EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 773668 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 examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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: Class III and Class IIb devices

Class III, Implantable	Intended purpose
SynthoGraft® Pure Phase Beta-Tricalcium Phosphate	See MDR 773684

Class IIb, Implantable, Well-established technologies	Intended purpose
Dental Implants	The purpose of Bicon implants and abutments is to aid in the restoration of the chewing function by providing a support for a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.
Dental Abutments	The purpose of Bicon implants and abutments is to aid in the restoration of the chewing function by providing a support for a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Dental Prostheses	Class IIa implantable
Odontostomatology Instruments	Class IIa
Reusable Odontostomatology Instruments	Class Ir

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

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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	3703887	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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