datumdental

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 membranes

OSSIX® Plus 15 x 25 mm (OXP1525)
OSSIX® Plus 25 x 30 mm (OXP 2530)
OSSIX® Plus 30 x 40 mm (OXP 3040)
OSSIX® Volumax 10 x 12.5 mm (OXV1012)
OSSIX® Volumax 25 x 30 mm (OXV2530)
OSSIX® Volumax 30 x 40 mm (OXV3040)
OSSIX® Volumax 10 x 40 mm (OXV1040)

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

OSSIX® Plus and OSSIX® Volumax biodegradable collagen membranes are intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as biodegradable barriers for:

- Ridge augmentation for later implant insertions.
- Simultaneous ridge augmentation and implant insertion.
- Ridge augmentation around implants inserted in delayed extraction sites.
- Ridge augmentation around implants inserted in immediate extraction sites.
- Alveolar ridge preservation consequent to tooth (teeth) extraction(s).
- Over the window in lateral window sinus elevation procedure.
- In implants with vertical bone loss due to infection, only in cases where satisfactory debridement and implant surface disinfection can be achieved.
- In intra bony defects around teeth.
- For treatment of recession defects, together with coronally positioned flap.
- In furcation defects in multi rooted teeth.

OSSIX® Volumax is also indicated for localized gingival augmentation.

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

The devices are manufactured utilizing animal tissue derivative (porcine collagen).

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

The devices **do 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 April 16, 2024.

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

Title: CEO, Datum Dental Ltd.

Signature:

Date: 28 October 2019