EU Technical Documentation Assessment Certificate

We hereby certify that the company

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

has submitted a technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/745, which meets the following requirements:

Annex IX – Chapter II (Assessment of the Technical Documentation)

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

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

Valid from	2024-04-22	Registration No.	D1478900007
Valid until	2027-08-29	Report No.	P20-01599-291541

Stuttgart, 2024-04-22

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-098

EU Authorized Representative:

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

Devices:

Ivory Dentin Graft
Vials: 0.25 g, 0.5 g, 1.0 g, 2.0 g, 5.0 g
Syringes: 0.5 g, 1.0 g

Intended purpose:
A sterile bone graft material for the repair or augmentation of bone defects in dental procedures

Risk class: III
Basic UDI-DI: 7290018472IDG001VG

Notes:

For the placing on the market of the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/745 on medical devices is also required.

The certificate is based on the previous certificate

D1478900004 (2022-08-30)

with the following changes to D1478900004:
Closure of conditions/restrictions:
- Stability data of 5 years of real time aging has to be submitted for review including a test of cytoxicity of the device in vial and in syringe after 5 years of real time aging.
- the BER has to be updated with the additional information provided during the review.