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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Phibo Dental Solutions, S.L
Manufacturer address and contact details	Polígono Ind Mas D'En Cisa, Carrer Gato Pérez, 3, 08181 Sentmenat, Barcelona Spain registros@phibo.com rsousa@phibo.com
Single Registration Number (SRN) (if available)	ES-MF-000024464

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

Notified body name (if applicable)	TÜV SÜD Product Service GmbH □ See attached schedule
Notified body number (if applicable)	0123 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 18 02 76131 008 Rev. 00 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2023-06-26 □ See attached schedule
End date of extended validity/transition period	• 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors) • 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function • 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments) □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Phibo Dental Solutions, S.L

Sentmenat, 29th of July 2024

Rita Sousa

Rita Sousa (Jul 29, 2024 14:46 GMT+2)

Rita Sousa
Quality Director

rsousa@phibo.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Device 1 0843656095ADAPTMECV5	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 2 0843656095ATORMECR2	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 3 084355673ATORMECQX	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 4 0843656095BISTURIRR	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 5 0843656095PROLONGYA	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 6 0843656095FRESA6E	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 7 0843656095MROSCARVT	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Device 8 **0843656095CONFORMA6E**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 9 **084355673TOPEH3**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 10 **084355673MROSCARVQ**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 11 **084355673FRESACT**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 12 **0843656095TOPE8W**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class IIa devices)	**Not applicable**
Device 13 **0843656095TORNILLOKE**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 14 **084355673INTERFASERW**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 15 **084355673TORNILLOH9**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 16 **0843656095INTERFASEVX**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 17 **0843656095IMPL6M**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027 (Class IIb implantable devices excluding Well-established technologies)	**Not applicable**
Device 18 **084355673IMPLES**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027 (Class IIb implantable devices excluding Well-	**Not applicable**

					established technologies)	
Device 19 0843656095CLICKFIXXY	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 20 0843656095COFIA3X	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 21 0843656095TAPON9N	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 22 084355673TAPONG3	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 23 084355673CLICKFIXVT	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 24 0843656095PILAR8C	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Other Class IIb devices)	**Not applicable**
Device 25 084355673ATORNIH4	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class Ir devices)	**Not applicable**
Device 26 084355673CAJAAC	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class Ir devices)	**Not applicable**
Device 27 084355673CARRACAH5	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class Ir devices)	**Not applicable**
Device 28 084355673KITEXTJ3	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class Ir devices)	**Not applicable**
Device 29 084355673LLAVEDG	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class Ir devices)	**Not applicable**
Device 30 084355673MANGOCN	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH	TÜV SÜD Product Service GmbH	31 December 2028 (Class Ir devices)	**Not applicable**

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Device 31 **084355673PARALELI26**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class Ir devices)	**Not applicable**
Device 32 **0843656095ADAPTA5B**	G1 18 02 76131 008 Rev. 00	2023-06-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2028 (Class Ir devices)	**Not applicable**

MDR_Manufacturer_Declaration_Phibo

Final Audit Report 2024-07-29

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