EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 773684 R000

Manufacturer: Bicon, LLC.

Address:
501 Arborway
Boston
Massachusetts
02130
USA

Single Registration Number: US-MF-000002782

EU Authorised Representative: Bicon Europe, Ltd.

Address:
Unit 4 Ballycummin Village
Ballycummin, Limerick
Ireland

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2024-03-06**

Current Issue Date: **2024-03-06**

Starting Validity Date: **2024-03-06**

Expiry Date: **2029-03-05**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

Matrix for bone augmentation in maxillary and mandibular bone.

Risk Classification: Class III Implantable

Basic UDI-DI: 081311002SYN9L

Type (Codes as per (EU) 2017/2185): MDN 1103

Device Name	Model
SynthoGraft® Pure Phase Beta-Tricalcium Phosphate, 50-500µm, 0.25g	260-400-125
SynthoGraft® Pure Phase Beta-Tricalcium Phosphate, 50-500µm, 0.5g	260-400-150
SynthoGraft® Pure Phase Beta-Tricalcium Phosphate, 50-500µm, 1.0g	260-400-151
SynthoGraft® Pure Phase Beta-Tricalcium Phosphate, 50-500µm, 2.0g	260-400-152
SynthoGraft® Pure Phase Beta-Tricalcium Phosphate, 500-1000µm, 0.5g	260-400-500
SynthoGraft® Pure Phase Beta-Tricalcium Phosphate, 500-1000µm, 1.0g	260-400-501
SynthoGraft® Pure Phase Beta-Tricalcium Phosphate, 500-1000µm, 2.0g	260-400-502
SynthoGraft® Pure Phase Beta-Tricalcium Phosphate, 500-1000µm, 0.25g	260-400-525

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3704044	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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