14 agosto 2019**

Responsable Legal  
Firma y Sello

Responsable Técnico  
Firma y Sello



**Ministerio de Salud**  
Secretaría de Regulación y Gestión Sanitaria  
A.N.M.A.T.

La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 727/13 y N°5706/17, quedando inscripta en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de **Orthodontika Argentina S.R.L.** bajo el número PM **2394-1**

Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad en la Ciudad de Buenos Aires a los días 14 agosto 2019 la cual tendrá una vigencia de cinco (5) años a contar de la fecha.

Dirección de Evaluación de Registro  
Firma y Sello

Dirección Nacional de Productos Médicos  
Firma y Sello



Tramitada por Expediente N°: 1-0047-3110-003766-19-4