EC DESIGN-EXAMINATION CERTIFICATE

Number: 2123758DE01

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Augma Biomaterials Ltd.

Alon Hatavor 20 St.
P.O.Box 3089
Southern Industrial Park
Caesarea 3088900
Israel

For the product

Resorbable dental bone graft:3D Bond ™ Bond Apatite™ 4MATRIX

Documents, that form the basis of this certificate:

Certification Notice 2123758CN, initially dated 30 July 2009
CE Marking of Conformity 2123758CE01

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 August 2023
Issued for the first time: 1 August 2012
Revised: 5 January 2016
Reissued: 1 August 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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