

Declaration of Conformity
Dental Instruments - Class IIa

Manufacturer:	Phibo Dental Solutions, S.L. C/Gato Pérez, 3-9, Polígono Industrial Mas d'En Cisa 08181 - Sentmenat, Barcelona, España/Spain
SRN (Single Registration Number)	ES-MF-000024464
European representative:	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.
Product name:	This Declaration of Conformity is valid for following medical devices: Dental instruments Class IIa
Intended use:	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.
BASIC UDI-DI	0843656095FRESA6E 084355673FRESACT 0843656095TOPE8W 084355673TOPEH3 0843656095BISTURIRR 0843656095PROLONGYA 084355673MROSCARVQ 0843656095MROSCARVT 0843656095ATORMECR2 084355673ATORMECQX 0843656095CONFORMA6E 0843656095ADAPTMECV5
Classification:	Surgical Invasive dental instruments are classified as Class IIa devices, by Rule 5 and 6, (Annex IX MDR 2017/745). Rule 5: 0843656095ADAPTMECV5 084355673ATORMECQX 0843656095ATORMECR2 0843656095TOPE8W 084355673TOPEH3 0843656095PROLONGYA 0843656095CONFORMA6E Rule 6: 0843656095FRESA6E 084355673FRESACT 0843656095BISTURIRR 084355673MROSCARVQ 0843656095MROSCARVT
Conformity assessment route:	Annex IX (Ch I, III) "Conformity Assessment based on a Quality Management System and on assessment of Technical Documentation".

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.

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.

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.

Common Specifications (CS) Not applicable.

Notified body: TÜV SÜD Product Service GmbH (NB 0123)
Ridlerstr. 65 · 80339 München, Germany

(EC) Certificate(s): G15 076131 0013 Rev. 00

Validity: 22-09-2030

Place, date of issue: Sentmenat,

Signature



Ignacio Mestre Juncosa
CEO Phibo Dental Solution

Dental Instruments

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

Table 1 Group: Drill, Subgroup: Precision Drill

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
EVO 23000	Precision Drill	Aurea® Evo	08436560958499	0843656095FRESA6E
175.0001	Precision Drill TSA® TSH®	TSA®-TSH®	08436560958512	0843656095FRESA6E

Table 2 Group: Drill, Subgroup: Pilot Drill

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
EVO 20000	Pilot Drill ø2.0mm	Aurea® Evo	08436560958543	0843656095FRESA6E
176.1123	Pilot Drill, Short ø 2.3mm TSA® TSH®	TSA®-TSH®	08436560958529	0843656095FRESA6E
176.1323	Pilot Drill, Long ø 2.3mm TSA® TSH®	TSA®-TSH®	08436560958536	0843656095FRESA6E
175.23000	Pilot Drill ø2.3mm TSA® TSH®	TSA®-TSH®	08436560958611	0843656095FRESA6E

Table 3 Group: Drill; Subgroup: Surgical Drill

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
EVO 31000	Surgical Drill Ø3.1mm Aurea Evo®	Aurea® Evo	08436560958680	0843656095FRESA6E
EVO 34000	Surgical Drill Ø3.4mm Aurea Evo®	Aurea® Evo	08435567313652	084355673FFRESACT
EVO 38000	Surgical Drill Ø3.8mm Aurea Evo®	Aurea® Evo	08436560958703	0843656095FRESA6E
EVO 41000	Surgical Drill Ø4.1mm Aurea Evo®	Aurea® Evo	08435567313669	084355673FFRESACT
EVO 44000	Surgical Drill Ø4.4mm Aurea Evo®	Aurea® Evo	08435567313676	084355673FFRESACT
EVO 46000	Surgical Drill Ø4.6mm Aurea Evo®	Aurea® Evo	08435567313683	084355673FFRESACT
EVO 52052	Surgical Drill Ø5.2mm Aurea Evo®	Aurea® Evo	08435567313690	084355673FFRESACT
EVO 54000	Surgical Drill Ø5.4mm Aurea Evo®	Aurea® Evo	08435567313706	084355673FFRESACT
178.1128	Surgical Drill, Short Ø 2.8mm TSA®	TSA®-TSH®	08436560958802	0843656095FRESA6E
178.1328	Surgical Drill, Long Ø 2.8mm TSA®	TSA®-TSH®	08436560958864	0843656095FRESA6E
178.1130	Surgical Drill, Short Ø 3.0mm TSA®	TSA®-TSH®	08436560958819	0843656095FRESA6E
178.1330	Surgical Drill, Long Ø 3.0mm TSA®	TSA®-TSH®	08436560958871	0843656095FRESA6E
178.1136	Surgical Drill, Short Ø 3.6mm TSA®	TSA®-TSH®	08436560958826	0843656095FRESA6E
178.1336	Surgical Drill, Long Ø 3.6mm TSA®	TSA®-TSH®	08436560958888	0843656095FRESA6E
178.1241	Surgical Drill Ø4.1mm TSH®	TSH®	08436560959014	0843656095FRESA6E
178.1243	Surgical Drill Ø4.3mm TSA®	TSA®	08436560959083	0843656095FRESA6E
178.1249	Surgical Drill Ø 4.9mm TSA®	TSA®	08436560959151	0843656095FRESA6E
TS 28000	Surgical Drill Ø2.8mm TSA®	TSA®-TSH®	08436560958741	0843656095FRESA6E
TS 30000	Surgical Drill Ø3.0mm TSA®	TSA®-TSH®	08436560958758	0843656095FRESA6E
TS 36000	Surgical Drill Ø3.6mm TSA®	TSA®-TSH®	08436560958765	0843656095FRESA6E
TS 41000	Surgical Drill Ø4.1mm TSA®	TSA®-TSH®	08436560958772	0843656095FRESA6E
TS 43000	Surgical Drill Ø4.3mm TSA®	TSA®-TSH®	08436560958789	0843656095FRESA6E
TS 49000	Surgical Drill Ø4.9mm TSA®	TSA®-TSH®	08436560958796	0843656095FRESA6E

Table 4 Group: Drill; Subgroup: Countersink Drill

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
178.0037	TSA® S3 Countersink Drill	TSA®	08436560958833	0843656095FRESA6E
178.0047	TSA® S4 Countersink Drill	TSA®	08436560958840	0843656095FRESA6E
178.0060	TSA® S5 Countersink Drill	TSA®	08436560958857	0843656095FRESA6E

Table 5 Group: Drill Accessories; Subgroup: Drill Stop

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
TOP NP 085	Drill stop Aurea Evo® NP 8,5mm	Aurea® Evo	08436560959502	0843656095TOP8W
TOP NP 100	Drill stop Aurea Evo® NP 10,0mm	Aurea® Evo	08436560959465	0843656095TOP8W
TOP NP 115	Drill stop Aurea Evo® NP 11,5mm	Aurea® Evo	08436560959472	0843656095TOP8W
TOP NP 130	Drill stop Aurea Evo® NP 13,0mm	Aurea® Evo	08436560959489	0843656095TOP8W
TOP NP 145	Drill stop Aurea Evo® NP 14,5mm	Aurea® Evo	08436560959496	0843656095TOP8W
TOP RP 085	Drill stop Aurea Evo® RP 8,5mm	Aurea® Evo	08436560959557	0843656095TOP8W
TOP RP 100	Drill stop Aurea Evo® RP 10,0mm	Aurea® Evo	08436560959519	0843656095TOP8W
TOP RP 115	Drill stop Aurea Evo® RP 11,5mm	Aurea® Evo	08436560959526	0843656095TOP8W
TOP RP 130	Drill stop Aurea Evo® RP 13,0mm	Aurea® Evo	08436560959533	0843656095TOP8W
TOP RP 145	Drill stop Aurea Evo® RP 14,5mm	Aurea® Evo	08436560959540	0843656095TOP8W
TOP RP48 085	Drill stop Aurea Evo® RP48 8,5mm	Aurea® Evo	08435567313713	084355673TOP8H3
TOP RP48 100	Drill stop Aurea Evo® RP48 10,0mm	Aurea® Evo	08435567313720	084355673TOP8H3
TOP RP48 115	Drill stop Aurea Evo® RP48 11,5mm	Aurea® Evo	08435567313737	084355673TOP8H3
TOP RP48 130	Drill stop Aurea Evo® RP48 13,0mm	Aurea® Evo	08435567313744	084355673TOP8H3
TOP RP48 145	Drill stop Aurea Evo® RP48 14,5mm	Aurea® Evo	08435567313751	084355673TOP8H3
TOP WP 085	Drill stop Aurea Evo® WP 8,5mm	Aurea® Evo	08436560959595	0843656095TOP8W
TOP WP 100	Drill stop Aurea Evo® WP 10,0mm	Aurea® Evo	08436560959564	0843656095TOP8W
TOP WP 115	Drill stop Aurea Evo® WP 11,5mm	Aurea® Evo	08436560959571	0843656095TOP8W
TOP WP 130	Drill stop Aurea Evo® WP 13,0mm	Aurea® Evo	08436560959588	0843656095TOP8W
DS23	Drill Stop Ø2,30mm	Phibo®	08435567312891	084355673TOP8H3
DS28	Drill Stop Ø2,80mm	Phibo®	08435567312907	084355673TOP8H3
DS30	Drill Stop Ø3,00mm	Phibo®	08435567312914	084355673TOP8H3
DS36	Drill Stop Ø3,60mm	Phibo®	08435567312921	084355673TOP8H3
DS41	Drill Stop Ø4,10mm	Phibo®	08435567312938	084355673TOP8H3
DS43	Drill Stop Ø4,30mm	Phibo®	08435567312945	084355673TOP8H3
DS49	Drill Stop Ø4,90mm	Phibo®	08435567312952	084355673TOP8H3
DS00	Screw Drill Stop	Phibo®	08435567312969	084355673TOP8H3

TOP S23 050	Drill stop TSA®-TSH® S2 S3 5.0mm	TSA®-TSH®	08435567313799	08435567313799	08435567313799
TOP S23 060	Drill stop TSA®-TSH® S2 S3 6.0mm	TSA®-TSH®	08436560959649	08436560959649	08436560959649
TOP S23 070	Drill stop TSA®-TSH® S2 S3 7.0mm	TSA®-TSH®	08436560959656	08436560959656	08436560959656
TOP S23 085	Drill stop TSA®-TSH® S2 S3 8.5mm	TSA®-TSH®	08436560959663	08436560959663	08436560959663
TOP S23 100	Drill stop TSA®-TSH® S2 S3 10.0mm	TSA®-TSH®	08436560959601	08436560959601	08436560959601
TOP S23 115	Drill stop TSA®-TSH® S2 S3 11.5mm	TSA®-TSH®	08436560959618	08436560959618	08436560959618
TOP S23 130	Drill stop TSA®-TSH® S2 S3 13.0mm	TSA®-TSH®	08436560959625	08436560959625	08436560959625
TOP S23 145	Drill stop TSA®-TSH® S2 S3 14.5mm	TSA®-TSH®	08436560959632	08436560959632	08436560959632
TOP S4 050	Drill stop TSA®-TSH® S4 S5 5.0mm	TSA®-TSH®	08435567313805	08435567313805	08435567313805
TOP S4 060	Drill stop TSA®-TSH® S4 S5 6.0mm	TSA®-TSH®	08436560959717	08436560959717	08436560959717
TOP S4 070	Drill stop TSA®-TSH® S4 S5 7.0mm	TSA®-TSH®	08436560959724	08436560959724	08436560959724
TOP S4 085	Drill stop TSA®-TSH® S4 S5 8.5mm	TSA®-TSH®	08436560959731	08436560959731	08436560959731
TOP S4 100	Drill stop TSA®-TSH® S4 S5 10.0mm	TSA®-TSH®	08436560959670	08436560959670	08436560959670
TOP S4 115	Drill stop TSA®-TSH® S4 S5 11.5mm	TSA®-TSH®	08436560959687	08436560959687	08436560959687
TOP S4 130	Drill stop TSA®-TSH® S4 S5 13.0mm	TSA®-TSH®	08436560959694	08436560959694	08436560959694
TOP S4 145	Drill stop TSA®-TSH® S4 S5 14.5mm	TSA®-TSH®	08436560959700	08436560959700	08436560959700
TOP S5 050	Drill stop TSA®-TSH® S5 S6 5.0mm	TSA®-TSH®	08435567313812	08435567313812	08435567313812
TOP S5 060	Drill stop TSA®-TSH® S5 S6 6.0mm	TSA®-TSH®	08436560959779	08436560959779	08436560959779
TOP S5 070	Drill stop TSA®-TSH® S5 S6 7.0mm	TSA®-TSH®	08436560959786	08436560959786	08436560959786
TOP S5 085	Drill stop TSA®-TSH® S5 S6 8.5mm	TSA®-TSH®	08436560959793	08436560959793	08436560959793
TOP S5 100	Drill stop TSA®-TSH® S5 S6 10.0mm	TSA®-TSH®	08436560959748	08436560959748	08436560959748
TOP S5 115	Drill stop TSA®-TSH® S5 S6 11.5mm	TSA®-TSH®	08436560959755	08436560959755	08436560959755
TOP S5 130	Drill stop TSA®-TSH® S5 S6 13.0mm	TSA®-TSH®	08436560959762	08436560959762	08436560959762

Table 6 Group: Drill Accessories; Subgroup: Drill Extender

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
173.0001	Short Drill Extender	Phibo®	08436560959458	08436560959458

Table 7 Group: Circular Scalpel; Subgroup: Circular Scalpel

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
152.0001	Circular Scalpel Ø3.70	Phibo®	08436560958413	08436560958413
152.0002	Circular Scalpel Ø4.70	Phibo®	08436560958420	08436560958420
152.0003	Circular Scalpel Ø6.00	Phibo®	08436560958437	08436560958437

Table 8 Group: Bone Tap; Subgroup: Manual / Mechanical Bone Tap

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
EVO 01035	Bone Tap Aurea® Evo® NP	Aurea® Evo	08436560959298	0843656095MR0SCARVT
EVO 01043	Bone Tap Aurea® Evo® RP	Aurea® Evo	08436560959304	0843656095MR0SCARVT
EVO 01048	Bone Tap Aurea® Evo® RP48	Aurea® Evo	08435567313782	084355673MR0SCARVQ
EVO 01055	Bone Tap Aurea® Evo® WP	Aurea® Evo	08436560959311	0843656095MR0SCARVT
181.0133	TSH® S2 Contra-Angle Bone Tap, Short	TSH®	08436560959342	0843656095MR0SCARVT
181.0333	TSH® S2 Contra-Angle Bone Tap, Long	TSH®	08436560959373	0843656095MR0SCARVT
181.0136	TSA® TSH® S3 Contra-Angle Bone Tap, Short	TSA®/TSH®	08436560959328	0843656095MR0SCARVT
181.0336	TSA® TSH® S3 Contra-Angle Bone Tap, Long	TSA®/TSH®	08436560959359	0843656095MR0SCARVT
181.0142	TSA® TSH® S4 Contra-Angle Bone Tap, Short	TSA®/TSH®	08436560959335	0843656095MR0SCARVT
181.0342	TSA® TSH® S4 Contra-Angle Bone Tap, Long	TSA®/TSH®	08436560959366	0843656095MR0SCARVT
181.0248	TSH® S5 Contra-Angle Bone Tap	TSH®	08436560959434	0843656095MR0SCARVT
181.0255	TSA® S5 Contra-Angle Bone Tap	TSH®	08436560959427	0843656095MR0SCARVT

Table 9 Group: Screwdriver; Subgroup: Contra-angle (Mechanical) Screwdriver

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
173.1106	Contra-Angle Axis® Hexalobular Angled Tool, Medium	Phibo®	08435567314093	084355673ATORMECQX
173.1251	Contra-Angle Hex Driver 1.25mm, Short	Phibo®	08436560958390	0843656095ATORMECR2
173.1252	Contra-Angle Hex Driver 1.25mm, Medium	Phibo®	08436560958406	0843656095ATORMECR2
173.1001	Contra-Angle Hex Driver 1.00mm, Short TSA®	TSA®	08436560958376	0843656095ATORMECR2
173.1002	Contra-Angle Hex Driver 1.00mm, Medium TSA®	TSA®	08436560958383	0843656095ATORMECR2



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Table 10 Group: Implant Tap; Subgroup: Contra-angle (Mechanical) Tap

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
190.0016	Contra-Angle Tap for TSA® S3	TSA®	08436560959250	0843656095CONFORMA6E
190.0018	Contra-Angle Tap for TSA® S4 S5 & TSA® S2	TSA®-TSH®	08436560959267	0843656095CONFORMA6E
190.0020	Contra-Angle Tap for TSH® S3 S4 S5	TSH®	08436560959274	0843656095CONFORMA6E

Table 11 Group: Adapter; Subgroup: Contra-angle (Mechanical) Adapter

REFERENCE	NAME/DESCRIPTION(EN)	SYSTEM	UDI-(DI)	BASIC UDI
173.0100	Contra-Angle Adapter, Short	Phibo®	08436560958352	0843656095ADAPTMECV5
173.0300	Contra-Angle Adapter, Long	Phibo®	08436560958369	0843656095ADAPTMECV5

VERSIONS CONTROL

VERSION	DATE	MODIFICATIONS
00	12/11/2025	Initial emission of the document. Prepared with template FORM4.1-00007 V.00 This document comes from the following Declaration of Conformity: Doc Phibo Instruments v4. Planned change in Planning TD under MDR

