

Nosotros:

We:

Phibo Dental Solutions, S.L.
C/Gato Pérez, 3-9, Polígono Industrial Mas d'En Cisa
08181 - Sentmenat, Barcelona, España/Spain

declaramos bajo nuestra responsabilidad, que el producto: *declare on our responsibility that the product:*

**INSTRUMENTOS QUIRÚRGICOS PARA USO
IMPLANTOLÓGICO DENTAL**

**SURGICAL INSTRUMENTS FOR DENTAL
IMPLANTOLOGICAL USE**

cuyas referencias están incluidas a continuación, el fabricante es exclusivamente responsable de esta Declaración de Conformidad

with the references included below, the manufacturer is exclusively responsible for this Declaration of Conformity

Clasificación:
CLASE IIa

Classification:
CLASS IIa

según regla 6 del Anexo IX de la Directiva 93/42/CEE para los productos denominados cómo Fresas, y sus componentes
y según regla 5 del Anexo IX de la Directiva 93/42/CEE para el resto de productos que aparecen en ésta Declaración de Conformidad

*According to rule 6 of Annex IX to Directive 93/42/EEC for products referred to as Drill, and their components
and in accordance with regulation 5 of Annex IX to Directive 93/42/EEC for the remainder of the products listed in this Declaration of conformity*

Cumple las disposiciones aplicables de la Directiva 93/42/CEE (DPS), Anexo II excepto el apartado 4, relativa a los productos sanitarios según certificado nº G1 18 02 76131 008 expedido por el Organismo Notificado:

Complies with the applicable provisions of Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding section 4, according to certificate nº G1 18 02 76131 008, issued by the Notified Body:

TÜV SÜD Product Service GmbH (NB 0123)
Ridlerstr. 65 · 80339 München, Germany

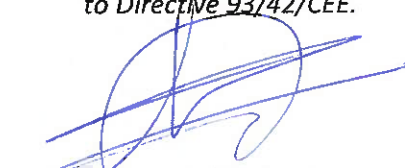
Está garantizado por el Sistema de Gestión de Calidad basado en los requisitos de las Norma Internacionales EN ISO 13485:2016 para productos sanitarios.

It is guaranteed by the Quality Management System based on the requirements of International Standard EN ISO 13485:2016 for medical devices.

Y es conforme con los requisitos esenciales según la Directiva 93/42/CEE.

And it complies with essential requirements according to Directive 93/42/CEE.

Sentmenat (Barcelona), 25/02/2025


Sr. Ignacio Mestre Juncosa
Chief Executive Officer

La presente Declaración de Conformidad tiene validez para todos los lotes de los productos descritos a continuación liberados a partir del 3 de marzo de 2010

This Declaration of Conformity is valid for all batches of the products described below released from March 3rd, 2010

y es válida hasta el 26 de Junio de 2023.

and it is valid until June 26th, 2023.

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
173.0000	Prolongador de Fresas / Drill Extender
173.0001	Prolongador de Fresas Corto / Short Drill Extender
173.0100	Adaptador Mecánico Corto / Contra-Angle Adapter, Short
173.0300	Adaptador Mecánico Largo / Contra-Angle Adapter, Long
173.1001	Atornillador Mecánico 1.00mm Corto TSA® / Contra-Angle Hex Driver 1.00mm, Short TSA®
173.1002	Atornillador Mecánico 1.00mm Medio TSA® / Contra-Angle Hex Driver 1.00mm, Medium TSA®
173.1251	Atornillador Mecánico 1.25mm Corto / Contra-Angle Hex Driver 1.25mm, Short
173.1252	Atornillador Mecánico 1.25mm Medio / Contra-Angle Hex Driver 1.25mm, Medium
175.0001	Fresa Lanceolada TSA® TSH® / Precision Drill TSA® TSH®
175.1018	Fresa de Marcar ø1.8mm / Round Marking Bur, ø 1.8mm
175.1023	Fresa de Marcar ø2.3mm / Round Marking Bur, ø 2.3mm
176.1123	Fresa Piloto Corta ø2.3mm TSA® TSH® / Pilot Drill, Short ø 2.3mm TSA® TSH®
176.1323	Fresa Piloto Larga ø2.3mm TSA® TSH® / Pilot Drill, Long ø 2.3mm TSA® TSH®
178.0037	Fresa Quirúrgica de Instrumentación Cortical TSA® S3 / TSA® S3 Countersink Drill
178.0047	Fresa Quirúrgica de Instrumentación Cortical TSA® S4 / TSA® S4 Countersink Drill
178.0060	Fresa Quirúrgica de Instrumentación Cortical TSA® S5 / TSA® S5 Countersink Drill
178.1128	Fresa Quirúrgica Corta ø2.8mm TSA® TSH® / Surgical Drill, Short ø 2.8mm TSA® TSH®
178.1130	Fresa Quirúrgica Corta ø3.0mm TSA® TSH® / Surgical Drill, Short ø 3.0mm TSA® TSH®
178.1136	Fresa Quirúrgica Corta ø3.6mm TSA® TSH® / Surgical Drill, Short ø 3.6mm TSA® TSH®
178.1241	Fresa Quirúrgica ø4.1mm TSH® / Surgical Drill ø4.1mm TSH®
178.1243	Fresa Quirúrgica ø4.3mm TSA® / Surgical Drill ø 4.3mm TSA®

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
178.1249	Fresa Quirúrgica ø4.9mm TSA® / Surgical Drill ø 4.9mm TSA®
178.1328	Fresa Quirúrgica Larga ø2.8mm TSA® TSH® / Surgical Drill, Long ø 2.8mm TSA® TSH®
178.1330	Fresa Quirúrgica Larga ø3.0mm TSA® TSH® / Surgical Drill, Long ø 3.0mm TSA® TSH®
178.1336	Fresa Quirúrgica Larga ø3.6mm TSA® TSH® / Surgical Drill, Long ø 3.6mm TSA® TSH®
181.0133	Macho de Roscar Corto TSH® S2 / TSH® S2 Contra-Angle Bone Tap, Short
181.0333	Macho de Roscar Largo TSH® S2 / TSH® S2 Contra-Angle Bone Tap, Long
181.0136	Macho de Roscar Corto TSA® TSH® S3 / TSA® TSH® S3 Contra-Angle Bone Tap, Short
181.0336	Macho de Roscar Largo TSA® TSH® S3 / TSA® TSH® S3 Contra-Angle Bone Tap, Long
181.0142	Macho de Roscar Corto TSA® TSH® S4 / TSA® TSH® S4 Contra-Angle Bone Tap, Short
181.0342	Macho de Roscar Largo TSA® TSH® S4 / TSA® TSH® S4 Contra-Angle Bone Tap, Long
181.0248	Macho de Roscar TSH® S5 / TSH® S5 Contra-Angle Bone Tap
181.0255	Macho de Roscar TSA® S5 / TSA® S5 Contra-Angle Bone Tap
190.0001	Kit Inicial de Activación Roscas / Initial Kit Thread Repair
190.0016	Macho de Repasar Roscas Mecánico TSA® S3 / Contra-Angle Tap for TSA® S3
190.0018	Macho de Repasar Roscas Mecánico TSA® S4 S5 TSH® S2 / Contra-Angle Tap for TSA® S4 S5 & TSH® S2
190.0020	Macho de Repasar Roscas Mecánico TSH® S3 S4 S5 / Contra-Angle Tap for TSH® S3 S4 S5
190.0120	Fresa de Bola TSA® S3 / Round Marking Bur for TSA® S3
190.0140	Fresa de Bola TSA® S4 S5 TSH® S2 / Round Marking Bur for TSA® S4 S5 & TSH® S2
190.0160	Fresa de Bola TSH® S3 S4 S5 / Round Marking Bur for TSH® S3 S4 S5
102.0003	Fresa Lanceolada GUIDE / Precision Drill GUIDE
102.0323	Fresa Piloto ø2,3mm GUIDE / Pilot Drill ø2,3mm GUIDE
102.0328	Fresa Quirúrgica ø2,8mm GUIDE / Surgical Drill ø2,8mm GUIDE
102.0330	Fresa Quirúrgica ø3,0mm GUIDE / Surgical Drill ø3,0mm GUIDE
102.0336	Fresa Quirúrgica ø3,6mm GUIDE / Surgical Drill ø3,6mm GUIDE
102.0341	Fresa Quirúrgica ø4,1mm GUIDE / Surgical Drill ø4,1mm GUIDE
102.0343	Fresa Quirúrgica ø4,3mm GUIDE / Surgical Drill ø4,3mm GUIDE

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
102.0349	Fresa Quirúrgica ø4,9mm GUIDE / Surgical Drill ø4,9mm GUIDE
DS23	Tope Fresa Ø2.30mm / Drill Stop Ø2.30mm
DS28	Tope Fresa Ø2.80mm / Drill Stop Ø2.80mm
DS30	Tope Fresa Ø3.00mm / Drill Stop Ø3.00mm
DS36	Tope Fresa Ø3.60mm / Drill Stop Ø3.60mm
DS41	Tope Fresa Ø4.10mm / Drill Stop Ø4.10mm
DS43	Tope Fresa Ø4.30mm / Drill Stop Ø4.30mm
DS49	Tope Fresa Ø4.90mm / Drill Stop Ø4.90mm
DS00	Tornillo Tope Fresa / Screw Drill Stop
AUR 23000	Fresa Lanceolada Aurea / Precision Drill Aurea
AUR 23085	Fresa Piloto ø2.3mm L8.5mm Aurea / Pilot Drill ø2.3mm L8.5mm Aurea
AUR 23100	Fresa Piloto ø2.3mm L10.0mm Aurea / Pilot Drill ø2.3mm L10.0mm Aurea
AUR 23115	Fresa Piloto ø2.3mm L11.5mm Aurea / Pilot Drill ø2.3mm L11.5mm Aurea
AUR 23130	Fresa Piloto ø2.3mm L13.0mm Aurea / Pilot Drill ø2.3mm L13.0mm Aurea
AUR 23145	Fresa Piloto ø2.3mm L14.5mm Aurea / Pilot Drill ø2.3mm L14.5mm Aurea
AUR 23160	Fresa Piloto ø2.3mm L16.0mm Aurea / Pilot Drill ø2.3mm L16.0mm Aurea
AUR 28085	Fresa Piloto ø2.8mm L8.5mm Aurea / Pilot Drill ø2.8mm L8.5mm Aurea
AUR 28100	Fresa Piloto ø2.8mm L10.0mm Aurea / Pilot Drill ø2.8mm L10.0mm Aurea
AUR 28115	Fresa Piloto ø2.8mm L11.5mm Aurea / Pilot Drill ø2.8mm L11.5mm Aurea
AUR 28130	Fresa Piloto ø2.8mm L13.0mm Aurea / Pilot Drill ø2.8mm L13.0mm Aurea
AUR 28145	Fresa Piloto ø2.8mm L14.5mm Aurea / Pilot Drill ø2.8mm L14.5mm Aurea
AUR 28160	Fresa Piloto ø2.8mm L16.0mm Aurea / Pilot Drill ø2.8mm L16.0mm Aurea
AUR 35085	Fresa Quirúrgica ø3.5mm L8.5mm Aurea / Surgical Drill ø3.5mm L8.5mm Aurea
AUR 35100	Fresa Quirúrgica ø3.5mm L10.0mm Aurea / Surgical Drill ø3.5mm L10.0mm Aurea
AUR 35115	Fresa Quirúrgica ø3.5mm L11.5mm Aurea / Surgical Drill ø3.5mm L11.5mm Aurea
AUR 35130	Fresa Quirúrgica ø3.5mm L13.0mm Aurea / Surgical Drill ø3.5mm L13.0mm Aurea

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
AUR 35145	Fresa Quirúrgica ø3.5mm L14.5mm Aurea / Surgical Drill ø3.5mm L14.5mm Aurea
AUR 35160	Fresa Quirúrgica ø3.5mm L16.0mm Aurea / Surgical Drill ø3.5mm L16.0mm Aurea
AUR 39085	Fresa Quirúrgica ø3.9mm L8.5mm Aurea / Surgical Drill ø3.9mm L8.5mm Aurea
AUR 39100	Fresa Quirúrgica ø3.9mm L10.0mm Aurea / Surgical Drill ø3.9mm L10.0mm Aurea
AUR 39115	Fresa Quirúrgica ø3.9mm L11.5mm Aurea / Surgical Drill ø3.9mm L11.5mm Aurea
AUR 39130	Fresa Quirúrgica ø3.9mm L13.0mm Aurea / Surgical Drill ø3.9mm L13.0mm Aurea
AUR 39145	Fresa Quirúrgica ø3.9mm L14.5mm Aurea / Surgical Drill ø3.9mm L14.5mm Aurea
AUR 39160	Fresa Quirúrgica ø3.9mm L16.0mm Aurea / Surgical Drill ø3.9mm L16.0mm Aurea
AUR 43085	Fresa Quirúrgica ø4.3mm L8.5mm Aurea / Surgical Drill ø4.3mm L8.5mm Aurea
AUR 43100	Fresa Quirúrgica ø4.3mm L10.0mm Aurea / Surgical Drill ø4.3mm L10.0mm Aurea
AUR 43115	Fresa Quirúrgica ø4.3mm L11.5mm Aurea / Surgical Drill ø4.3mm L11.5mm Aurea
AUR 43130	Fresa Quirúrgica ø4.3mm L13.0mm Aurea / Surgical Drill ø4.3mm L13.0mm Aurea
AUR 43145	Fresa Quirúrgica ø4.3mm L14.5mm Aurea / Surgical Drill ø4.3mm L14.5mm Aurea
AUR 43160	Fresa Quirúrgica ø4.3mm L16.0mm Aurea / Surgical Drill ø4.3mm L16.0mm Aurea
AUR 48085	Fresa Quirúrgica ø4.8mm L8.5mm Aurea / Surgical Drill ø4.8mm L8.5mm Aurea
AUR 48100	Fresa Quirúrgica ø4.8mm L10.0mm Aurea / Surgical Drill ø4.8mm L10.0mm Aurea
AUR 48115	Fresa Quirúrgica ø4.8mm L11.5mm Aurea / Surgical Drill ø4.8mm L11.5mm Aurea
AUR 48130	Fresa Quirúrgica ø4.8mm L13.0mm Aurea / Surgical Drill ø4.8mm L13.0mm Aurea
AUR 48145	Fresa Quirúrgica ø4.8mm L14.5mm Aurea / Surgical Drill ø4.8mm L14.5mm Aurea
AUR 48160	Fresa Quirúrgica ø4.8mm L16.0mm Aurea / Surgical Drill ø4.8mm L16.0mm Aurea
AUR 55085	Fresa Quirúrgica ø5.5mm L8.5mm Aurea / Surgical Drill ø5.5mm L8.5mm Aurea
AUR 55100	Fresa Quirúrgica ø5.5mm 10.0mm Aurea / Surgical Drill ø5.5mm 10.0mm Aurea
AUR 55115	Fresa Quirúrgica ø5.5mm L11.5mm Aurea / Surgical Drill ø5.5mm L11.5mm Aurea
AUR 55130	Fresa Quirúrgica ø5.5mm L13.0mm Aurea / Surgical Drill ø5.5mm L13.0mm Aurea
AUR 60085	Fresa Quirúrgica ø6.0mm L8.5mm Aurea / Surgical Drill ø6.0mm L8.5mm Aurea
AUR 60100	Fresa Quirúrgica ø6.0mm L10.0mm Aurea / Surgical Drill ø6.0mm L10.0mm Aurea

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
AUR 60115	Fresa Quirúrgica ø6.0mm L11.5mm Aurea / Surgical Drill ø6.0mm L11.5mm Aurea
AUR 60130	Fresa Quirúrgica ø6.0mm L13.0mm Aurea / Surgical Drill ø6.0mm L13.0mm Aurea
AUR NP 35	Macho de Roscar ø3.5mm Aurea / Contra-Angle Bone Tap ø3.5mm Aurea
AUR RP 43	Macho de Roscar ø4.3mm Aurea / Contra-Angle Bone Tap ø4.3mm Aurea
AUR RP 48	Macho de Roscar ø4.8mm Aurea / Contra-Angle Bone Tap ø4.8mm Aurea
AUR WP 55	Macho de Roscar ø5.5mm Aurea / Contra-Angle Bone Tap ø5.5mm Aurea
AUR WP 60	Macho de Roscar ø6.0mm Aurea / Contra-Angle Bone Tap ø6.0mm Aurea
152.0001	Bisturí Circular Ø3.70 / Circular Scalpel Ø3.70
152.0002	Bisturí Circular Ø4.70 / Circular Scalpel Ø4.70
152.0003	Bisturí Circular Ø6.00 / Circular Scalpel Ø6.00
006 CG	Portaimplantes CG 1 / CG 1 Implant Holder
007 CG	Portaimplantes CG 2 / CG 2 Implant Holder
008 CG	Portaimplantes CG 3 / CG 3 Implant Holder
009 CG	Portaimplantes CG 4 / CG 4 Implant Holder
010 CG	Portaimplantes CG 5 / CG 5 Implant Holder
011 CG	Portaimplantes CG 6 / CG 6 Implant Holder
EVO 23000	Fresa Lanceolada / Precision Drill
EVO 20000	Fresa Piloto ø2.0mm / Pilot Drill ø2.0mm
EVO 31000	Fresa Quirúrgica ø3.1mm Aurea Evo / Surgical Drill ø3.1mm Aurea Evo
EVO 33000	Fresa Quirúrgica ø3.3mm Aurea Evo / Surgical Drill ø3.3mm Aurea Evo
EVO 38000	Fresa Quirúrgica ø3.8mm Aurea Evo / Surgical Drill ø3.8mm Aurea Evo
EVO 40000	Fresa Quirúrgica ø4.0mm Aurea Evo / Surgical Drill ø4.0mm Aurea Evo
EVO 50000	Fresa Quirúrgica ø5.0mm Aurea Evo / Surgical Drill ø5.0mm Aurea Evo
EVO 52000	Fresa Quirúrgica ø5.2mm Aurea Evo / Surgical Drill ø5.2mm Aurea Evo
TOP NP 085	Tope Fresa Aurea Evo NP 8.5mm / Drill stop Aurea Evo NP 8.5mm
TOP NP 100	Tope Fresa Aurea Evo NP 10.0mm / Drill stop Aurea Evo NP 10.0mm

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
TOP NP 115	Tope Fresa Aurea Evo NP 11.5mm / Drill stop Aurea Evo NP 11.5mm
TOP NP 130	Tope Fresa Aurea Evo NP 13.0mm / Drill stop Aurea Evo NP 13.0mm
TOP NP 145	Tope Fresa Aurea Evo NP 14.5mm / Drill stop Aurea Evo NP 14.5mm
TOP RP 085	Tope Fresa Aurea Evo RP 8.5mm / Drill stop Aurea Evo RP 8.5mm
TOP RP 100	Tope Fresa Aurea Evo RP 10.0mm / Drill stop Aurea Evo RP 10.0mm
TOP RP 115	Tope Fresa Aurea Evo RP 11.5mm / Drill stop Aurea Evo RP 11.5mm
TOP RP 130	Tope Fresa Aurea Evo RP 13.0mm / Drill stop Aurea Evo RP 13.0mm
TOP RP 145	Tope Fresa Aurea Evo RP 14.5mm / Drill stop Aurea Evo RP 14.5mm
TOP WP 085	Tope Fresa Aurea Evo WP 8.5mm / Drill stop Aurea Evo WP 8.5mm
TOP WP 100	Tope Fresa Aurea Evo WP 10.0mm / Drill stop Aurea Evo WP 10.0mm
TOP WP 115	Tope Fresa Aurea Evo WP 11.5mm / Drill stop Aurea Evo WP 11.5mm
TOP WP 130	Tope Fresa Aurea Evo WP 13.0mm / Drill stop Aurea Evo WP 13.0mm
EVO 01035	Macho de Roscar Aurea Evo NP / Bone Tap Aurea Evo NP
EVO 01043	Macho de Roscar Aurea Evo RP / Bone Tap Aurea Evo RP
EVO 01055	Macho de Roscar Aurea Evo WP / Bone Tap Aurea Evo WP
164.1070	Tope altura 7.0mm TSA® / Height limit 7.0mm TSA®
164.1085	Tope altura 8.5mm TSA® TSA® / Height limit 8.5mm TSA®
164.1100	Tope altura 10.0mm TSA® / Height limit 10.0mm TSA®
164.1115	Tope altura 11.5mm TSA® / Height limit 11.5mm TSA®
164.1130	Tope altura 13.0mm TSA® / Height limit 13.0mm TSA®
164.1145	Tope altura 14.5mm TSA® / Height limit 14.5mm TSA®
164.1160	Tope altura 16.0mm TSA® / Height limit 16.0mm TSA®
TS 23000	Fresa Piloto ø2.3mm TSA® TSH® Pilot Drill ø2.3mm TSA® TSH®
TS 28000	Fresa Quirúrgica ø2.8mm TSA® TSH® Surgical Drill ø2.8mm TSA® TSH®
TS 30000	Fresa Quirúrgica ø3.0mm TSA® TSH® Surgical Drill ø3.0mm TSA® TSH®
TS 36000	Fresa Quirúrgica ø3.6mm TSA® TSH® Surgical Drill ø3.6mm TSA® TSH®

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
TS 41000	Fresa Quirúrgica ø4.1mm TSA® TSH® Surgical Drill ø4.1mm TSA® TSH®
TS 43000	Fresa Quirúrgica ø4.3mm TSA® TSH® Surgical Drill ø4.3mm TSA® TSH®
TS 49000	Fresa Quirúrgica ø4.9mm TSA® TSH® Surgical Drill ø4.9mm TSA® TSH®
TOP S23 060	Tope Fresa TSA-TSH S2 S3 6.0mm Drill stop TSA-TSH S2 S3 6.0mm
TOP S23 070	Tope Fresa TSA-TSH S2 S3 7.0mm Drill stop TSA-TSH S2 S3 7.0mm
TOP S23 085	Tope Fresa TSA-TSH S2 S3 8.5mm Drill stop TSA-TSH S2 S3 8.5mm
TOP S23 100	Tope Fresa TSA-TSH S2 S3 10.0mm Drill stop TSA-TSH S2 S3 10.0mm
TOP S23 115	Tope Fresa TSA-TSH S2 S3 11.5mm Drill stop TSA-TSH S2 S3 11.5mm
TOP S23 130	Tope Fresa TSA-TSH S2 S3 13.0mm Drill stop TSA-TSH S2 S3 13.0mm
TOP S23 145	Tope Fresa TSA-TSH S2 S3 14.5mm Drill stop TSA-TSH S2 S3 14.5mm
TOP S4 060	Tope Fresa TSA-TSH S4 6.0mm Drill stop TSA-TSH S4 6.0mm
TOP S4 070	Tope Fresa TSA-TSH S4 7.0mm Drill stop TSA-TSH S4 7.0mm
TOP S4 085	Tope Fresa TSA-TSH S4 8.5mm Drill stop TSA-TSH S4 8.5mm
TOP S4 100	Tope Fresa TSA-TSH S4 10.0mm Drill stop TSA-TSH S4 10.0mm
TOP S4 115	Tope Fresa TSA-TSH S4 11.5mm Drill stop TSA-TSH S4 11.5mm
TOP S4 130	Tope Fresa TSA-TSH S4 13.0mm Drill stop TSA-TSH S4 13.0mm
TOP S4 145	Tope Fresa TSA-TSH S4 14.5mm Drill stop TSA-TSH S4 14.5mm
TOP S5 060	Tope Fresa TSA-TSH S5 6.0mm Drill stop TSA-TSH S5 6.0mm
TOP S5 070	Tope Fresa TSA-TSH S5 7.0mm Drill stop TSA-TSH S5 7.0mm
TOP S5 085	Tope Fresa TSA-TSH S5 8.5mm Drill stop TSA-TSH S5 8.5mm
TOP S5 100	Tope Fresa TSA-TSH S5 10.0mm Drill stop TSA-TSH S5 10.0mm
TOP S5 115	Tope Fresa TSA-TSH S5 11.5mm Drill stop TSA-TSH S5 11.5mm
TOP S5 130	Tope Fresa TSA-TSH S5 13.0mm Drill stop TSA-TSH S5 13.0mm
EVO 34000	Fresa Quirúrgica ø3.4mm Aurea Evo Surgical Drill ø3.4mm Aurea Evo
EVO 41000	Fresa Quirúrgica ø4.1mm Aurea Evo Surgical Drill ø4.1mm Aurea Evo
EVO 44000	Fresa Quirúrgica ø4.4mm Aurea Evo Surgical Drill ø4.4mm Aurea Evo

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
EVO 46000	Fresa Quirúrgica ø4.6mm Aurea Evo Surgical Drill ø4.6mm Aurea Evo
EVO 52052	Fresa Quirúrgica ø5.2mm Aurea Evo Surgical Drill ø5.2mm Aurea Evo
TOP RP48 085	Tope Fresa Aurea Evo RP48 8.5mm Drill stop Aurea Evo RP48 8.5mm
TOP RP48 100	Tope Fresa Aurea Evo RP48 10.0mm Drill stop Aurea Evo RP48 10.0mm
TOP RP48 115	Tope Fresa Aurea Evo RP48 11.5mm Drill stop Aurea Evo RP48 11.5mm
TOP RP48 130	Tope Fresa Aurea Evo RP48 13.0mm Drill stop Aurea Evo RP48 13.0mm
TOP RP48 145	Tope Fresa Aurea Evo RP48 14.5mm Drill stop Aurea Evo RP48 14.5mm
EVO 01048	Macho de Roscar Aurea Evo RP48 Bone Tap Aurea Evo RP48
EVO 54000	Fresa Quirúrgica ø5.4mm Aurea Evo Surgical Drill ø5.4mm Aurea Evo
173.1106	Punta Atornillador Hexalobular Angular Axis® Media Mecánica Contra-Angle Axis® Hexalobular Angled Tool, Medium

CONTROL DE VERSIONES / VERSIONS CONTROL

REVISIÓN VERSION	FECHA DATE	MODIFICACIONES / MODIFICATIONS
7	2016/03/09	Se sustituye la norma UNE-EN 10088-1:2006 por la UNE-EN 10088-1:2015 / Replacement of standard UNE-EN 10088-1:2006 by UNE-EN 10088-1:2015. Se sustituye la norma UNE-EN 10088-3:2008 por la UNE-EN 10088-3:2015 / Replacement of standard UNE-EN 10088-3:2008 by UNE-EN 10088-3:2015. Se sustituye la norma EN 1041:2008 por la UNE-EN 1041:2009+A1 / Replacement of standard EN 1041:2008 by UNE-EN 1041:2009+A1. Inclusión de referencias / Inclusion of references: EVO 23000, EVO 20000, EVO 31000, EVO 33000, EVO 38000, EVO 40000, EVO 50000, EVO 52000, TOP NP 085, TOP NP 100, TOP NP 115, TOP NP 130, TOP NP 145, TOP RP 085, TOP RP 100, TOP RP 115, TOP RP 130, TOP RP 145, TOP WP 085, TOP WP 100, TOP WP 115, TOP WP 130.
8	2016/06/17	Inclusión de referencias / Inclusion of references: EVO 01035, EVO 01043, EVO 01055.
9	2016/12/14	Se utiliza la plantilla vigente / The current template is used.
10	2018/05/04	Eliminación de referencias de productos TSA Advance y BNT / TSA Advance and BNT product references are deleted: 101.0241, 101.0133, 101.0333, 101.0248, 101.0001, 101.0123, 101.0323, 101.0128, 101.0328, 101.0130, 101.0330, 101.0136, 101.0336, 101.0243, 101.0249, 101.1336, 101.1136, 101.0142, 101.0342, 101.0255.
11	2018/06/20	Actualización del número y fecha de validez del Certificado CE. / Updating of the number and date of validity of the EC Certificate Se indica relación entre tipo de producto y Regla de clasificación según Directiva 93/42/CEE Anexo II sobre productos sanitarios / The relationship between product type and classification rule is indicated in accordance with of Directive 93/42/CEE, Annex II about medical devices. Se añaden referencias de Tope de Altura de osteotomo antes clasificadas como Instrumental I y que pasan a ser Instrumental IIa / References of height limit for osteotome previously classified as instrumental I are classified as instrumental IIa are added: 164.1070, 164.1085, 164.1100, 164.1115, 164.1130, 164.1145, 164.1160.
12	2019/01/28	Se elimina la referencia ATORX / The reference ATORX is deleted Inclusión de referencias / Inclusion of references :TS 23000, TS 28000, TS 30000, TS 36000, TS 41000, TS 43000, TS 49000, TOP S23 060, TOP S23 070, TOP S23 085, TOP S23 100, TOP S23 115, TOP S23 130, TOP S23 145, TOP S4 060, TOP S4 070, TOP S4 085, TOP S4 100, TOP S4 115, TOP S4 130, TOP S4 145, TOP S5 060, TOP S5 070, TOP S5 085, TOP S5 100, TOP S5 115 y TOP S5 130

REVISIÓN VERSION	FECHA DATE	MODIFICACIONES / MODIFICATIONS
13	2019/02/20	Se eliminan las referencias 150.0003, 150.0004, 150.0005, 151.0002, 151.0003, 151.0004 y 151.0005 / The next references are deleted : 150.0003, 150.0004, 150.0005, 151.0002, 151.0003, 151.0004 y 151.0005
14	2019/08/15	Inclusión de referencias / Inclusion of references : EVO 34000, EVO 41000, EVO 44000, EVO 46000, EVO 52000, EVO 52052, TOP RP48 085, TOP RP48 100, TOP RP48 115, TOP RP48 130, TOP RP48 145, EVO 01048.
15	2020/09/28	Se corrige error en la referencia comercial EVO 52000 (aparecia duplicada) y se añade la referencia EVO 54000 / An error is corrected in the commercial reference EVO 52000 (duplicated entry) and reference EVO 54000 is added.
16	2020/12/14	Inclusión de referencia / Inclusion of reference : 173.1106
17	2024/02/25	Se especifica que la Declaración de Conformidad cumple la Directiva 93/42/CEE, Anexo II exepto el apartado 4 / It is specified that the Declaration of Conformity is according Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding section 4.

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