

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 Internacionale 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), May 26th, 2021.



Montse Gutiérrez
RAQA Manager / PRRC

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
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
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
102.0349	Fresa Quirúrgica ø4,9mm GUIDE	Surgical Drill ø4,9mm GUIDE
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
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®

REFERENCIA / REFERENCE	DESCRIPCIÓN	DESCRIPTION
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 ø4.3mm TSA®
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
181.0136	Macho de Roscar Corto TSA® TSH® S3	TSA® TSH® S3 Contra-Angle Bone Tap, Short
181.0142	Macho de Roscar Corto TSA® TSH® S4	TSA® TSH® S4 Contra-Angle Bone Tap, Short
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
181.0333	Macho de Roscar Largo TSH® S2	TSH® S2 Contra-Angle Bone Tap, Long
181.0336	Macho de Roscar Largo TSA® TSH® S3	TSA® TSH® S3 Contra-Angle Bone Tap, Long
181.0342	Macho de Roscar Largo TSA® TSH® S4	TSA® TSH® S4 Contra-Angle Bone Tap, Long
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
DS00	Tornillo Tope Fresa	Screw Drill Stop
DS23	Tope Fresa ø2.30mm	Drill Stop ø2.30mm
DS28	Tope Fresa ø2.80mm	Drill Stop ø2.80mm

REFERENCIA / REFERENCE	DESCRIPCIÓN	DESCRIPTION
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
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 01048	Macho de Roscar Aurea Evo RP48	Bone Tap Aurea Evo RP48
EVO 01055	Macho de Roscar Aurea Evo WP	Bone Tap Aurea Evo WP
EVO 20000	Fresa Piloto ø2.0mm	Pilot Drill ø2.0mm
EVO 23000	Fresa Lanceolada	Precision Drill
EVO 31000	Fresa Quirúrgica ø3.1mm Aurea Evo	Surgical Drill ø3.1mm Aurea Evo
EVO 34000	Fresa Quirúrgica ø3.4mm Aurea Evo	Surgical Drill ø3.4mm Aurea Evo
EVO 38000	Fresa Quirúrgica ø3.8mm Aurea Evo	Surgical Drill ø3.8mm 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
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
EVO 54000	Fresa Quirúrgica ø5.4mm Aurea Evo	Surgical Drill ø5.4mm 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
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 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
TOP S23 050	Tope Fresa TSA-TSH S2 S3 5.0mm	Drill stop TSA-TSH S2 S3 5.0mm

REFERENCIA / REFERENCE	DESCRIPCIÓN	DESCRIPTION
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 050	Tope Fresa TSA-TSH S4 5.0mm	Drill stop TSA-TSH S4 5.0mm
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 050	Tope Fresa TSA-TSH S5 5.0mm	Drill stop TSA-TSH S5 5.0mm
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
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
TS 23000	Fresa Piloto \varnothing 2.3mm TSA® TSH®	Pilot Drill \varnothing 2.3mm TSA® TSH®
TS 28000	Fresa Quirúrgica \varnothing 2.8mm TSA® TSH®	Surgical Drill \varnothing 2.8mm TSA® TSH®
TS 30000	Fresa Quirúrgica \varnothing 3.0mm TSA® TSH®	Surgical Drill \varnothing 3.0mm TSA® TSH®
TS 36000	Fresa Quirúrgica \varnothing 3.6mm TSA® TSH®	Surgical Drill \varnothing 3.6mm TSA® TSH®
TS 41000	Fresa Quirúrgica \varnothing 4.1mm TSA® TSH®	Surgical Drill \varnothing 4.1mm TSA® TSH®
TS 43000	Fresa Quirúrgica \varnothing 4.3mm TSA® TSH®	Surgical Drill \varnothing 4.3mm TSA® TSH®
TS 49000	Fresa Quirúrgica \varnothing 4.9mm TSA® TSH®	Surgical Drill \varnothing 4.9mm TSA® TSH®