

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 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 a 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.*

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 |
|------------------------|--|---|
| EVO NP 12.1 | Cofia Provisional Titanio Antirrotatoria Aurea Evo Narrow Platform | Aurea Evo Narrow Platform Hexed Temporary Titanium Cap |
| EVO NP 21.1 | Cofia Provisional Titanio Rotatoria Aurea Evo Narrow Platform | Aurea Evo Narrow Platform No-Hexed Temporary Titanium Cap |
| EVO NP 49.0 | Tapón Provisional Aurea Evo Narrow Platform | Aurea Evo Narrow Platform Healing Cap |
| EVO NP 49.1 | Tapón Provisional Corto Aurea Evo Narrow Platform | Aurea Evo Narrow Platform Short Healing Cap |
| EVO NP 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 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 NR 30.1 | Tapón Provisional Angulado Corto Aurea Evo Narrow/Regular Platform | Aurea Evo Narrow/Regular Platform Short Angled Healing Cap |
| EVO RP 12.1 | Cofia Provisional Titanio Antirrotatoria Aurea Evo Regular Platform | Aurea Evo Regular Platform 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 RP 49.0 | Tapón Provisional Aurea Evo Regular Platform | Aurea Evo Regular Platform Healing Cap |
| EVO RP 49.1 | Tapón Provisional Corto Aurea Evo Regular Platform | Aurea Evo Regular Platform Short Healing Cap |
| EVO RP 53.0 | Pilar Provisional Rot Aurea Evo | Aurea Evo Non-Hexed Temporary Abutment |
| EVO RP 53.1 | Pilar Provisional No Rot Aurea Evo | Aurea Evo Temporary Hexed Abutment |
| 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 WP 21.1 | Cofia Provisional Titanio Rotatoria Aurea Evo Wide Platform | Aurea Evo Wide Platform No-Hexed Temporary Titanium Cap |
| EVO WP 49.0 | Tapón Provisional Aurea Evo Wide Platform | Aurea Evo Wide Platform Healing Cap |
| EVO WP 49.1 | Tapón Provisional Corto Aurea Evo Wide Platform | Aurea Evo Wide Platform Short Healing Cap |
| EVO WP 53.0 | Pilar Provisional Rot Aurea Evo | Aurea Evo Non-Hexed Temporary Abutment |
| EVO WP 53.1 | Pilar Provisional No Rot Aurea Evo | Aurea Evo Temporary Hexed Abutment |
| 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 TSH® S2 | TSH® S2 Temporary Plastic Abutment |
| H39.2002 | Pilar Provisional Rot Plástico TSH® S2 | TSH® S2 Non-Hexed Temporary Plastic Abutment |
| H39.3401 | Pilar Provisional Plástico TSH® S3 S4 | TSH® S3 S4 Temporary Plastic Abutment |
| H39.3402 | Pilar Provisional Rot Plástico TSH® S3 S4 | TSH® S3 S4 Non-Hexed Temporary Plastic Abutment |
| H39.5001 | Pilar Provisional Plástico TSH® S5 | TSH® S5 Temporary Plastic Abutment |
| H39.5002 | Pilar Provisional Rot Plástico TSH® S5 | TSH® S5 Non-Hexed Temporary Plastic Abutment |
| H40.2001 | Pilar Provisional Titanio TSH® S2 | TSH® S2 Temporary Titanium Abutment |
| H40.2002 | Pilar Provisional Rot Titanio TSH® S2 | TSH® S2 Non-Hexed Temporary Titanium Abutment |
| H40.3401 | Pilar Provisional Titanio TSH® S3 S4 | TSH® S3 S4 Temporary Titanium Abutment |

| REFERENCIA / REFERENCE | DESCRIPCIÓN | DESCRIPTION |
|---------------------------|---|--|
| H40.3402 | Pilar Provisional Rot Titanio TSH® S3 S4 | TSH® S3 S4 Non-Hexed Temporary Titanium Abutment |
| H40.5001 | Pilar Provisional Titanio TSH® S5 | TSH® S5 Temporary Titanium Abutment |
| H40.5002 | Pilar Provisional Rot Titanio TSH® S5 | TSH® S5 Non-Hexed Temporary Titanium Abutment |
| 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 |