

EC Design Examination Certificate

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the design of the medical device(s):

Dental membranes

- **OSSIX[®] Plus: 15x25 mm, 25x30 mm, 30x40 mm**
- **OSSIX[®] Volumax: 10x12.5 mm, 15x25 mm, 25x30 mm, 10x40 mm**

of the manufacturer:

**Datum Dental Ltd.
1 Bat Sheva St., P.O. Box 6170
Lod 7116003
Israel**

fulfills the below mentioned requirements of the **Council Directive 93/42/EEC**:

Annex II, section 4

This certificate assumes that MEDCERT has to be informed about any changes of the approved design. Changes need further approval by MEDCERT.

For the placing on the market of medical devices covered by this certificate, a separate EC certificate of conformity according to Annex II without section 4 of Council Directive 93/42/EEC is required.

This certificate is valid until 16 April 2024

Report No.: 13570FS06F
Process No.: PP – 13570
Certificate No.: 13570GB411191028

Hamburg, 28 October 2019



MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

