

# EU Quality Management System Certificate

We hereby certify the company

**Ivory Graft Ltd.**  
**1 HaTahana Street**  
**Kefar Sava, 4453001**  
**Israel**

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

## **Annex IX – Chapter I (Quality Management System)**

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2024-02-23  
Valid until 2027-02-11

Registration No. D1478900005  
Report No. P23-00702-268953

Stuttgart, 2024-02-23



Notified Body



## EU Authorized Representative:

MedEnvoy Global BV  
Princes Margrietplantsoen 33, Suite 123  
2595 AM The Hague  
The Netherlands  
AR-SRN: NL-AR-000024028

## Devices:

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sterile bone graft material for the repair or augmentation of bone defects in dental procedures

Risk class: III

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## Notes:

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.

## The certificate is based on the previous certificate

D1478900003 dated 2022-08-30 with the following changes:

New EU REP:

MedEnvoy Global B.V., Prinses Margrietplantsoen 33, Suite 123, 2595 AM The Hague, The Netherlands