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| | EU Declaration of Conformity Osgide | Doc: QS-FO-0203-B Page: 1 of 2 |

EU DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF COUNCIL OF 05 APRIL 2017


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| Manufacturer's Name: | Matricel GmbH |
| Legal Manufacturer Main Site: | Kaiserstr. 100, 52134 Herzogenrath, Germany |
| Manufacturer Additional Site: | Konrad-Zuse-Str. 6, 52134 Herzogenrath, Germany |
| SRN (Single Registration Number): | DE-MF-000005969 |
| Medical Device(s): | Osgide 15x20mm (OSG1520) Osgide 25x30mm (OSG2530) Osgide 30x40mm (OSG3040) |
| Intended purpose: | Osgide is intended for use during the process of Guided Bone Regeneration (GBR) and Guided Tissue Regeneration (GTR) as a biodegradable barrier membrane. |
| Product code: | Q010301 (Periodontal Membranes) |
| Classification: | class III, according to Annex VIII, rule 8 and 18 of Regulation (EU) 2017/745 |
| Basic UDI-DI: | 4250830900016X |
| Conformity assessment route: | Annex IX chapter I and II of Regulation (EU) 2017/745, Conformity assessment based on a quality management system and on assessment of technical documentation |
| Notified Body involved: | BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands ID: 2797 |

This declaration of conformity is issued under sole responsibility of Matricel GmbH in compliance to Article 19 of Regulation (EU) 2017/745. We hereby declare that the medical device specified above meet the provision of the Annex IV of Regulation (EU) 2017/745 for medical devices.

Harmonized standards:

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|------------------------------|-----------------------------|
| EN ISO 11135:2014/A1:2019 | EN ISO 13485:2016/A11:2021 |
| EN ISO 10993-23:2021 | EN ISO 15223-1:2021 |
| EN ISO 11737-1:2018 | EN ISO 10993-12:2021 |
| EN ISO 11737-2:2020 | EN ISO 14971:2019/A11:2021 |
| EN ISO 10993-10:2023 | EN ISO 11607-1:2020/A1:2023 |
| EN ISO 10993-18:2020/A1:2023 | EN ISO 11607-2:2020/A1:2023 |

Common Specification (CS): N/A

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Identification of certificates issued:


Quality Management System:

EU Quality Management System Certificate,
certificate no. MDR 740050 R000, expire date 11.Dec.27

Technical Documentation Assessment:

EU Technical Documentation Assessment Certificate,
certificate no. MDR 740051 R000, expire date 11.Dec.27

Authorized Signatory:



Head of Regulatory Affairs
For and on behalf of Dr Leon Olde Damink, Person Responsible for Regulatory Compliance according to MDR Art. 15

Herzogenrath, 25 Apr 24
Place & Date