

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:*

PRODUCTOS IMPLANTABLES NO ACTIVOS

*NON ACTIVE IMPLANTABLE PRODUCTS*

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), 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 3<sup>rd</sup>, 2010*

y es válida hasta el 26 de Junio de 2023.

*and it is valid until June 26<sup>th</sup>, 2023.*

Todos los productos descritos tienen asociado el código GMDN 55847.  
*All products described are associated with GMDN code 55847.*

REFERENCIA / REFERENCE	DESCRIPCIÓN	DESCRIPTION
EVO NP 085	Implante Aurea Evo Narrow Platform Ø 3.5mm Longitud 8.5mm	Aurea Evo Narrow Platform Implant Ø 3.5mm Length 8.5mm
EVO NP 100	Implante Aurea Evo Narrow Platform Ø 3.5mm Longitud 10.0mm	Aurea Evo Narrow Platform Implant Ø 3.5mm Length 10.0mm
EVO NP 115	Implante Aurea Evo Narrow Platform Ø 3.5mm Longitud 11.5mm	Aurea Evo Narrow Platform Implant Ø 3.5mm Length 11.5mm
EVO NP 130	Implante Aurea Evo Narrow Platform Ø 3.5mm Longitud 13.0mm	Aurea Evo Narrow Platform Implant Ø 3.5mm Length 13.0mm
EVO NP 145	Implante Aurea Evo Narrow Platform Ø 3.5mm Longitud 14.5mm	Aurea Evo Narrow Platform Implant Ø 3.5mm Length 14.5mm
EVO RP 085	Implante Aurea Evo Regular Platform Ø 4.3mm Longitud 8.5mm	Aurea Evo Regular Platform Implant Ø 4.3mm Length 8.5mm
EVO RP 100	Implante Aurea Evo Regular Platform Ø 4.3mm Longitud 10.0mm	Aurea Evo Regular Platform Implant Ø 4.3mm Length 10.0mm
EVO RP 115	Implante Aurea Evo Regular Platform Ø 4.3mm Longitud 11.5mm	Aurea Evo Regular Platform Implant Ø 4.3mm Length 11.5mm
EVO RP 130	Implante Aurea Evo Regular Platform Ø 4.3mm Longitud 13.0mm	Aurea Evo Regular Platform Implant Ø 4.3mm Length 13.0mm
EVO RP 145	Implante Aurea Evo Regular Platform Ø 4.3mm Longitud 14.5mm	Aurea Evo Regular Platform Implant Ø 4.3mm Length 14.5mm
EVO RP 48085	Implante Aurea Evo Regular Platform Ø 4.8mm Longitud 8.5mm	Aurea Evo Regular Platform Implant Ø 4.8mm Length 8.5mm
EVO RP 48100	Implante Aurea Evo Regular Platform Ø 4.8mm Longitud 10.0mm	Aurea Evo Regular Platform Implant Ø 4.8mm Length 10.0mm
EVO RP 48115	Implante Aurea Evo Regular Platform Ø 4.8mm Longitud 11.5mm	Aurea Evo Regular Platform Implant Ø 4.8mm Length 11.5mm
EVO RP 48130	Implante Aurea Evo Regular Platform Ø 4.8mm Longitud 13.0mm	Aurea Evo Regular Platform Implant Ø 4.8mm Length 13.0mm
EVO RP 48145	Implante Aurea Evo Regular Platform Ø 4.8mm Longitud 14.5mm	Aurea Evo Regular Platform Implant Ø 4.8mm Length 14.5mm
EVO WP 085	Implante Aurea Evo Wide Platform Ø 5.5mm Longitud 8.5mm	Aurea Evo Wide Platform Implant Ø 5.5mm Length 8.5mm

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EVO WP 100	Implante Aurea Evo Wide Platform Ø 5.5mm Longitud 10.0mm	Aurea Evo Wide Platform Implant Ø 5.5mm Length 10.0mm
EVO WP 115	Implante Aurea Evo Wide Platform Ø 5.5mm Longitud 11.5mm	Aurea Evo Wide Platform Implant Ø 5.5mm Length 11.5mm
EVO WP 130	Implante Aurea Evo Wide Platform Ø 5.5mm Longitud 13.0mm	Aurea Evo Wide Platform Implant Ø 5.5mm Length 13.0mm
TSA 03.085	Implante Autorroscante Avantblast TSA® S3 L8.5mm	Avantblast TSA® S3 L8.5mm Self-Tapping Implant
TSA 03.100	Implante Autorroscante Avantblast TSA® S3 L10.0mm	Avantblast TSA® S3 L10.0mm Self-Tapping Implant
TSA 03.115	Implante Autorroscante Avantblast TSA® S3 L11.5mm	Avantblast TSA® S3 L11.5mm Self-Tapping Implant
TSA 03.130	Implante Autorroscante Avantblast TSA® S3 L13.0mm	Avantblast TSA® S3 L13.0mm Self-Tapping Implant
TSA 03.145	Implante Autorroscante Avantblast TSA® S3 L14.5mm	Avantblast TSA® S3 L14.5mm Self-Tapping Implant
TSA 03.160	Implante Autorroscante Avantblast TSA® S3 L16.0mm	Avantblast TSA® S3 L16.0mm Self-Tapping Implant
TSA 04.060	Implante Autorroscante Avantblast TSA® S4 L6.0mm	Avantblast TSA® S4 L6.0mm Self-Tapping Implant
TSA 04.070	Implante Autorroscante Avantblast TSA® S4 L7.0mm	Avantblast TSA® S4 L7.0mm Self-Tapping Implant
TSA 04.085	Implante Autorroscante Avantblast TSA® S4 L8.5mm	Avantblast TSA® S4 L8.5mm Self-Tapping Implant
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TSA 04.115	Implante Autorroscante Avantblast TSA® S4 L11.5mm	Avantblast TSA® S4 L11.5mm Self-Tapping Implant
TSA 04.130	Implante Autorroscante Avantblast TSA® S4 L13.0mm	Avantblast TSA® S4 L13.0mm Self-Tapping Implant
TSA 04.145	Implante Autorroscante Avantblast TSA® S4 L14.5mm	Avantblast TSA® S4 L14.5mm Self-Tapping Implant
TSA 04.160	Implante Autorroscante Avantblast TSA® S4 L16.0mm	Avantblast TSA® S4 L16.0mm Self-Tapping Implant
TSA 05.060	Implante Autorroscante Avantblast TSA® S5 L6.0mm	Avantblast TSA® S5 L6.0mm Self-Tapping Implant
TSA 05.070	Implante Autorroscante Avantblast TSA® S5 L7.0mm	Avantblast TSA® S5 L7.0mm Self-Tapping Implant
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TSA 05.100	Implante Autorroscante Avantblast TSA® S5 L10.0mm	Avantblast TSA® S5 L10.0mm Self-Tapping Implant
TSA 05.115	Implante Autorroscante Avantblast TSA® S5 L11.5mm	Avantblast TSA® S5 L11.5mm Self-Tapping Implant

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TSA 05.130	Implante Autorroscante Avantblast TSA® S5 L13.0mm	Avantblast TSA® S5 L13.0mm Self-Tapping Implant
TSH 02.100	Implante Autorroscante Avantblast TSH® S2 L10.0mm	Avantblast TSH® S2 L10.0mm Self-Tapping Implant
TSH 02.115	Implante Autorroscante Avantblast TSH® S2 L11.5mm	Avantblast TSH® S2 L11.5mm Self-Tapping Implant
TSH 02.130	Implante Autorroscante Avantblast TSH® S2 L13.0mm	Avantblast TSH® S2 L13.0mm Self-Tapping Implant
TSH 02.145	Implante Autorroscante Avantblast TSH® S2 L14.5mm	Avantblast TSH® S2 L14.5mm Self-Tapping Implant
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TSH 05.060	Implante Autorroscante Avantblast TSH® S5 L6.0mm	Avantblast TSH® S5 L6.0mm Self-Tapping Implant
TSH 05.070	Implante Autorroscante Avantblast TSH® S5 L7.0mm	Avantblast TSH® S5 L7.0mm Self-Tapping Implant

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