

# EC CERTIFICATE

Number: 2131708CE01

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**  
(Devices in Class IIa, IIb or III)

Manufacturer:

**BonAlive Biomaterials Ltd**

**Biolinja 12  
20750 Turku  
Finland**

For the product category(ies)

**Synthetic bioactive glass based bone cavity filling and reconstruction devices for orthopaedic and cranio-maxillo-facial implantation**

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 EC-Directive which apply to them:

# 0344

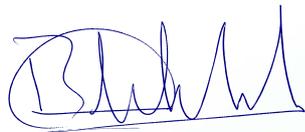
Documents, that form the basis of this certificate:

**Certification Notice 2131708CN, initially dated 24 March 2010**  
**Addendum, initially dated 24 March 2010**

DEKRA hereby declares that the above mentioned manufacturer 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. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 March 2024  
Issued for the first time: 24 March 2010  
Reissued: 31 March 2019

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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

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# ADDENDUM

Belonging to certificate: 2131708CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Synthetic bioactive glass based bone cavity filling and reconstruction devices for orthopaedic and cranio-maxillo-facial implantation

Issued to:

### **BonAlive Biomaterials Ltd**

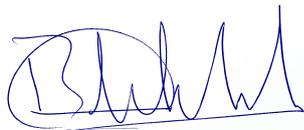
**Biolinja 12  
20750 Turku  
Finland**

This certificate covers the following product(s):

- BonAlive® granules (Bioactive Glass bone filler)
- BonAlive® putty (Bioactive Glass bone filler)
- BonAlive® putty MIS (Bioactive Glass bone filler)

Initial date: 24 March 2010

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

**B.T.M. Holtus**  
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing 'J' and 'V'.

**J.A. van Vugt**  
Certification Manager

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