

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

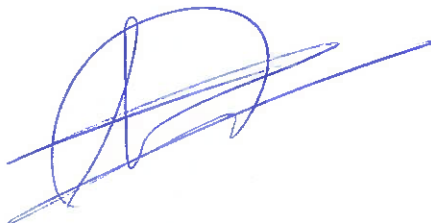
Está garantizado por el Sistema de Gestión de Calidad basado en los requisitos de la Norma Internacional EN ISO 13485:2016 para productos sanitarios.

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), 25 / 02 / 2021



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 55847.

All products described are associated with GMDN code 55847.

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
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 04.085	Implante Autorroscante Avantblast TSA® S4 L8.5mm / Avantblast TSA® S4 L8.5mm Self-Tapping Implant
TSA 04.100	Implante Autorroscante Avantblast TSA® S4 L10.0mm / Avantblast TSA® S4 L10.0mm Self-Tapping Implant
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 05.070	Implante Autorroscante Avantblast TSA® S5 L7.0mm / Avantblast TSA® S5 L7.0mm Self-Tapping Implant
TSA 05.080	Implante Autorroscante Avantblast TSA® S5 L8.0mm / Avantblast TSA® S5 L8.0mm Self-Tapping Implant
TSA 05.085	Implante Autorroscante Avantblast TSA® S5 L8.5mm / Avantblast TSA® S5 L8.5mm Self-Tapping Implant
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
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

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
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
TSH 02.160	Implante Autorroscante Avantblast TSH® S2 L16.0mm / Avantblast TSH® S2 L16.0mm Self-Tapping Implant
TSH 03.085	Implante Autorroscante Avantblast TSH® S3 L8.5mm / Avantblast TSH® S3 L8.5mm Self-Tapping Implant
TSH 03.100	Implante Autorroscante Avantblast TSH® S3 L10.0mm / Avantblast TSH® S3 L10.0mm Self-Tapping Implant
TSH 03.115	Implante Autorroscante Avantblast TSH® S3 L11.5mm / Avantblast TSH® S3 L11.5mm Self-Tapping Implant
TSH 03.130	Implante Autorroscante Avantblast TSH® S3 L13.0mm / Avantblast TSH® S3 L13.0mm Self-Tapping Implant
TSH 03.145	Implante Autorroscante Avantblast TSH® S3 L14.5mm / Avantblast TSH® S3 L14.5mm Self-Tapping Implant
TSH 03.160	Implante Autorroscante Avantblast TSH® S3 L16.0mm / Avantblast TSH® S3 L16.0mm Self-Tapping Implant
TSH 04.085	Implante Autorroscante Avantblast TSH® S4 L8.5mm / Avantblast TSH® S4 L8.5mm Self-Tapping Implant
TSH 04.100	Implante Autorroscante Avantblast TSH® S4 L10.0mm / Avantblast TSH® S4 L10.0mm Self-Tapping Implant
TSH 04.115	Implante Autorroscante Avantblast TSH® S4 L11.5mm / Avantblast TSH® S4 L11.5mm Self-Tapping Implant
TSH 04.130	Implante Autorroscante Avantblast TSH® S4 L13.0mm / Avantblast TSH® S4 L13.0mm Self-Tapping Implant
TSH 04.145	Implante Autorroscante Avantblast TSH® S4 L14.5mm / Avantblast TSH® S4 L14.5mm Self-Tapping Implant
TSH 04.160	Implante Autorroscante Avantblast TSH® S4 L16.0mm / Avantblast TSH® S4 L16.0mm Self-Tapping Implant
TSH 05.085	Implante Autorroscante Avantblast TSH® S5 L8.5mm / Avantblast TSH® S5 L8.5mm Self-Tapping Implant
TSH 05.100	Implante Autorroscante Avantblast TSH® S5 L10.0mm / Avantblast TSH® S5 L10.0mm Self-Tapping Implant
TSH 05.115	Implante Autorroscante Avantblast TSH® S5 L11.5mm / Avantblast TSH® S5 L11.5mm Self-Tapping Implant
TSH 05.130	Implante Autorroscante Avantblast TSH® S5 L13.0mm / Avantblast TSH® S5 L13.0mm Self-Tapping Implant
AUR NP 35085	Implante Aurea Narrow Platform Ø 3.5mm Longitud 8.5mm / Aurea Narrow Platform Implant Ø 3.5mm Length 8.5mm
AUR NP 35100	Implante Aurea Narrow Platform Ø 3.5mm Longitud 10.0mm / Aurea Narrow Platform Implant Ø 3.5mm Length 10.0mm
AUR NP 35115	Implante Aurea Narrow Platform Ø 3.5mm Longitud 11.5mm / Aurea Narrow Platform Implant Ø 3.5mm Length 11.5mm
AUR NP 35130	Implante Aurea Narrow Platform Ø 3.5mm Longitud 13.0mm / Aurea Narrow Platform Implant Ø 3.5mm Length 13.0mm
AUR NP 35145	Implante Aurea Narrow Platform Ø 3.5mm Longitud 14.5mm / Aurea Narrow Platform Implant Ø 3.5mm Length 14.5mm
AUR RP 43085	Implante Aurea Regular Platform Ø 4.3mm Longitud 8.5mm /

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
	Aurea Regular Platform Implant Ø 4.3mm Length 8.5mm
AUR RP 43100	Implante Aurea Regular Platform Ø 4.3mm Longitud 10.0mm / Aurea Regular Platform Implant Ø 4.3mm Length 10.0mm
AUR RP 43115	Implante Aurea Regular Platform Ø 4.3mm Longitud 11.5mm / Aurea Regular Platform Implant Ø 4.3mm Length 11.5mm
AUR RP 43130	Implante Aurea Regular Platform Ø 4.3mm Longitud 13.0mm / Aurea Regular Platform Implant Ø 4.3mm Length 13.0mm
AUR RP 43145	Implante Aurea Regular Platform Ø 4.3mm Longitud 14.5mm / Aurea Regular Platform Implant Ø 4.3mm Length 14.5mm
AUR RP 43160	Implante Aurea Regular Platform Ø 4.3mm Longitud 16.0mm / Aurea Regular Platform Implant Ø 4.3mm Length 16.0mm
AUR RP 48085	Implante Aurea Regular Platform Ø 4.8mm Longitud 8.5mm / Aurea Regular Platform Implant Ø 4.8mm Length 8.5mm
AUR RP 48100	Implante Aurea Regular Platform Ø 4.8mm Longitud 10.0mm / Aurea Regular Platform Implant Ø 4.8mm Length 10.0mm
AUR RP 48115	Implante Aurea Regular Platform Ø 4.8mm Longitud 11.5mm / Aurea Regular Platform Implant Ø 4.8mm Length 11.5mm
AUR RP 48130	Implante Aurea Regular Platform Ø 4.8mm Longitud 13.0mm / Aurea Regular Platform Implant Ø 4.8mm Length 13.0mm
AUR RP 48145	Implante Aurea Regular Platform Ø 4.8mm Longitud 14.5mm / Aurea Regular Platform Implant Ø 4.8mm Length 14.5mm
AUR RP 48160	Implante Aurea Regular Platform Ø 4.8mm Longitud 16.0mm / Aurea Regular Platform Implant Ø 4.8mm Length 16.0mm
AUR WP 55085	Implante Aurea Wide Platform Ø 5.5mm Longitud 8.5mm / Aurea Wide Platform Implant Ø 5.5mm Length 8.5mm
AUR WP 55100	Implante Aurea Wide Platform Ø 5.5mm Longitud 10.0mm / Aurea Wide Platform Implant Ø 5.5mm Length 10.0mm
AUR WP 55115	Implante Aurea Wide Platform Ø 5.5mm Longitud 11.5mm / Aurea Wide Platform Implant Ø 5.5mm Length 11.5mm
AUR WP 55130	Implante Aurea Wide Platform Ø 5.5mm Longitud 13.0mm / Aurea Wide Platform Implant Ø 5.5mm Length 13.0mm
AUR WP 60085	Implante Aurea Wide Platform Ø 6.0mm Longitud 8.5mm / Aurea Wide Platform Implant Ø 6.0mm Length 8.5mm
AUR WP 60100	Implante Aurea Wide Platform Ø 6.0mm Longitud 10.0mm / Aurea Wide Platform Implant Ø 6.0mm Length 10.0mm
AUR WP 60115	Implante Aurea Wide Platform Ø 6.0mm Longitud 11.5mm / Aurea Wide Platform Implant Ø 6.0mm Length 11.5mm
AUR WP 60130	Implante Aurea Wide Platform Ø 6.0mm Longitud 13.0mm / Aurea Wide Platform Implant Ø 6.0mm Length 13.0mm
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

REFERENCIA / REFERENCE	DESCRIPCIÓN / DESCRIPTION
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 WP 085	Implante Aurea Evo Wide Platform Ø 5.5mm Longitud 8.5mm / Aurea Evo Wide Platform Implant Ø 5.5mm Length 8.5mm
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 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 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
TSH 04.060	Implante Autorroscante Avantblast TSH® S4 L6.0mm Avantblast TSH® S4 L6.0mm Self-Tapping Implant
TSH 04.070	Implante Autorroscante Avantblast TSH® S4 L7.0mm Avantblast TSH® S4 L7.0mm Self-Tapping Implant
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
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

CONTROL DE VERSIONES / VERSIONS CONTROL

REVISIÓN / VERSION	FECHA / DATE	MODIFICACIONES / MODIFICATIONS
8	2016/04/01	Inclusión de referencias / Inclusion of references: EVO NP 145, EVO RP 085.
9	2016/04/04	Inclusión de referencia / Inclusion of reference: EVO RP 145.
10	2016/12/14	Se utiliza la plantilla vigente / The current template is used.
11	2018/05/04	Eliminación de referencias de implantes TSA Advance y BNT / References of implants TSA Advance and BNT are deleted: TSADV 03.085, TSADV 03.100, TSADV 03.115, TSADV 03.130, TSADV 03.145, TSADV 03.160, TSADV 04.085, TSADV 04.100, TSADV 04.115, TSADV 04.130, TSADV 04.145, TSADV 04.160, TSADV 05.060, TSADV 05.070, TSADV 05.085, TSADV 05.100, TSADV 05.115, TSADV 05.130 ; BNT 02.100, BNT 02.115, BNT 02.130, BNT 02.145, BNT 02.160, BNT 03.085, BNT 03.100, BNT 03.115, BNT 03.130, BNT 03.145, BNT 03.160, BNT 04.085, BNT 04.100, BNT 04.115, BNT 04.130, BNT 04.145, BNT 04.160, BNT 05.085, BNT 05.100, BNT 05.115, BNT 05.130.
12	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.
13	14/09/2018	Inclusión de referencias / Inclusion of references: TSA 04.060, TSA 04.070, TSA 05.060, TSA 05.070, TSH 04.060, TSH 04.070, TSH 05.060, TSH 05.070
14	09/12/2019	Inclusión de referencias / Inclusion of references: EVO RP 48085, EVO RP 48100, EVO RP 48115, EVO RP 48130, EVO RP 48145.
15	2020/07/20	Error de tipeo en el cambio de revisión.
16	2021/02/25	Se especifica que la Declaración de Conformidad cumple la Directiva 93/42/CEE, Anexo II excepto 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.