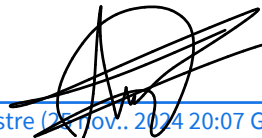


|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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>Dental instruments                                                                                                                                                               |
| <b>Intended use:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Dental instruments are intended to support surgical and prosthodontic procedures in implantology and restorative dentistry. They are designed to assist with various tasks, including bone preparation, tissue management, and the assembly of components. |
| <b>BASIC UDI-DI</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 084355673MANGOCN<br>084355673ATORNIH4<br>0843656095ADAPTA5B<br>084355673PARALELI26<br>084355673CARRACAH5<br>084355673LLAVEDG<br>084355673KITEXTJ3<br>084355673CAJAAC                                                                                       |
| <b>Classification:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Phibo dental Prosthetics are classified as Class I devices by Rule 5 (Annex VIII MDR 2017/745).                                                                                                                                                            |
| <b>Conformity assessment route:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Annex IV, according to the provisions of the Regulation, is subject to self-certification. As such, we have not involved a notified body in the conformity assessment procedure                                                                            |
| <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.</p> <p>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 specified 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.                                                                                                                                                                                                                                            |

**Declaration of Conformity**  
*Phibo dental Instruments*

|                              |                                                                                                                                                                                                                           |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Notified body:</b>        | The product is classified as a Class I device and, according to the provisions of the Regulation, is subject to self-certification. As such, we have not involved a notified body in the conformity assessment procedure. |
| <b>(EC) Certificate(s):</b>  | Not applicable.                                                                                                                                                                                                           |
| <b>Validity:</b>             | Not applicable.                                                                                                                                                                                                           |
| <b>Place, date of issue:</b> | Sentmenat, 25-nov.-2024                                                                                                                                                                                                   |
| <b>Signature</b>             | <br><u>Nacho Mestre (25 Nov.. 2024 20:07 GMT+3)</u><br>Ignacio Mestre Juncosa<br>CEO Phibo Dental Solution                              |

**Dental Instruments**

The tables below show the instruments references for each group and subgroup. The table also presents the product name, system, the UDI-DI code and Basic UDI-DI.

*Table 1. Axis Screwdrivers Tip*

| REFERENCE       | NAME/DESCRIPTION(EN)                             | SYSTEM | UDI- (DI)      | BASIC UDI-DI      |
|-----------------|--------------------------------------------------|--------|----------------|-------------------|
| <b>172.1103</b> | Axis® Hexalobular Angled Tool Short - to Wrench  | Axis   | 08435567312341 | 084355673ATORNIH4 |
| <b>172.1104</b> | Axis® Hexalobular Angled Tool Medium - to Wrench | Axis   | 08435567312358 | 084355673ATORNIH4 |
| <b>172.1105</b> | Axis® Hexalobular Angled Tool Long - to Wrench   | Axis   | 08435567312365 | 084355673ATORNIH4 |

*Table 2. Manual Handle*

| REFERENCE       | NAME/DESCRIPTION(EN)  | SYSTEM                  | UDI- (DI)      | BASIC UDI-DI     |
|-----------------|-----------------------|-------------------------|----------------|------------------|
| <b>172.1100</b> | Phibo® manual handle  | TSA<br>TSH<br>AUREA EVO | 08435567312310 | 084355673MANGOCN |
| <b>190.0002</b> | Handle for manual use | TSA<br>TSH<br>AUREA EVO | 08435567312556 | 084355673MANGOCN |

*Table 3. Syntesis Screwdriver Tip*

| REFERENCE       | NAME/DESCRIPTION(EN)                 | SYSTEM                  | UDI- (DI)      | BASIC UDI-DI      |
|-----------------|--------------------------------------|-------------------------|----------------|-------------------|
| <b>172.1101</b> | Hexalobular tool, short - to wrench  | TSA<br>TSH<br>AUREA EVO | 08435567312327 | 084355673ATORNIH4 |
| <b>172.1102</b> | Hexalobular tool, medium - to wrench | TSA<br>TSH<br>AUREA EVO | 08435567312334 | 084355673ATORNIH4 |

*Table 4. Manual Screwdrivers*

| REFERENCE       | NAME/DESCRIPTION(EN)                                  | SYSTEM                  | UDI- (DI)      | BASIC UDI-DI      |
|-----------------|-------------------------------------------------------|-------------------------|----------------|-------------------|
| <b>174.1001</b> | Manual Hex Driver 1.00mm, Short TSA®<br>TSA® Advance  | TSA                     | 08435567312419 | 084355673ATORNIH4 |
| <b>174.1002</b> | Manual Hex Driver 1.00mm, Medium TSA®<br>TSA® Advance | TSA                     | 08435567312426 | 084355673ATORNIH4 |
| <b>174.1251</b> | Manual Hex Driver 1.25mm, Short                       | TSA<br>TSH<br>AUREA EVO | 08435567312433 | 084355673ATORNIH4 |
| <b>174.1252</b> | Manual Hex Driver 1.25mm, Medium                      | TSA<br>TSH<br>AUREA EVO | 08435567312440 | 084355673ATORNIH4 |
| <b>174.1253</b> | Manual Hex Driver 1.25mm, Long                        | TSA<br>TSH<br>AUREA EVO | 08435567312457 | 084355673ATORNIH4 |
| <b>174.2301</b> | Manual Hex Driver Short Abutment ConHex TSH®<br>BNT®  | TSH                     | 08435567312464 | 084355673ATORNIH4 |
| <b>174.2302</b> | Manual Hex Driver Medium Abutment ConHex TSH®<br>BNT® | TSH                     | 08435567312471 | 084355673ATORNIH4 |

Table 5. Wrench Screwdriver Tips

| REFERENCE | NAME/DESCRIPTION(EN)                                    | SYSTEM                  | UDI- (DI)      | BASIC UDI-DI      |
|-----------|---------------------------------------------------------|-------------------------|----------------|-------------------|
| 172.1001  | Hex Tool 1.00mm, Short - to Wrench TSA®<br>TSA®Advance  | TSA                     | 08435567312297 | 084355673ATORNIH4 |
| 172.1002  | Hex Tool 1.00mm, Medium - to Wrench TSA®<br>TSA®Advance | TSA                     | 08435567312303 | 084355673ATORNIH4 |
| 172.1251  | Hex Tool 1.25mm, Short - to Wrench                      | TSA<br>TSH<br>AUREA EVO | 08435567312372 | 084355673ATORNIH4 |
| 172.1252  | Hex Tool 1.25mm, Medium – to Wrench                     | TSA<br>TSH<br>AUREA EVO | 08435567312389 | 084355673ATORNIH4 |
| 172.2301  | Hex Tool Short Abutment ConHex TSH® BNT®                | TSH                     | 08435567312396 | 084355673ATORNIH4 |
| 172.2302  | Hex Tool Medium Abutment ConHex TSH® BNT®               | TSH                     | 08435567312402 | 084355673ATORNIH4 |

Table 6. Ratchet Adapters

| REFERENCE | NAME/DESCRIPTION(EN)                | SYSTEM                  | UDI- (DI)      | BASIC UDI-DI       |
|-----------|-------------------------------------|-------------------------|----------------|--------------------|
| 172.0100  | Ratchet Adapter, Short - to Mounter | TSA<br>TSH<br>AUREA EVO | 08436560958338 | 0843656095ADAPTA5B |
| 172.0300  | Ratchet Adapter, Long – to Mounter  | TSA<br>TSH<br>AUREA EVO | 08436560958345 | 0843656095ADAPTA5B |

Table 7. Depth Indicator

| REFERENCE | NAME/DESCRIPTION(EN)                                    | SYSTEM                  | UDI- (DI)      | BASIC UDI-DI        |
|-----------|---------------------------------------------------------|-------------------------|----------------|---------------------|
| 177.0000  | Depth Indicator Drill Parallelizer ø 2.3mm TSA®<br>TSH® | TSA<br>TSH              | 08435567312488 | 084355673PARALELI26 |
| 179.0028  | Depth Indicator Drill ø 2.8mm TSA® TSH®                 | TSA<br>TSH              | 08435567312495 | 084355673PARALELI26 |
| 179.0030  | Depth Indicator Drill ø 3.0mm TSA® TSH®                 | TSA<br>TSH              | 08435567312501 | 084355673PARALELI26 |
| 179.0036  | Depth Indicator Drill ø 3.6mm TSA® TSH®                 | TSA<br>TSH              | 08435567312518 | 084355673PARALELI26 |
| 179.0041  | Depth Indicator Drill ø 4.1mm TSH®                      | TSH                     | 08435567312525 | 084355673PARALELI26 |
| 179.0043  | Depth Indicator Drill ø4.3mm TSA®                       | TSA                     | 08435567312532 | 084355673PARALELI26 |
| 179.0049  | Depth Indicator Drill ø4.9mm TSA®                       | TSA                     | 08435567312549 | 084355673PARALELI26 |
| EVO 00200 | Depth Indicator Drill ø2.0 mm PHIBO                     | TSA<br>TSH<br>AUREA EVO | 08435567312716 | 084355673PARALELI26 |

Table 8. Torque Wrench

| REFERENCE | NAME/DESCRIPTION(EN) | SYSTEM                  | UDI- (DI)      | BASIC UDI-DI           |
|-----------|----------------------|-------------------------|----------------|------------------------|
| 172.0172  | Torque Wrench        | TSA<br>TSH<br>AUREA EVO | 08435567312280 | 084355673CARRACAH<br>5 |

*Table 9. Open and wrench*

| REFERENCE       | NAME/DESCRIPTION(EN) | SYSTEM                  | UDI- (DI)      | BASIC UDI-DI     |
|-----------------|----------------------|-------------------------|----------------|------------------|
| <b>172.0001</b> | Open end Wrench      | TSA<br>TSH<br>AUREA EVO | 08435567312273 | 084355673LLAVEDG |

*Table 10. Surgical Boxes*

| REFERENCE        | NAME/DESCRIPTION(EN)   | SYSTEM     | UDI- (DI)      | BASIC UDI-DI    |
|------------------|------------------------|------------|----------------|-----------------|
| <b>EVO 00001</b> | Aurea Evo Surgical Box | AUREA EVO  | 08435567312709 | 084355673CAJAAC |
| <b>SBX 00001</b> | TSA® TSH® Surgical Box | TSA<br>TSH | 08435567313591 | 084355673CAJAAC |

*Table 11. Extraction Kit*

| REFERENCE         | NAME/DESCRIPTION(EN) | SYSTEM | UDI-(DI)       | BASIC UDI         |
|-------------------|----------------------|--------|----------------|-------------------|
| <b>KITEXTLIT</b>  | Extraction Kit       | Phibo® | 08435567312754 | 084355673KITEXTJ3 |
| <b>EXT1IT</b>     | Number 1 Extractor   | Phibo® | 08435567312785 | 084355673KITEXTJ3 |
| <b>EXT2IT</b>     | Number 2 Extractor   | Phibo® | 08435567312792 | 084355673KITEXTJ3 |
| <b>EXT3IT</b>     | Number 3 Extractor   | Phibo® | 08435567312808 | 084355673KITEXTJ3 |
| <b>EXT4IT</b>     | Number 4 Extractor   | Phibo® | 08435567312815 | 084355673KITEXTJ3 |
| <b>EXTC4IT</b>    | Ratchet extender     | Phibo® | 08435567312778 | 084355673KITEXTJ3 |
| <b>LLMANCC4IT</b> | Manual spanner       | Phibo® | 08435567312761 | 084355673KITEXTJ3 |

**VERSIONS CONTROL**

| VERSION | DATE       | MODIFICATIONS                                                                                                                                                                                                             |
|---------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 00      | 26/11/2024 | Initial emission of the document. Prepared with template FORM4.1-00007 V.00<br>This document comes from the following Declaration of Conformity: DoC Phibo Instruments_v4. Planned change in <b>Planning TD under MDR</b> |

# DOC-00005 V.00 Dental Instruments - Class I

Informe de auditoría final

2024-11-26

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