| | | | |
|---|---|---|---|
| **DEVICE FAMILY** | **CALCIUM MATRIX** | **DEVICE** | **STIMULAN®** |
| **SECTION 1.2** | **DECLARATION OF CONFORMITY (EU)** | **REVISION** | **11** |
| **AUTHORISED** (Print Name) | Kirsty-Louise Marrow | **ISSUE DATE** | 14th July 2023 |
| **AUTHORISED** (Job Title) | Regulatory Affairs Projects Manager | **AUTHORISED** (Signature) | |
| **CHANGES** | GMDN code updated | | |

We,

Biocomposites Ltd, Keele Science Park, Keele, Staffordshire, ST5 5NL, England,
Tel: - email: e@biocomposites.com

declare that this Declaration of Conformity is issued under our sole name at the address above for the products listed below in accordance with:

The Medical Devices Directive 93/42/EEC (as amended by 2007/47/EC)
Annex II (Full Quality Assurance System) - Annex II.3, Annex II.4 and Annex IX, Rule 8, Class III

The above manufacturer is exclusively responsible for this declaration of conformity

| Product Code (Ref) | Description | Size | Shelf Life (expiry) | UDI-DI (GTIN-14) | GMDN Code |
|---|---|---|---|---|---|
| 600-005 | Stimulan Kit | 5cc | 3 years | 15060155710119 | 17751 |
| 600-010 | Stimulan Kit | 10cc | 3 years | 15060155710126 | 17751 |
| 620-005 | Stimulan Rapid Cure | 5cc | 3 years | 15060155711024 | 17751 |
| 620-010 | Stimulan Rapid Cure | 10cc | 3 years | 15060155711031 | 17751 |
| 620-020 | Stimulan Rapid Cure | 20cc | 3 years | 15060155711048 | 17751 |

Notified Body (0123): TÜV-SÜD Product Service GmbH, Ridlerstraβe. 65, D- 80339 München, Germany

EC Full Quality Assurance Certificate: No. G1 004200 0005 Rev. 00
valid from 14/04/2020 valid until 26/05/2024

DE Design Examination Certificate: No. G7 004200 0006 Rev. 0017751
valid from 14/04/2020 valid until 26/05/2024

This Declaration is valid until: 26/05/2024

Place of signing:

EU Authorised Representative: Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands