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This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.

This Apostille does not certify the content of the document for which it was issued.

## Apostille

		(Convention de La Haye du 5 octobre 1961)
1.	District of Co	lumbia, United States of America
2.	This public d	ROBYN EVANS ocument has been signed by
3.	acting in the	NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA spacity of
		ROBYN EVANS, NOTARY PUBLIC IN AND FOR THE
4.	bears the seal	stamp of DISTRICT OF COLUMBIA
		<b>EERTIFIED</b>
5.	at Washington	a, D.C. AUGUST 2023
б.	the	day of
7.	by <u>Secretary</u>	of the District of Columbia
8.	No. 685	<b>273</b>
9.	Seal/Stamp	10. Signature:
		11. 1 1.00 #

Secretary of the District of Columbia



### **CERTIFICATION STATEMENT**

On behalf of ZimVie Dental, I hereby certify that the attached copy of the ISO 13485 Certificate is a true and accurate copy of the ISO 13485:2016 & EN ISO 13485:2016 certificate of BIOMET 3i, LLC, issued on April 12, 2023 with reference number MDSAP 687004.

ZimVie Dental, 4555 Riverside Drive, Palm Beach Gardens, Florida 33410, USA, is an authorized distributor of Biomet 3i LLC at 4555 Riverside Drive, Palm Beach Gardens, Florida 33410, USA, Products.

Jovan Bords	09	-AUG-23
Jóvan Bonds Regulatory Affairs Manager BIOMET 3i	Dat	e
District of Columbia SS		
Subscribed and sworn to before me.  This 10 day of August, 2023  Day Month Year	μ	
by <u>Robyn Evans</u>		

Seal

Robyn Evans, Notary Public of District of Columbia
My commission expires May 14th, 2027



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Biomet 3i, LLC 4555 Riverside Drive Palm Beach Gardens

Florida 33410 USA

Facility ID Number: F000091

Holds Certificate No:

MDSAP 687004

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scopé page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-05-09 Effective Date: 2023-04-12 Expiry Date: 2024-05-12

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This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companie

Certificate No:

**MDSAP 687004** 

### Registered Scope:

Design, manufacture and distribution of sterile and non-sterile instruments for dental applications, sterile dental implants, sterile and non-sterile reconstructive devices, sterile resorbable material implants, sterile augmentation bone graft materials and sterile calcium- based bone void fillers. This includes but not limited to the product families of dental implants, abutments, copings and crowns.

Original Registration Date: 2019-05-09

Effective Date: 2023-04-12

Expiry Date: 2024-05-12

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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.

Certificate No:

MDSAP 687004

Location	Registered Activities	
Biomet 3i, LLC 4555 Riverside Drive Palm Beach Gardens Florida 33410 USA Facility ID Number: F000091	Design, manufacture and distribution of sterile and non- sterile instruments for dental applications, sterile dental implants, sterile and non-sterile reconstructive devices, sterile resorbable material implants, sterile augmentation bone graft materials and sterile calcium- based bone void fillers. This includes but not limited to the product families of dental implants, abutments, copings and crowns.	
BIOMET 3i Dental Ibérica, S.L.U. C/ Islas Baleares, 50 Pol. Ind. Fuente del Jarro Paterna Valencia 46988 Spain Facility ID Number: F001813	Manufacture of sterile and non-sterile instruments for dental applications, sterile dental implants, sterile and non-sterile reconstructive devices.	
BIOMET 3i Dental Ibérica, S.L.U. Calle Ciudad de Onda, 18 Polígono Fuente del Jarro Paterna-Valencia 46988 Spain Facility ID Number: F001813	Importing, warehousing and distribution of sterile and non- sterile instruments for dental applications, sterile dental implants, sterile, non-sterile reconstructive devices, sterile, resorbable material implants, sterile augmentation bone graft materials and sterile calcium-based bone void fillers, intraoral scanner and CAD/CAM materials.	

Original Registration Date: 2019-05-09 Effective Date: 2023-04-12 Expiry Date: 2024-05-12

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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.

bsi.



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Zimmer Dental, Inc. 1900 Aston Ave Carlsbad California 92008 USA

Facility ID Number: F005446

Holds Certificate No:

**MDSAP 725462** 

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Development, Manufacture and Distribution of Dental Implants, Prosthetic Components, Instruments and Materials.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-11-06 Effective Date: 2022-04-04 Expiry Date: 2024-05-12

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AL DEVICE SANCIE AUDIT PROSERM

OUP America Inc. is an MOSAP authorized auditing organization ....making excellence a habit."

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To be read in conjunction with the scope above or the attached appendix.