Biocomposites®

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*
- 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	Biocomposites Ltd
Manufacturer address and contact details	Keele Science Park, Keele, Staffordshire, ST5 5NL, United Kingdom Tel: +44 (0) 1782338580 Email: info@biocomposites.com Web: www.biocomposites.com
Single Registration Number (SRN)	GB-MF-000008690

Authorised Representative name	Emergo Europe BV
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AT, Arnhem THE NETHERLANDS
Single Registration Number (SRN)	NL-AR-000000116

Notified body name and registered place of business	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. H- 2092, Budakeszi, Erdő u. 101, Hungary
Notified body number	NB 2409
Directive Certificate number(s) to which this confirmation is made	• 145003-20-05-26 • 145004-20-05-26 • 145005-20-05-26 • 145006-20-05-26 • G1 004200 0005 Rev. 00 • G7 004200 0006 Rev. 00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	26th May 2024
End date of extended validity/transition period	31st December 2027

Registered Office

Biocomposites Ltd.
Keele Science Park, Keele,
Staffordshire,
England. ST5 5NL

Tel: +44 (0) 1782 338580
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email: info@biocomposites.com
web: www.biocomposites.com

Registered in England and Wales: 03291943

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We, Biocomposites Ltd, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificates,** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** 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 Certificates** as listed above

- Directive Certificates covering the listed devices were issued after 25th May 2017, were valid on 26th May 2021 and have not been withdrawn afterwards.

- Expires after 20 March 2023:
  Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been submitted by us to a notified body for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

➢ **Quality Management System (QMS)**

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

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices 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:

Full Company Name: Biocomposites Ltd.

Location: Keele Science Park, Keele, Staffordshire, ST5 5NL, United Kingdom

Signature:

posites.com

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Schedule of Devices

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

Identification of the devices	Models	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Classification and rule under the MDR	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
Bone substitutes, Calcium matrix for bone and soft tissue implantation	Stimulan Kit 5 cc Stimulan Kit 10 cc Stimulan Rapid Cure 5 cc Stimulan Rapid Cure 10 cc Stimulan Rapid Cure 20 cc	Full Quality Assurance system Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) Devices in Class IIa, IIb or III No. G1 004200 0005 Rev. 00 and EC Design examination No. G7 004200 0006 Rev. 00	26th May 2024	TÜV SÜD Product service GmbH, with identification no 0123	Class III-MDR Annex VIII, Chapter III, 5.4 Rule 8	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. H- 2092, Budakeszi, Erdő u. 101, Hungary (NB 2409)	31st December 2027
Void Fillers	geneX - 5cc geneX -10cc geneX Putty -2.5cc geneX Putty -5cc geneX Putty -10cc geneX DS -2.5cc geneX DS -5cc geneX DS -2 x 2.5cc	145004-20-05-26	26th May 2024	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. H- 2092, Budakeszi, Erdő u. 101, Hungary (NB 2409)	Class III-MDR Annex VIII, Chapter III, 5.4 Rule 8	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. H- 2092, Budakeszi, Erdő u. 101, Hungary (NB 2409)	31st December 2027

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Fixation Devices	Biosteon Screw (6 x 23 mm 6 x 28 mm 7 x 23 mm 8 x 23 mm 9 x 23 mm 10 x 23 mm 7 x 28 mm 8 x 28 mm 9 x 28 mm 10 x 28 mm 11 x 28 mm 9 x 35 mm 10 x 35 mm)	145005-20-05-26	26th May 2024	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. H- 2092, Budakeszi, Erdő u. 101, Hungary (NB 2409)	Class III- MDR Annex VIII, Chapter III, 5.4 Rule 8	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. H- 2092, Budakeszi, Erdő u. 101, Hungary (NB 2409)	31st December 2027
Fixation Devices	Biosteon® IntraLine -2 sutures w/o needles 4.5mm Biosteon® IntraLine -2 sutures w/o needles 5.5mm Biosteon® IntraLine -2 sutures w/ needles 5.5mm Biosteon® IntraLine -3 sutures w/o needles 5.5mm Biosteon® IntraLine -2 sutures w/o needles 6.5mm Biosteon® IntraLine -2 sutures w/ needles 6.5mm Biosteon® IntraLine -3 sutures w/o needles 6.5mm	145006-20-05-26	26th May 2024	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. H- 2092, Budakeszi, Erdő u. 101, Hungary (NB 2409)	Class III- MDR Annex VIII, Chapter III, 5.4 Rule 8	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. H- 2092, Budakeszi, Erdő u. 101, Hungary (NB 2409)	31st December 2027

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