

**Declaration of Conformity**  
**Phibo dental implants**

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| <b>Manufacturer:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Phibo Dental Solutions, S.L.<br>C/Gato Pérez, 3-9, Polígono Industrial Mas d'En Cisa<br>08181 - Sentmenat, Barcelona, España/Spain                                                                                              |
| <b>SRN (Single Registration Number)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | ES-MF-000024464                                                                                                                                                                                                                 |
| <b>European representative:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Not applicable. Phibo Dental Solutions, S.L. has its registered place of business in Spain, a member state of the European Union, therefore there is no need to designate an authorized representative that acts on its behalf. |
| <b>Product name:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | This Declaration of Conformity is valid for following medical devices:<br>Phibo dental implants                                                                                                                                 |
| <b>Intended use:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Phibo <sup>®</sup> dental implants are intended to be surgically introduced in the remaining bone tissue to replace the dental root. Dental implants are versatile implants designed for different types of restorations.       |
| <b>BASIC UDI-DI</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 084355673IMPLES<br>0843656095IMPL6M                                                                                                                                                                                             |
| <b>Classification:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Phibo dental implants are classified as Class IIb devices by Rule 8 (Annex VII MDR 2017/745).                                                                                                                                   |
| <b>Conformity assessment route:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Annex IX (Ch I & III) "Conformity Assessment based on a Quality Management System and on assessment of Technical Documentation".                                                                                                |
| <p>This declaration of conformity is issued under the sole responsibility of Phibo Dental Solutions, S.L. in compliance with the provisions of Regulation (EU) 2017/745. We hereby declare that the specified medical device meets the provision of the Annex IV and Article 19 of Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained under the premises of the manufacturer.</p> <p>In addition, this declaration of conformity complies with Chapter III section 23.1(f) of Regulation (EU) 2017/745. We hereby declare that the specified medical device meets the provision the Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices.</p> |                                                                                                                                                                                                                                 |
| <b>Standards applied:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | A list of applicable/applied standards with the year of publication is part of the Technical Product Documentation, Part D. The list indicates whether or not the standards are harmonized with the MDR.                        |
| <b>Common Specifications (CS)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Not applicable.                                                                                                                                                                                                                 |
| <b>Notified body:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | TÜV SÜD Product Service GmbH (NB 0123)<br>Ridlerstr. 65 · 80339 München, Germany                                                                                                                                                |
| <b>(EC) Certificate(s):</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | G15 076131 0013 Rev. 00                                                                                                                                                                                                         |
| <b>Validity:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 22-09-2030                                                                                                                                                                                                                      |
| <b>Place, date of issue:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Sentmenat, 2025-11-12.                                                                                                                                                                                                          |
| <b>Signature</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <br>Ignacio Mestre Juncosa<br>CEO Phibo Dental Solution                                                                                     |

**Dental implants**

**Table 1. TSA<sup>®</sup> dental implants**

| REFERENCE  | NAME/DESCRIPTION                                            | System | UDI-DI         | BASIC UDI-DI     |
|------------|-------------------------------------------------------------|--------|----------------|------------------|
| TSA 03.085 | Avantblast TSA <sup>®</sup> S3 L8.5mm Self-Tapping Implant  | TSA    | 08436560950158 | 084355673IMPLES  |
| TSA 03.100 | Avantblast TSA <sup>®</sup> S3 L10.0mm Self-Tapping Implant | TSA    | 08436560950165 | 084355673IMPLES  |
| TSA 03.115 | Avantblast TSA <sup>®</sup> S3 L11.5mm Self-Tapping Implant | TSA    | 08436560950172 | 084355673IMPLES  |
| TSA 03.130 | Avantblast TSA <sup>®</sup> S3 L13.0mm Self-Tapping Implant | TSA    | 08436560950189 | 084355673IMPLES  |
| TSA 03.145 | Avantblast TSA <sup>®</sup> S3 L14.5mm Self-Tapping Implant | TSA    | 08436560950196 | 084355673IMPLES  |
| TSA 03.160 | Avantblast TSA <sup>®</sup> S3 L16.0mm Self-Tapping Implant | TSA    | 08436560950202 | 084355673IMPLES  |
| TSA 04.060 | Avantblast TSA <sup>®</sup> S4 L6.0mm Self-Tapping Implant  | TSA    | 08435567311559 | 0843656095IMPL6M |
| TSA 04.070 | Avantblast TSA <sup>®</sup> S4 L7.0mm Self-Tapping Implant  | TSA    | 08435567311566 | 0843656095IMPL6M |
| TSA 04.085 | Avantblast TSA <sup>®</sup> S4 L8.5mm Self-Tapping Implant  | TSA    | 08436560950219 | 084355673IMPLES  |
| TSA 04.100 | Avantblast TSA <sup>®</sup> S4 L10.0mm Self-Tapping Implant | TSA    | 08436560950226 | 084355673IMPLES  |
| TSA 04.115 | Avantblast TSA <sup>®</sup> S4 L11.5mm Self-Tapping Implant | TSA    | 08436560950233 | 084355673IMPLES  |
| TSA 04.130 | Avantblast TSA <sup>®</sup> S4 L13.0mm Self-Tapping Implant | TSA    | 08436560950240 | 084355673IMPLES  |
| TSA 04.145 | Avantblast TSA <sup>®</sup> S4 L14.5mm Self-Tapping Implant | TSA    | 08436560950257 | 084355673IMPLES  |
| TSA 04.160 | Avantblast TSA <sup>®</sup> S4 L16.0mm Self-Tapping Implant | TSA    | 08436560950264 | 084355673IMPLES  |
| TSA 05.060 | Avantblast TSA <sup>®</sup> S5 L6.0mm Self-Tapping Implant  | TSA    | 08435567311573 | 0843656095IMPL6M |
| TSA 05.070 | Avantblast TSA <sup>®</sup> S5 L7.0mm Self-Tapping Implant  | TSA    | 08435567311580 | 0843656095IMPL6M |
| TSA 05.085 | Avantblast TSA <sup>®</sup> S5 L8.5mm Self-Tapping Implant  | TSA    | 08436560950288 | 084355673IMPLES  |
| TSA 05.100 | Avantblast TSA <sup>®</sup> S5 L10.0mm Self-Tapping Implant | TSA    | 08436560950295 | 084355673IMPLES  |
| TSA 05.115 | Avantblast TSA <sup>®</sup> S5 L11.5mm Self-Tapping Implant | TSA    | 08436560950301 | 084355673IMPLES  |
| TSA 05.130 | Avantblast TSA <sup>®</sup> S5 L13.0mm Self-Tapping Implant | TSA    | 08436560950318 | 084355673IMPLES  |

Table 2. TSH dental implants

| REFERENCE  | NAME/DESCRIPTION(EN)                            | System | UDI-DI         | BASIC UDI-DI     |
|------------|-------------------------------------------------|--------|----------------|------------------|
| TSH 02.100 | Avantblast TSH® S2 L10.0mm Self-Tapping Implant | TSH    | 08436560950325 | 084355673IMPLES  |
| TSH 02.115 | Avantblast TSH® S2 L11.5mm Self-Tapping Implant | TSH    | 08436560950332 | 084355673IMPLES  |
| TSH 02.130 | Avantblast TSH® S2 L13.0mm Self-Tapping Implant | TSH    | 08436560950349 | 084355673IMPLES  |
| TSH 02.145 | Avantblast TSH® S2 L14.5mm Self-Tapping Implant | TSH    | 08436560950356 | 084355673IMPLES  |
| TSH 02.160 | Avantblast TSH® S2 L16.0mm Self-Tapping Implant | TSH    | 08436560950363 | 084355673IMPLES  |
| TSH 03.085 | Avantblast TSH® S3 L8.5mm Self-Tapping Implant  | TSH    | 08436560950370 | 084355673IMPLES  |
| TSH 03.100 | Avantblast TSH® S3 L10.0mm Self-Tapping Implant | TSH    | 08436560950387 | 084355673IMPLES  |
| TSH 03.115 | Avantblast TSH® S3 L11.5mm Self-Tapping Implant | TSH    | 08436560950394 | 084355673IMPLES  |
| TSH 03.130 | Avantblast TSH® S3 L13.0mm Self-Tapping Implant | TSH    | 08436560950400 | 084355673IMPLES  |
| TSH 03.145 | Avantblast TSH® S3 L14.5mm Self-Tapping Implant | TSH    | 08436560950417 | 084355673IMPLES  |
| TSH 03.160 | Avantblast TSH® S3 L16.0mm Self-Tapping Implant | TSH    | 08436560950424 | 084355673IMPLES  |
| TSH 04.060 | Avantblast TSH® S4 L6.0mm Self-Tapping Implant  | TSH    | 08435567311511 | 0843656095IMPL6M |
| TSH 04.070 | Avantblast TSH® S4 L7.0mm Self-Tapping Implant  | TSH    | 08435567311528 | 0843656095IMPL6M |
| TSH 04.085 | Avantblast TSH® S4 L8.5mm Self-Tapping Implant  | TSH    | 08436560950431 | 084355673IMPLES  |
| TSH 04.100 | Avantblast TSH® S4 L10.0mm Self-Tapping Implant | TSH    | 08436560950448 | 084355673IMPLES  |
| TSH 04.115 | Avantblast TSH® S4 L11.5mm Self-Tapping Implant | TSH    | 08436560950455 | 084355673IMPLES  |
| TSH 04.130 | Avantblast TSH® S4 L13.0mm Self-Tapping Implant | TSH    | 08436560950462 | 084355673IMPLES  |
| TSH 04.145 | Avantblast TSH® S4 L14.5mm Self-Tapping Implant | TSH    | 08436560950479 | 084355673IMPLES  |
| TSH 04.160 | Avantblast TSH® S4 L16.0mm Self-Tapping Implant | TSH    | 08436560950486 | 084355673IMPLES  |
| TSH 05.060 | Avantblast TSH® S5 L6.0mm Self-Tapping Implant  | TSH    | 08435567311535 | 0843656095IMPL6M |
| TSH 05.070 | Avantblast TSH® S5 L7.0mm Self-Tapping Implant  | TSH    | 08435567311542 | 0843656095IMPL6M |
| TSH 05.085 | Avantblast TSH® S5 L8.5mm Self-Tapping Implant  | TSH    | 08436560950493 | 084355673IMPLES  |

| REFERENCE  | NAME/DESCRIPTION(EN)                            | System | UDI-DI         | BASIC UDI-DI    |
|------------|-------------------------------------------------|--------|----------------|-----------------|
| TSH 05.100 | Avantblast TSH® S5 L10.0mm Self-Tapping Implant | TSH    | 08436560950509 | 084355673IMPLES |
| TSH 05.115 | Avantblast TSH® S5 L11.5mm Self-Tapping Implant | TSH    | 08436560950516 | 084355673IMPLES |
| TSH 05.130 | Avantblast TSH® S5 L13.0mm Self-Tapping Implant | TSH    | 08436560950523 | 084355673IMPLES |

Table 3. Aurea Evo dental implants

| REFERENCE    | NAME/DESCRIPTION(EN)                                        | System    | UDI-DI         | BASIC UDI-DI     |
|--------------|-------------------------------------------------------------|-----------|----------------|------------------|
| EVO NP 085   | Aurea Evo Narrow Platform Implant Ø 3.5mm<br>Length 8.5mm   | AUREA EVO | 08436560950011 | 084355673IMPLES  |
| EVO NP 100   | Aurea Evo Narrow Platform Implant Ø 3.5mm<br>Length 10.0mm  | AUREA EVO | 08436560950028 | 084355673IMPLES  |
| EVO NP 115   | Aurea Evo Narrow Platform Implant Ø 3.5mm<br>Length 11.5mm  | AUREA EVO | 08436560950035 | 084355673IMPLES  |
| EVO NP 130   | Aurea Evo Narrow Platform Implant Ø 3.5mm<br>Length 13.0mm  | AUREA EVO | 08436560950042 | 084355673IMPLES  |
| EVO NP 145   | Aurea Evo Narrow Platform Implant Ø 3.5mm<br>Length 14.5mm  | AUREA EVO | 08436560950059 | 084355673IMPLES  |
| EVO RP 085   | Aurea Evo Regular Platform Implant Ø 4.3mm<br>Length 8.5mm  | AUREA EVO | 08436560950066 | 084355673IMPLES  |
| EVO RP 100   | Aurea Evo Regular Platform Implant Ø 4.3mm<br>Length 10.0mm | AUREA EVO | 08436560950073 | 084355673IMPLES  |
| EVO RP 115   | Aurea Evo Regular Platform Implant Ø 4.3mm<br>Length 11.5mm | AUREA EVO | 08436560950080 | 084355673IMPLES  |
| EVO RP 130   | Aurea Evo Regular Platform Implant Ø 4.3mm<br>Length 13.0mm | AUREA EVO | 08436560950097 | 084355673IMPLES  |
| EVO RP 145   | Aurea Evo Regular Platform Implant Ø 4.3mm<br>Length 14.5mm | AUREA EVO | 08436560950103 | 084355673IMPLES  |
| EVO RP 48085 | Aurea Evo Regular Platform Implant Ø 4.8mm<br>Length 8.5mm  | AUREA EVO | 08435567311634 | 0843656095IMPL6M |
| EVO RP 48100 | Aurea Evo Regular Platform Implant Ø 4.8mm<br>Length 10.0mm | AUREA EVO | 08435567311597 | 0843656095IMPL6M |
| EVO RP 48115 | Aurea Evo Regular Platform Implant Ø 4.8mm<br>Length 11.5mm | AUREA EVO | 08435567311603 | 0843656095IMPL6M |
| EVO RP 48130 | Aurea Evo Regular Platform Implant Ø 4.8mm<br>Length 13.0mm | AUREA EVO | 08435567311610 | 0843656095IMPL6M |
| EVO RP 48145 | Aurea Evo Regular Platform Implant Ø 4.8mm<br>Length 14.5mm | AUREA EVO | 08435567311627 | 0843656095IMPL6M |
| EVO WP 085   | Aurea Evo Wide Platform Implant Ø 5.5mm<br>Length 8.5mm     | AUREA EVO | 08436560950110 | 084355673IMPLES  |
| EVO WP 100   | Aurea Evo Wide Platform Implant Ø 5.5mm<br>Length 10.0mm    | AUREA EVO | 08436560950127 | 084355673IMPLES  |
| EVO WP 115   | Aurea Evo Wide Platform Implant Ø 5.5mm<br>Length 11.5mm    | AUREA EVO | 08436560950134 | 084355673IMPLES  |

| REFERENCE  | NAME/DESCRIPTION(EN)                                     | System    | UDI-DI         | BASIC UDI-DI    |
|------------|----------------------------------------------------------|-----------|----------------|-----------------|
| EVO WP 130 | Aurea Evo Wide Platform Implant Ø 5.5mm<br>Length 13.0mm | AUREA EVO | 08436560950141 | 084355673IMPLES |

**VERSIONS CONTROL**

| VERSION | DATE       | MODIFICATIONS                  |
|---------|------------|--------------------------------|
| 00      | 12/11/2025 | First version of the document. |

