

ATTESTATION CE / EC CERTIFICATE

Examen CE de la Conception (du produit) / EC Design Examination (of the product)

ANNEXE II point 4 de la directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II section 4 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant / Manufacturer

LDR MEDICAL

**Parc D'Entreprises du Grand Troyes, Quartier Europe de l'Ouest, 5 rue de Berlin
10300 SAINTE-SAVINE FRANCE**

Catégorie du(des) dispositif(s) / Device(s) category

Implants orthopédiques du rachis et accessoires associés

Spinal orthopaedic implants and associated accessories

Identification du(des) dispositif(s) / Identification of device(s)

MOBI C® Plug&Fit

MOBI C® Plug&Fit

Voir document complémentaire GMED / See GMED additional document

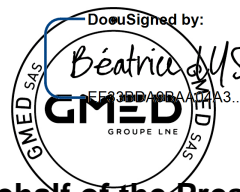
n° 38420

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) P601285, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file(s) referenced P601285, the product(s) complie(s) with the requirements of the directive 93/42/EEC, annex 1

Début de validité / Effective date : May 4th, 2021 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)



**On behalf of the President
Béatrice LYS
Technical Director**

GMED - 29620 rev. 8
Modifie le certificat 29620-7

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Ce document complémentaire GMED n° 38420 rev. 0 atteste de la validité du certificat CE n° 29620 rev. 8 au regard des informations listées ci-dessous.

This GMED additional document n° 38420 rev. 0 attests to the validity of CE certificate n° 29620 rev. 8 with regard to the information listed below.

Fabricant / Manufacturer:

LDR MEDICAL

**Parc D'Entreprises du Grand Troyes, Quartier Europe de l'Ouest, 5 rue de Berlin
10300 SAINTE-SAVINE FRANCE**

Identification des dispositifs / Identification of devices

**Implants MOBI C® Plug & Fit
(Code GMDN : 48164)**

Désignation	Reference commerciale	Classe du DM
IMPLANT MOBI C M STANDARD 13x15 H4,5	MB 2354	III
IMPLANT MOBI C M STANDARD 13x15 H5	MB 2355	
IMPLANT MOBI C M STANDARD 13x15 H6	MB 2356	
IMPLANT MOBI C M STANDARD 13x15 H7	MB 2357	
IMPLANT MOBI C M STANDARD 15x15 H4,5	MB 2554	
IMPLANT MOBI C M STANDARD 15x15 H5	MB 2555	
IMPLANT MOBI C M STANDARD 15x15 H6	MB 2556	
IMPLANT MOBI C M STANDARD 15x15 H7	MB 2557	
IMPLANT MOBI C M STANDARD 13x17 H4,5	MB 2374	
IMPLANT MOBI C M STANDARD 13x17 H5	MB 2375	
IMPLANT MOBI C M STANDARD 13x17 H6	MB 2376	
IMPLANT MOBI C M STANDARD 13x17 H7	MB 2377	
IMPLANT MOBI C M STANDARD 15x17 H4,5	MB 2574	
IMPLANT MOBI C M STANDARD 15x17 H5	MB 2575	
IMPLANT MOBI C M STANDARD 15x17 H6	MB 2576	
IMPLANT MOBI C M STANDARD 15x17 H7	MB 2577	

GMED 0459

GMED - 38420 rev. 0



Béatrice LYS
EF33BDA9BAA04A3...

**On behalf of the President
Béatrice LYS
Technical Director**

Désignation	Reference commerciale	Classe du DM
IMPLANT MOBI C M STANDARD 17x17 H4,5	MB 2774	III
IMPLANT MOBI C M STANDARD 17x17 H5	MB 2775	
IMPLANT MOBI C M STANDARD 17x17 H6	MB 2776	
IMPLANT MOBI C M STANDARD 17x17 H7	MB 2777	
IMPLANT MOBI C M STANDARD 15x19 H4,5	MB 2594	
IMPLANT MOBI C M STANDARD 15x19 H5	MB 2595	
IMPLANT MOBI C M STANDARD 15x19 H6	MB 2596	
IMPLANT MOBI C M STANDARD 15x19 H7	MB 2597	
IMPLANT MOBI C M STANDARD 17x19 H4,5	MB 2794	
IMPLANT MOBI C M STANDARD 17x19 H5	MB 2795	
IMPLANT MOBI C M STANDARD 17x19 H6	MB 2796	
IMPLANT MOBI C M STANDARD 17x19 H7	MB 2797	
IMPLANT MOBI C M STANDARD 19x19 H4,5	MB 2994	
IMPLANT MOBI C M STANDARD 19x19 H5	MB 2995	
IMPLANT MOBI C M STANDARD 19x19 H6	MB 2996	
IMPLANT MOBI C M STANDARD 19x19 H7	MB 2997	

32 alinéas / 32 intended lines

GMED 0459

GMED - 38420 rev. 0



Béatrice LYS

On behalf of the President
Béatrice LYS
 Technical Director



D e c l a r a t i o n : E U M D R E x t e n s i o n

To Whom it May Concern,

We, Zimmer Biomet Spine, Inc., (d/b/a ZimVie Spine), located at 10225 Westmoor Dr., Westminster, CO 80021, USA declares its intention to take advantage of the extension proposed by the EU Commission and approved by the European Council on March 7, 2023 to update the transition of the EU Medical Device Regulation and Sell-Off Clause.

The proposal was published in the Official Journal of the European Union on 23rd March 2023, which document the following changes of possible application:

Changes impacting Art 120, 122 and 123 of EU MDR 2017/745:

Art 120

- **Section 2 extends the validity of certificates issued under MDD** that were valid on the day of the MDR's date of application (26 May 2021) and have not been withdrawn by a notified body. The extension is directly applicable, so that **notified bodies are not required to change the date on the individual certificates.**

Regarding **certificates that have already expired**, the extension would be applicable if:

- At the moment of the expiry, the manufacturer **signed a contract with a notified body for the conformity assessment.**
- A **national competent authority** may have granted a derogation from the applicable conformity assessment procedure in accordance with Article 59 of the MDR or have required the manufacturer to carry out the conformity assessment procedure within a specific time period in accordance with Article 97 of the MDR.
- **Section 3 extends the transition period** from 26 May 2024 until:
 - **31 December 2027**, for **Class III devices and for Class IIb implantable devices**, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors (considered well-established technology or WET)
 - **31 December 2028**, for **class IIb devices (WET)** other than those covered above, as well as **Class II, Im, and Is** devices.

In the case of change of Notified Body, the manufacturer can reach an agreement with a MDR Notified Body that they shall carry out any required surveillance activities. **No later than 26 September 2024, the notified body that has signed the written agreement shall be responsible for the surveillance in respect to the devices covered by the written agreement.**

- **Section 4 removes the current 'sell-off' date** of 27 May 2025. **Devices placed on the market before the end of the transition period** can be made further available on the market **without a legal time restriction.**

Art 122 and 123 are aligned with Art 120 Section 4.

In the light of the above changes, ZimVie Spine Inc, wishes to communicate to EMEA Health Authorities our intention to take advantage of this extension for the Medical Device MDR transition, for the following commercial brands:

- Aspen®MIS Fusion System
- MaxAn®Anterior Cervical Plate System
- The Tether™-Vertebral Body Tethering System
- Virage OCT Spinal Fixation System
- Vitality® Spinal Fixation System



- Zyston Curve Interbody Spacer System
- Zyston Straight Spacer System

This decision has been discussed and approved by the corresponding Notified Bodies, BSI and TÜV SÜD Product Service GmbH, who will be extending their CE Certificates for the medical devices subject to the MDR transition.

The following CE certificates are subject to this extension and their validity dates have been extended to 31-Dec-2028:

- N° 662710
- N° G1 106554 0001 Rev.00

For legacy devices that will not be submitted under the EU MDR, the EU MDR 2017/745 regulations allows us to maintain devices CE market under MDD 93/42/EECC Directive until May 26, 2024. This rationale is applicable to our following brands:

- Lineum™ OCT Fixation System
- Pathfinder NXT Minimally Invasive Pedicle Screw System
- Polaris™ 4.75 Spinal System
- Polaris™ 5.5 Spinal System
- Trinica® ALP System
- Trinica/Trinica Select® Anterior Cervical Plate Systems
- Timberline Lateral Fusion System
- Timberline MPF Spacer System

DocuSigned by:

Alex Pawlowski



Signer Name: Alex Pawlowski

Signing Reason: I approve this document

Signing Time: 29-Jun-2023 | 09:52:31 EDT

Alex Pawlowski F67B79CEA6B43509C3BDDD8CE18ABF7

Regulatory Affairs Director
ZimVie Spine, Inc.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 662710****Issued To:**

**ZimmerBiomet Spine, Inc.
10225 Westmoor Drive
Westminster
Colorado
80021
USA**

In respect of:

Design and manufacture of implantable spinal fixation devices, spinal dynamic stabilisation implants, spinal interbody implants, trial orthopaedic implants, vertebroplasty delivery systems, single use instruments and reusable surgical instruments intended for connection to active devices.

For those aspects of Annex II related to the metrological requirements in the design and manufacture of surgical instruments.

For those aspects of Annex II related to securing and maintaining sterility in the design and manufacture of surgical instruments.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-12-21**

Date: **2021-05-21**

Expiry Date: **2023-09-30**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 662710**
 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
3D Systems, Inc 5381 South Alkire Circle Littleton Colorado 80127 USA	Design Manufacture
Anjon, Inc. 4801 Dawin Road Jacksonville Florida 32207 USA	Manufacture
Banister Tool, Inc. 3009 W Grimes Blvd # A Pflugerville Texas 78660 USA	Crucial Supplier

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Date: **2021-05-21**
Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:**Service(s) supplied**

Biomet GSCC B.V.
Hazeldonk 6530
4836 LD Breda
The Netherlands

EU Representative

Changzhou Biomet Medical Devices Co., Ltd
No. 235 Chuangxin Road
Export Processing Zone
Xinbei District, Changzhou
Jiangsu
213031
China

**Manufacture
Packaging**

Culver Tool & Engineering Inc.
1901 Walter Glaub Drive
Plymouth
Indiana
46563
USA

Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
Donatelle Plastics, Inc. 501 County Road E-2 Extension New Brighton Minnesota 55112 USA	Manufacture Other Critical Processes Packaging
Fort Wayne Metals Research Products Corporation 9609 Ardmore Ave Fort Wayne Indiana 46809 USA	Crucial Supplier
Invio Ltd. Invio Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4QD United Kingdom	Crucial Supplier

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
Isomedix Operations Inc 435 Whitney Street Northborough Massachusetts 01532 USA	Radiation (Gamma Sterilization)
Isomedix Operations, Inc. 380 90th Ave NW Minneapolis Minnesota USA	ETO Sterilization
J & B Precision 9261 Cordova Park Road Cordova Tennessee 38018 USA	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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 Date: **2021-05-21**
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10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
Jade Precision Medical Components, LLC 3063-B Philmont Avenue Huntingdon Valley Pennsylvania 19006 USA	Manufacture
LISI Medical Remmele 441 93rd Avenue NW Coon Rapids Minnesota 55443 USA	Manufacture
Lowell, Inc. 9425 83rd Avenue North Minneapolis Minnesota 55445 USA	Crucial Supplier

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No: **CE 662710**
 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
Maitland Engineering, Inc. 2713 Foundation Drive South Bend Indiana 46628 USA	Crucial Supplier
Marox Corporation 373 Whitney Avenue Holyoke Massachusetts 01040-2766 USA	Manufacture
Medtorque, Inc. 612 W. Lamont Rd Elmhurst IL 60126 USA	Crucial Supplier

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
Mendell, Inc 21463 Grenada Avenue Lakeville Minnesota 55044 USA	Manufacture
Micropulse, Inc. 5865 East State Road 14 Columbia City Indiana 46725 USA	Manufacture
Millstone Medical Outsourcing LLC 8836 Polk Lane Suite 100 Olive Branch Michigan 38654 USA	Manufacture Packaging

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
Millstone Medical Outsourcing, LLC 580 Commerce Drive Fall River Massachusetts 02720 USA	Manufacture Packaging
MMX, LLC 99 4th Ave Haskell New Jersey 07420 USA	Manufacture
NN, Inc. Precision Engineered Products Group, Vandalia 4201 Little York Rd. Dayton OH 45414 USA	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Date: **2021-05-21**
Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:**Service(s) supplied**

Norman Noble, Inc.
5507 Avion Park Dr.
Highland Heights
Ohio
44143
USA

Crucial Supplier

Phillips Precision, Inc.
7 Paul Kohner Place
Elmwood Park
New Jersey 07407
USA

Manufacture

Quality Tech Services, Inc.
10525 Hampshire Avenue
Bloomington
Minnesota
55438
USA

Other Critical Processes
Packaging

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 662710**
 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
rms Company 8600 Evergreen Boulevard Minneapolis Minnesota 55433 USA	Manufacture Other Critical Processes Packaging
Sterigenics 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	Radiation (Gamma Sterilization)
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	Radiation (Gamma Sterilization)

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 662710**
 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
STERIS Laboratories, Inc. 9303 West Broadway Ave Brooklyn Park Minnesota USA	Other Critical Processes Packaging
Symmetry Medical Manufacturing, Inc. US Delivery Systems dba Tecomet 253 Abby Road Manchester New Hampshire 03103 USA	Crucial Supplier
Tecomet Inc 170 New Boston Street Woburn Massachusetts 01801 USA	Crucial Supplier

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
Tecomet Inc. 5307 95TH Ave Kenosha WI 53144 USA	Crucial Supplier
Tecomet Riviera Beach 1006 West 15th Street Riviera Beach Florida 33404 USA	Crucial Supplier
TOMZ Corp. 47 Episcopal Rd Berlin Connecticut 06037 USA	Crucial Supplier

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:	Service(s) supplied
TURNER Medical, Inc. 130 Durham Drive Athens Alabama 35611 USA	Crucial Supplier
Xian Friendship Medical Electronics Co., LTD No. 9 Gao Xin 1st Road High-Tech Development Zone Xi'an, Shaanxi 710075 China	Manufacture
Zhejiang Biomet Medical Products 980 Shenli Road Jinhua Zhejiang 321016 China	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No: **CE 662710**
 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Subcontractor:

Zimmer Biomet Spine, Inc.
 5400 Meltech Blvd. Suite 119
 Memphis
 Tennessee
 38118
 USA

Service(s) supplied

Manufacture
Other Critical Processes
Packaging

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 662710**
 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Date	Reference Number	Action
21 December 2016	8457274	First Issue. New Certificate for new Legal Manufacturer traceable to Biomet Spine, LLC Certificate CE 547006 and CE 508909.
15 December 2017	8635627	<p>Extension to scope to include 'spinal dynamic stabilisation implants and spinal interbody implants'.</p> <p>Address change for subcontractor Arcamed LLC to '5101 Decatur Blvd., Ste A'</p> <p>Address correction for Changzhou Biomet Medical Devices to include 'No.' next to house number, Millstone Medical Outsourcing, LLC (Fall River) to short zip code, Zheijang Biomet Medical Products to remove 'No.' before house number.</p> <p>Subcontractor name corrections: 'Culver Tool' to 'Culver Tool & Engineering, Inc.'; 'DRT Mfg' to 'DRT Medical'; 'Fort Wayne Metals' to 'Fort Wayne Metals, Research Products Coporation'; 'Advantis Medical' to 'Advantis Medical, DBA Avalign Cases & Trays'; 'Inland Midwest' to 'Medtorque, Inc.'; 'Phillips Precision' to 'Phillips Precision, Inc.'; '3D Medical Machining' to 'Tecomet Riviera Beach' and 'Zheijang Biomet Medical Products Co. Ltd.' to 'Zheijang Biomet Medical Products'.</p> <p>Addition of crucial suppliers: Banister Tool, Inc., Norman Noble, Inc., Quantum Concepts, Symmetry Medical Manufacturing, Inc. (Warsaw and Manchester), Tecomet, Inc. (Kenosha), Tecomet Riviera Beach (2000 Avenue P), Tecomet, Inc. (115 Eames Street) Invibio Ltd. and TOMZ Corp.</p> <p>Addition of critical subcontractors: 3D Systems, Inc., STERIS Laboratories, Inc., Donatelle, Jade Precision Medical Components, LLC (Huntingdon Valley), LISI Medical Remmele, Quality Tech Services, Inc., Rms Company,</p>

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 662710**
 Date: **2021-05-21**
 Issued To: **ZimmerBiomet Spine, Inc.**
10225 Westmoor Drive
Westminster
Colorado
80021
USA

Date	Reference Number	Action
		Sterigenics US, LLC (Charlotte), Sterigenics US, LLC (Gurnee), Isomedix Operations, Inc. (Minneapolis and Northborough), Zimmer Biomet Spine, Inc. and Zimmer GmbH. Removal of subcontractors: Biomet UK Ltd and Steris Isomedix Services (Ontario), Medical Modelling (3D Systems), Invibio, Inc. and Jade Precision Medical Components (JPMC) – (Southampton), Clarification of sterilization activities.
18 October 2018	8997917	Certificate Renewal. Change of manufacturer name: DRT Medical LLC to "NN, Inc. Precision Engineered Products Group, Vandalia". Removal of subcontractors: Advantis Medical, Inc. DBA Avalign Cases & Trays; Arcamed, LLC; Medcraft Inc.; Symmetry Medical Manufacturing Inc. Address change for subcontractor Medtorque from '5555 N Northwest Hwy, Chicago, Illinois, 60236, USA' to '612 W. Lamont Rd, Elmhurst, IL 60126'
07 March 2019	9750369	Traceable to NB 0086.
Current	3427473	Reduction in scope to remove reference to bone void fillers/bone graft substitutes. Removal of critical subcontractor Interpore Cross International, Irvine, California for the activities of Design & Manufacture.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
03 September 2021	3498710	Change EU Representative details from Zimmer GmbH, Winterthur, Switzerland to Biomet GSCC B.V. Breda, The Netherlands

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This certificate was issued electronically and is bound by the conditions of the contract.

03 September 2021

ZimmerBiomet Spine, Inc.
10225 Westmoor Drive
Westminster
Colorado
80021
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 662710	93/42/EEC Annex II excluding Section 4	3498710	Change EU Representative details from Zimmer GmbH, Sulzerallee 8, Winterthur 8404, Switzerland to Biomet GSCC B.V., Hazeldonk 6530, 4836 LD Breda, the Netherlands

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Gary Slack
Senior Vice President, Medical Devices



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)

(Devices in Class III)

No. G7 004200 0006 Rev. 00

Manufacturer:

Biocomposites Ltd

Keele Science Park
Keele, Staffordshire ST5 5NL
UNITED KINGDOM

Product:

Bone substitutes

**Calcium matrix for bone and soft tissue
implantation**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.:

713131301

Valid from:

2020-04-14

Valid until:

2024-05-26

Date,

2020-04-14

Christoph Dicks
Head of Certification/Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)


(Devices in Class III)

No. G7 004200 0006 Rev. 00

Model(s):


Stimulan® Kit
Stimulan® Rapid Cure

Product Code (Ref)	Description	Size
600-005	Stimulan Kit	5cc
600-010	Stimulan Kit	10cc
620-005	Stimulan Rapid Cure	5cc
620-010	Stimulan Rapid Cure	10cc
620-020	Stimulan Rapid Cure	20cc

 TSUNAMI MEDICAL S.r.l.	<p align="center">CAGE INTERSOMATICHE IN TITANIO PER ARTRODESI / TITANIUM INTERSOMATIC CAGE FOR ARTHODESIS</p> <hr/> <p align="center">ANNEX B</p>	DATA: 03-05-23 REV.: 05 PAG. 1 di 3
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<p>ALLEGATO TECNICO ALLA DICHIARAZIONE DI CONFORMITÀ CE NO. TECHNICAL ANNEX TO CE DECLARATION NO.</p> <p>Il presente documento è parte integrante della dichiarazione di conformità CE Present document is an integral part of CE Declaration</p>	<p align="center">10</p>
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REF	POSSIBLE CUSTOMER ORDER CODE	NOME E DESCRIZIONE / NAME AND DESCRIPTION	CONFEZIONE PACKAGING
ACCxxyyzzaa	TICxxyy-zzaa	Cage per artrodesi cervicale / Cage for cervical arthrodesis	In blister doppio / Double blister
ACTxxyyzzaa	TITxxyy-zzaa	Cage per artrodesi transforaminale “TLIF” / Transforaminal arthrodesis Cage “TLIF”	In blister doppio / Double blister
ACAxxyyzzaa	TIAxxyy-zzaa	Cage per artrodesi anteriore “ALIF” / Cage for anterior arthrodesis “ALIF”	In blister doppio / Double blister
ACPxxyyzzaa	TIPxxyy-zzaa	Cage per artrodesi posteriore “PLIF” / Cage for posterior arthrodesis “PLIF”	In blister doppio / Double blister
ACXxxyyzzaa	TILxxyy-zzaa	Cage per artrodesi laterale “XLIF” / Cage for lateral arthrodesis “XLIF”	In blister doppio / Double blister
ACLxxyyzz	Not applicable	Cage per artrodesi postero-laterale oblique “OLIF” / Cage for Posterior-Oblique arthrodesis “OLIF”	In blister doppio / Double blister
ACOXxxyyzzaa	Not applicable	Cage anteriore per artrodesi lombare / Anterior cage for lumbar arthrodesis	In blister doppio / Double blister
ACTHxxyyzzaa	TITExxxyy-zzaa	Cage lombare espandibile / Expandable lumbar cage	In blister doppio / Double blister
ACXHxxyyzzaa	TILExxxyy-zzaa	Cage extra-laterale espandibile e lordosi variabile per artrodesi lombare / Expandable and variable lordosis extra-lateral cage for lumbar arthrodesis	In blister doppio / Double blister
ACPHxxyyzzaa	TIPExxxyy-zzaa	Cage espandibile a lordosi variabile per artrodesi postero laterale / Expandable cage with variable lordosis for lateral postero arthrodesis	In blister doppio / Double blister
MMxxyyzzaa	Not applicable	Cage anteriore espandibile per artrodesi lombare / Expandable anterior cage for lumbar arthrodesis	In blister doppio / Double blister











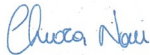

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CTxxyyzzaa	Not applicable	Cage antero-laterale espandibile per artrodesi lombare / Expandable antero-lateral cage for lumbar arthrodesis	In blister doppio / Double blister
MMJxxyyzzaa	Not applicable	Cage anteriore espandibile autobloccante per artrodesi lombare / Expandable self-locking anterior cage for lumbar arthrodesis	In blister doppio / Double blister
ACXJxxyyzzaa	TILFxxyy-zzaa	Cage autobloccante extra-laterale per artrodesi lombare / Extra-lateral self-locking cage for lumbar arthrodesis	In blister doppio / Double blister
ACAJxxyyzzaa	TIAFxxyy-zzaa	Cage anteriore autobloccante per artrodesi lombare / Self-locking anterior cage for lumbar arthrodesis	In blister doppio / Double blister
ACOJxxyyzzaa	Not applicable	Cage anteriore autobloccante per artrodesi lombare / Self-locking anterior cage for lumbar arthrodesis	In blister doppio / Double blister
ACCKxxyyzzaa	Not applicable	Cage per artrodesi cervicale autobloccante micrometrica / Self-locking micrometric cervical arthrodesis cage	In blister doppio / Double blister
ACCZxxyyzzaa	TICFxxyy-zzaa	Cage per artrodesi cervicale autobloccante / Cage for self-locking cervical arthrodesis	In blister doppio / Double blister
ACTZxxyyzzaa	Not applicable	Cage lombare / Lumbar cage	In blister doppio / Double blister

Legenda / Legend:

- yy Lunghezza (mm) per un intervallo di valori compresi fra 9 mm e 58 mm / Length (mm) for a range of values between 9 mm and 58 mm
- xx Larghezza (mm) per un intervallo di valori compresi fra 9 mm e 58 mm / Width (mm) for a range of values between 9 mm and 58 mm
- zz Altezza (mm) per un intervallo di valori compresi fra 4 mm e 16 mm / Height (mm) for a range of values between 4 mm and 16 mm
- aa Angolo (°) per un intervallo di valori compreso fra 0° e 25° / Angle (°) for a range of values between 0° and 25°

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REV.	DATA	MODIFICHE	Preparato da / Issue by: QA/RA	Approvato da: / Approved by GM
05	03-05-23	AGGIUNTO POSSIBILE CODICE ORDINE CLIENTI / POSSIBLE CUSTOMER ORDER CODE ADDED		
04	21-05-20	MODIFICA INTERO FT PER AGGIUNTA NUOVI MODELLI / MODIFY WHOLE TF TO ADD NEW MODELS		
03	13-12-19	AGGIORNAMENTI VARI / VARIOUS UPDATES		
02	02-01-19	AGGIORNAMENTI VARI / VARIOUS UPDATES		
01	01-01-18	AGGIORNAMENTI VARI / VARIOUS UPDATES		
00	01-12-16	PRIMA EMISSIONE PER CERTIFICAZIONE / FIRST ISSUE FOR CERTIFICATION		

**Extension of CE Certificate(s): CE78026 Annex II.4
CE69489 Annex II.3**

Legal Manufacturer: Ceramisys Ltd
EU Single Reg. No.: GB-MF-000008083
Notified Body: BSI Group The Netherlands B.V. (NB 2797)

Self-declaration relating to the following medical Devices: **Calcibon blocks & granules**, see schedule*

This is to certify that the expiry date of the CE certificate as referenced above has been legally extended based on proposal 2023/0005 (COD) resulting in regulation 2023/607 which was approved and published in the Official Journal of the European Union Volume 66 on 20th March 2023.

The transitional period and the concomitant extension of the certificate's validity is automatic by European law, provided the conditions laid down in Article 120(3c) MDR are fulfilled. In the case of devices where the certificate has expired before the 20th March 2023 additional conditions laid in the second subparagraph of Article 120(2), points (a) or (b), of the MDR need to be fulfilled.

We hereby declare that the relevant requirements have been fulfilled as explained below and the expiry date of the certification is now 31 December 2027.


The published legislative text indicates that the transition period for high risk medical devices is extended until 31 December 2027, and during this period Notified Bodies cannot issue new certificates but Manufactures may issue a self-declaration and Competent Authorities may issue certificates of free sale, providing that:

- (a) the devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
- (b) there are no significant changes in the design and intended purpose;
- (c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- (d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);
- (e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect to the device or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

The referenced certificate remained valid on 20 March 2023, and we confirm that the devices are compliant to the above specified extension conditions (a) - (e), including that an application for MDR conformity assessment (contract reference number Q657907 dated 1st August 2022) has been signed by the manufacturer and the notified body (BSi).

Therefore, subject to ongoing Notified Body conformity assessment procedures **the certificate is now extended and shall be recognised as being valid beyond its expiry date until the 31st December 2027, enabling the manufacturer to continue to place the specified devices on the market based on the existing certificate and conditions stated above.**

Signed under the sole responsibility of the legal manufacturer Ceramisys Ltd.


Wayne Austin,
Technical Director
Sheffield, UK, 18th April 2023

* Schedule of devices

ZBxxx	Calcibon HA/TCP bone graft substitute, Blocks
ZBxxxxxx	
ZB0000xx	Calcibon HA/TCP bone graft substitute, 1.0-4.0mm Granules

End of schedule

**Extension of CE Certificate(s): CE76681 Annex II.4
CE69489 Annex II.3**

Legal Manufacturer: Ceramisys Ltd
EU Single Reg. No.: GB-MF-000008083
Notified Body: BSI Group The Netherlands B.V. (NB 2797)

Self-declaration relating to the following medical Devices: Calcibon Inject (see schedule*)

This is to certify that the expiry date of the CE certificate as referenced above has been legally extended based on proposal 2023/0005 (COD) resulting in regulation 2023/607 which was approved and published in the Official Journal of the European Union Volume 66 on 20th March 2023.

The transitional period and the concomitant extension of the certificate's validity is automatic by European law, provided the conditions laid down in Article 120(3c) MDR are fulfilled. In the case of devices where the certificate has expired before the 20th March 2023 additional conditions laid in the second subparagraph of Article 120(2), points (a) or (b), of the MDR need to be fulfilled.

We hereby declare that the relevant requirements have been fulfilled as explained below and the expiry date of the certification is now 31 December 2027.


The published legislative text indicates that the transition period for high risk medical devices is extended until 31 December 2027, and during this period Notified Bodies cannot issue new certificates but Manufactures may issue a self-declaration and Competent Authorities may issue certificates of free sale, providing that:

- (a) the devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
- (b) there are no significant changes in the design and intended purpose;
- (c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- (d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);
- (e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect to the device or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

The referenced certificate remained valid on 20 March 2023, and we confirm that the devices are compliant to the above specified extension conditions (a) - (e), including that an application for MDR conformity assessment (contract reference number Q657907 dated 1st August 2022) has been signed by the manufacturer and the notified body (BSI).

Therefore, subject to ongoing Notified Body conformity assessment procedures **the certificate is now extended and shall be recognised as being valid beyond its expiry date until the 31st December 2027, enabling the manufacturer to continue to place the specified devices on the market based on the existing certificate and conditions stated above.**

Signed under the sole responsibility of the legal manufacturer Ceramisys Ltd.


Wayne Austin,
Technical Director
Sheffield, UK, 18th April 2023

* Schedule of devices

3040010001	Calcibon® Inject
3040020001	Calcibon® Inject
3040050001	Calcibon® Inject
3040017001	Calcibon® Inject (sample)
3040027001	Calcibon® Inject (sample)
3040057001	Calcibon® Inject (sample)
3040050002	Calcibon® Inject (multipack)

End of schedule



To whom it may concern,

Cages manufactured by Tsunami and under Avenue Tx brand such as:

Avenue-A Ti

Avenue-A Fix Ti

Avenue-A Ta

Avenue-C Ti

Avenue-C Fix Ti

Avenue-C Ta

Avenue-L Ti

Avenue-L Exp Ti

Avenue-L Fix Ti

Avenue-L Ta

Avenue-P Ti

Avenue-P Exp Ti

Avenue-P Ta

Avenue-T Ti

Avenue-T Exp Ti

Avenue-T Ta



Are part of the ZimVie portfolio, therefore ZimVie is the responsible for the commercial release of this product.

Sincerely,

Mirandola, lì 14/12/2023

Stefano Caselli

GM

Tsunami Medical S.r.l.

A handwritten signature in blue ink, appearing to read 'Stefano Caselli', is positioned to the right of the printed name.