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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 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	Osteogenics Biomedical, Inc.
Manufacturer address	4620 71st Street, Building 78-79 Lubbock, TX, 79424, United States
Manufacturer Contact Person	Elizabeth Bastian, Email: liz.bastian@envistaco.com Phone: 806-516-7757/806-796-1923
Single Registration Number (SRN) (if available)	US-MF-000004534

Authorised Representative name (if applicable)	Emergo Europe BV
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AT Arnhem The Netherlands Office: +31.70.345.8570 Email: EmergoEurope@ul.com
Single Registration Number (SRN) (if available)	NL-AR-000000116

Notified body name (if applicable)	BSI Group The Netherlands B.V.
Notified body number (if applicable)	2797
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 670712

[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.

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Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024
End date of extended validity/transition period	See device schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** also listed in the attached schedule, the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*
- 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 and in the attached schedule.

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covering the listed device(s) was/were issued before 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

☒ 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 been made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement(s) are 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, **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 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.

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Signed for and on behalf of the manufacturer:

Manufacturer name	Osteogenics Biomedical, Inc.
Manufacturer address	4620 71st Street, Building 78-79 Lubbock, TX, 79424, United States
Manufacturer Contact Person	Elizabeth Bastian
Title	Director of Regulatory Affairs
Manufacturer Contact Details	Email: liz.bastian@envistaco.com Phone: 806-516-7757/806-796-1923
Signature	DocuSigned by: Elizabeth Bastian 42F5E78D058D439...
Date	4/1/2024

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Device Schedule

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

Identification of the device(s)[1] (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**	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**
Cytoplast™ Titanium-Reinforced PTFE Membranes	CE 670712	May 26 2024	BSI Group The Netherlands B.V., 2797	BSI Group The Netherlands B.V., 2797	31 Dec 2027
Cytoplast™ Dense PTFE Barrier Membranes	CE 670712	May 26 2024	BSI Group The Netherlands B.V., 2797	BSI Group The Netherlands B.V., 2797	31 Dec 2027
RPM™ Reinforced PTFE Mesh	CE 670712	May 26 2024	BSI Group The Netherlands B.V., 2797	BSI Group The Netherlands B.V., 2797	31 Dec 2027
Pro-Fix™ Precision Fixation System	CE 670712	May 26 2024	BSI Group The Netherlands B.V., 2797	BSI Group The Netherlands B.V., 2797	31 Dec 2027
Cytoplast™ PTFE Suture	CE 670712	May 26 2024	BSI Group The Netherlands B.V., 2797	BSI Group The Netherlands B.V., 2797	31 Dec 2028

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