

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:*

ADITAMENTOS PROSTÉTICOS PROVISIONALES
DENTALES

TEMPORARY DENTAL PROSTHETIC ABUTMENTS

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 IIb

Classification:
CLASS IIb

según Regla 8 del Anexo IX de la Directiva 93/42/CEE

according to Rule 8 of Annex IX of Directive 93/42/CEE

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 la Norma Internacional 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 a 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 / 2024



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.

Todos los productos descritos tienen asociado el código GMDN 44880 para prótesis provisionales.
All products described are associated with GMDN code 44880 to temporary dental prosthetic abutments.

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
060.3000	Cofia Provisional Plástico ProUnic Plus TSA® S3 / TSA® S3 ProUnic Plus Temporary Plastic Cap
060.4000	Cofia Provisional Plástico ProUnic Plus TSA® S4 / TSA® S4 ProUnic Plus Temporary Plastic Cap
060.5000	Cofia Provisional Plástico ProUnic Plus TSA® S5 / TSA® S5 ProUnic Plus Temporary Plastic Cap
099.3000	Tapón Protección ProUnic Plus TSA® S3 / ProUnic Plus TSA® S3 Healing Cap
099.4000	Tapón Protección ProUnic Plus TSA® S4 / ProUnic Plus TSA® S4 Healing Cap
099.5000	Tapón Protección ProUnic Plus TSA® S5 / ProUnic Plus TSA® S5 Healing Cap
H10.2340	Tapón Protección Conhex TSH® S2 S3 S4 / TSH® S2 S3 S4 Conhex Healing Cap
H10.5000	Tapón Protección Conhex TSH® S5 / TSH® S5 Conhex Healing Cap
H39.2001	Pilar provisional plástico S2 TSH® / Temporary Plastic Abutment S2 TSH® ®
H39.2002	Pilar provisional rot. plástico S2 TSH® / Temporary Plastic Abutment Non Hexed S2 TSH® ®
H39.3401	Pilar provisional plástico S3 S4 TSH® / Temporary Plastic Abutment S3 S4 TSH® ®
H39.3402	Pilar Provisional Rot Plástico TSH® S3 S4 / Temporary Plastic Non-Hexed Abutment S3 S4 TSH® ®
H39.5001	Pilar provisional plástico S5 TSH® / Temporary Plastic Abutment Non Hexed S3S4 TSH® ®
H39.5002	Pilar provisional rot. plástico S5 TSH® / Temporary Plastic Abutment Non Hexed S5 TSH® ®
H40.2001	Pilar provisional titanio S2 TSH® / Temporary Titanium Abutment S2 TSH® ®
H40.2002	Pilar provisional rot. titanio S2 TSH® / Temporary Titanium Abutment NonHexed S2 TSH®
H40.3401	Pilar provisional titanio S3 S4 TSH® / Temporary Titanium Abutment S3 S4 TSH®
H40.3402	Pilar provisional rot. titanio S3S4 TSH® / Temporary Titanium Abutment NonHexed S3S4 TSH®
H40.5001	Pilar provisional titanio S5 TSH® / Temporary Titanium Abutment S5 TSH®
H40.5002	Pilar provisional rot. titanio S5 TSH® / Temporary Titanium Abutment NonHexed S5 TSH®

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
H60.2341	Cofia Provisional Conhex Plástico TSH® S2 S3 S4 / TSH® S2 S3 S4 Conhex Temporary Plastic Cap
H60.2342	Cofia Provisional Conhex Titanio TSH® S2 S3 S4 / TSH® S2 S3 S4 Conhex Temporary Titanium Cap
H60.5001	Cofia Provisional Conhex Plástico TSH® S5 / TSH® S5 Conhex Temporary Plastic Cap
H60.5002	Cofia Provisional Conhex Titanio TSH® S5 / TSH® S5 Conhex Temporary Titanium Cap
H61.2342	Cofia Prov. Conhex Ti Fenestrada TSH® S2 S3 S4 / TSH® S2 S3 S4 Conhex Temporary Titanium
AUR NP 12.0	Cofia Provisional Plástico Antirrotatoria Aurea Narrow / Aurea Narrow Platform Hexed Temporary Plastic Cap
AUR RP 12.0	Cofia Provisional Plástico Antirrotatoria Aurea Regular Platform / Regular Platform Hexed Temporary Plastic Cap
AUR WP 12.0	Cofia Provisional Plástico Antirrotatoria Aurea Wide / Aurea Wide Platform Hexed Temporary Plastic Cap
AUR NP 12.1	Cofia Provisional Titanio Antirrotatoria Aurea Narrow Platform / Aurea Narrow Platform Non-Hexed Temporary Titanium Cap
AUR RP 12.1	Cofia Provisional Titanio Antirrotatoria Aurea Regular Platform / Aurea Regular Platform Non-Hexed Temporary Titanium Cap
AUR WP 12.1	Cofia Provisional Titanio Antirrotatoria Aurea Wide Platform / Aurea Wide Platform Non-Hexed Temporary Titanium Cap
AUR NP 13.0	Tapón Provisional Aurea Narrow Platform / Aurea Narrow Platform Healing Cap
AUR RP 13.0	Tapón Provisional Aurea Regular Platform / Aurea Regular Platform Healing Cap
AUR WP 13.0	Tapón Provisional Aurea Wide Platform / Aurea Wide Platform Healing Cap
AUR NP 21.0	Cofia Provisional Plástico Rotatoria Aurea Narrow Platform / Aurea Narrow Platform Non-Hexed Temporary Plastic Cap
AUR RP 21.0	Cofia Provisional Plástico Rotatoria Aurea Regular Platform / Aurea Regular Platform Non-Hexed Temporary Plastic Cap
AUR WP 21.0	Cofia Provisional Plástico Rotatoria Aurea Wide Platform / Aurea Wide Platform Non-Hexed Temporary Plastic Cap
AUR NP 21.1	Cofia Provisional Titanio Rotatoria Aurea Narrow Platform / Aurea Narrow Platform Hexed Temporary Titanium Cap
AUR RP 21.1	Cofia Provisional Titanio Rotatoria Aurea Regular Platform / Aurea Regular Platform Hexed Temporary Titanium Cap
AUR WP 21.1	Cofia Provisional Titanio Rotatoria Aurea Wide Platform / Aurea Wide Platform Hexed Temporary Titanium Cap
AUR NR 24.0	Cofia Provisional Plástico Rotatoria Aurea Narrow/Regular Platform / Aurea Narrow/Regular Platform Temporary Angled Abutment Cap
AUR NR 24.1	Cofia Provisional Titanio Rotatoria Aurea Narrow/Regular Platform / Aurea Narrow/Regular Platform Temporary Angled Abutment Cap Ti.
AUR NR 30.0	Tapón Provisional Angulado Aurea Narrow/Regular Platform / Angled Aurea Narrow/Regular Platform Healing Cap
EVO NP 12.1	Cofia Provisional Titanio Antirrotatoria Aurea Evo Narrow Platform / Aurea Evo Narrow Platform Hexed Temporary Titanium Cap
EVO RP 12.1	Cofia Provisional Titanio Antirrotatoria Aurea Evo Regular Platform / Aurea Evo Regular Platform Hexed Temporary Titanium Cap
EVO WP 12.1	Cofia Provisional Titanio Antirrotatoria Aurea Evo Wide Platform / Aurea Evo Wide Platform Hexed Temporary Titanium Cap

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
EVO NP 21.1	Cofia Provisional Titanio Rotatoria Aurea Evo Narrow Platform / Aurea Evo Narrow Platform No-Hexed Temporary Titanium Cap
EVO RP 21.1	Cofia Provisional Titanio Rotatoria Aurea Evo Regular Platform / Aurea Evo Regular Platform No-Hexed Temporary Titanium Cap
EVO WP 21.1	Cofia Provisional Titanio Rotatoria Aurea Evo Wide Platform / Aurea Evo Wide Platform No-Hexed Temporary Titanium Cap
EVO NR 24.0	Cofia Provisional Ti Rotatoria Aurea Evo Angulado Narrow/Regular Platform / Aurea Evo Narrow/Regular Platform No-Hexed Temporary Angled Ti Abutment Cap
EVO NR 24.1	Cofia Provisional Ti Antirrotatoria Aurea Evo Angulado Narrow/Regular Platform / Aurea Evo Narrow/Regular Platform Hexed Temporary Angled Ti Abutment Cap
EVO NR 30.0	Tapón Provisional Angulado Aurea Evo Narrow/Regular Platform / Angled Aurea Evo Narrow/Regular Platform Healing Cap
EVO NP 49.0	Tapón Provisional Aurea Evo Narrow Platform / Aurea Evo Narrow Platform Healing Cap
EVO RP 49.0	Tapón Provisional Aurea Evo Regular Platform / Aurea Evo Regular Platform Healing Cap
EVO WP 49.0	Tapón Provisional Aurea Evo Wide Platform / Aurea Evo Wide Platform Healing Cap
EVO NP 53.0	Pilar Provisional Rot Aurea Evo / Aurea Evo Non-Hexed Temporary Abutment
EVO RP 53.0	Pilar Provisional Rot Aurea Evo / Aurea Evo Non-Hexed Temporary Abutment
EVO WP 53.0	Pilar Provisional Rot Aurea Evo / Aurea Evo Non-Hexed Temporary Abutment
EVO NP 53.1	Pilar Provisional No Rot Aurea Evo / Aurea Evo Temporary Hexed Abutment
EVO RP 53.1	Pilar Provisional No Rot Aurea Evo / Aurea Evo Temporary Hexed Abutment
EVO WP 53.1	Pilar Provisional No Rot Aurea Evo / Aurea Evo Temporary Hexed Abutment

CONTROL DE VERSIONES / VERSIONS CONTROL

REVISIÓN / VERSION	FECHA / DATE	MODIFICACIONES / MODIFICATIONS
1	2018/09/06	Primera edición del documento / First document edition Documento proveniente de <i>Declaración de Conformidad Prótesis IIb Phibo rev.22.</i> / Document originated from <i>Declaración de Conformidad Prótesis IIb Phibo rev.22.</i>
2	2021/02/25	Se especifica que la Declaración de Conformidad cumple la Directiva 93/42/CEE, Anexo II exepcto 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.