datumdental

OSSIX™ BONE EU DECLARATION OF CONFORMITY
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EU DECLARATION OF CONFORMITY

with regard to the Council Directive 93/42/EEC concerning medical devices

Datum Dental Ltd.
1 Bat Sheva St., P.O.Box 6170, Lod 7116003, Israel
Phone 972 8 6705400, Fax 972 8 6705429

Declare under our sole responsibility that the dental bone grafting material

OSSIX™ Bone 0.125 cc (OXB0125)
OSSIX™ Bone 0.25 cc (OXB0250)
OSSIX™ Bone 0.5 cc (OXB0500)

Fulfills the essential requirements of the Directive 93/42/EEC.

OSSIX BONE is intended for the following uses:

- Augmentation or reconstructive treatment of the alveolar ridge;
- Filling of periodontal defects;
- Filling of defects after root resection, apicoectomy and cystectomy;
- Filling of extraction sockets to enhance preservation of the alveolar ridge;
- Elevation of the maxillary sinus floor;
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR);
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

The product is classified in Class III according to Rules 8 and 17 of Annex IX of the Directive 93/42/EEC.

The device is manufactured utilizing animal tissue derivative (porcine collagen).

The device **is not** manufactured utilizing tissues of animal origin listed in Commission Regulation (EU) No 722/2012 of 8 August 2012.

The device **does not** incorporate, as an integral part, a substance or human blood derivative as referred to in Section 7.4 of Annex I of Directive 93/42/EEC.

The conformity procedure referred to in Annex II of the Directive 93/42/EEC has been followed utilizing the list of applicable standards in order to comply with the relevant essential requirements of the above directive.

This Declaration of Conformity is valid from the date of signing until the product is changed but no longer than May 25, 2023.

EU Authorized Representative:
MedNet GmbH
Borkstraße 10
48163 Münster
Germany
Phone 49 0 251 32266-0
Fax 49 0 251 32266-22

Notified Body:
MEDCERT GmbH (ID number 0482)
Pilatuspool 2
20355 Hamburg
Germany
Phone 49 40 2263325-0
Fax 49 40 2263325-15

Name: Dr. Arie Goldlust **Signature:** _____

Title: CEO, Datum Dental Ltd. **Date:** May 29, 2018

Action Name	User Name	Title	Signature Date
Approve DCR	Jeffrey Davis	QA Director	31-May-2018 17:11 (GMT+2)
Review	Mila Kipnis	RA Manager	31-May-2018 17:35 (GMT+2)
Review	Jeffrey Davis	QA Director	31-May-2018 17:42 (GMT+2)
Send for Approval	Jeffrey Davis	QA Director	31-May-2018 17:42 (GMT+2)
Start Approval	Jeffrey Davis	QA Director	31-May-2018 17:43 (GMT+2)
Start Approval	Mila Kipnis	RA Manager	31-May-2018 17:43 (GMT+2)
QA Approval	Jeffrey Davis	QA Director	01-Jun-2018 07:31 (GMT+2)
Sign Training Completion	Jeffrey Davis	QA Director	01-Jun-2018 07:31 (GMT+2)