Number: 3902867TD01

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

Augma Biomaterials Ltd.

Alon Hatavor 20 St.
P.O.Box 3089
Southern Industrial Park
Caesarea 3088900
Israel
SRN ID.: IL-MF-000020802

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2123758CN

Authorized Representative: MedNet EC-REP III GmbH, Borkstrasse 10 48163 Münster, Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745. For placing these products on the market an Annex IX EU Quality Management System certificate is also required.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **16-February-2025** Date: **18-March-2025** Expiry date**: 1-February-2030**

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s):

Class III	
Basic UDI-DI: 7290014838ABM5143YW **Device Name:** Resorbable dental bone graft family **Type:** Q010302 'Dental graft devices' **Model:** - Bond Apatite P/N HA-BB-Pack - 3D Bond P/N DD-100 - 3D Bond+ P/N 3D-ND-050	*Intended Purpose: The Resorbable dental bone graft family is intended to fill, augment, or reconstruct bony defects in the oral and maxillofacial region*

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Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	16-February-2025	2123758CN28	first issue
1	18-March-2025	2123758CN28.1	revised

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