

# EC Certificate - Full Quality Assurance System

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

**No.****CE 515162****Issued To:**

**Zimmer Inc.  
1800 W. Center Street  
Warsaw  
Indiana  
46580  
USA**

In respect of:

**Design, development and manufacture of joint replacement implants, fracture fixation devices, bone cement accessories, trial prostheses and instruments for use with active devices. Those aspects related to securing and maintaining sterility in the manufacture of orthopaedic instruments, fracture fixation devices and bone cement instruments. Those aspects related to the accuracy of metrology in the manufacture of orthopaedic instruments and fracture fixation devices.**

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: **2007-08-13**

Date: **2021-01-25**

Expiry Date: **2024-05-26**

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

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**Indiana**  
**46580**  
**USA**

Date	Reference Number	Action
13 August 2007	-	Transfer from another Notified Body, Certificate No. #G1 06 03 21021 031.
01 September 2009	7374311	Addition of significant subcontractors; 'Zimmer U.K. Ltd' for EU Representative, 'Zimmer Orthopedics Manufacturing Limited' for Manufacture, 'Isotron Westport Ltd' for Gamma Sterilization and 'CeramTec AG' for manufacture
30 September 2010	7572341	Addition of significant subcontractors; 'Steris Isomedix Services' for Gamma Sterilization and ETO Sterilization and 'Zimmer Trabecular Metal Technology, Inc' for Manufacture and Symmetry Medical USA, Inc for manufacture.
10 February 2011	7632482	Certificate renewal Addition of the following sub-contractors for manufacturing: 'Alhenia AG, European Medical Contract manufacturing B.V., Greatbatch Medical Orthopaedics, Columbia City and Indianapolis'. Sub-contractor name change: from 'Precimed AG' to 'Greatbatch Medical Orthopaedics'. Sub-contractor name and address change: name change from 'CeramTec AG to 'CeramTec GmbH', address change from 'Fabrikstrasse 23-29' to 'CeramTec Platz 1-9 73207 Plochingen'.

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Date	Reference Number	Action
03 October 2012	7880032	<p>Addition of significant subcontractors:</p> <p>'Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 USA' for ETO Sterilization.</p> <p>'Edwards Lifesciences Technology Sàrl, State Road 402, Km 1.4, Industrial Park, 00610-1577 Añasco, Puerto Rico, USA' for ETO Sterilization.</p> <p>'Micropulse, Inc., 5865 East State Road 14, Columbia City, IN 46725, USA' for Manufacture.</p> <p>'Spire Biomedical, Inc, One Patriots Park, Bedford, MA 01730-2396, USA' for Manufacture and Other Critical Processes.</p> <p>'Surface Dynamics, 231 Northland Blvd., Cincinnati, OH 45246, USA' for Manufacture and Other Critical Processes.</p> <p>'CeramTec GmbH, CeramTec-Weg 1, 95615 Marktreidwitz, Germany' for Manufacture.</p> <p>'Sterigenics US, LLC, 7775 South Quincy, Willowbrook, IL 60527, USA' for ETO Sterilization.</p> <p>'Synergy Health Däniken AG, 4658 Däniken, Switzerland' for Gamma Sterilization</p> <p>'Synergy Health Allershausen GmbH, Kesselbodenstrasse 7, D-85391 Allershausen, Germany' for Gamma Sterilization.</p> <p>Sub-contractor name change: from 'Ethox International Medical Manufacturing Corporation' to 'Moog Medical Devices Group OEM'</p> <p>Sub-contractor name change: from 'Isotron Westport Ltd' to 'Synergy Health Westport Limited'</p>

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Date	Reference Number	Action
27 March 2013	7972761	Addition of 'APS Materials, Inc., 4011 Riverside Drive, Dayton, OH 45404, USA' as a subcontractor for 'Other critical processes'.
12 March 2015	8282135	Addition of significant subcontractor "Synergy Health Ireland Ltd." for the activities of ETO sterilization.

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Date	Reference Number	Action
22 February 2016	8456737	<p>Renewal of certificate.</p> <p>Removal of subcontractors "Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614, USA"; "Edwards Lifesciences Technologies Sàrl, State Road 402, Km 1.4, Industrial Park, 00610-1577 Añasco, Puerto Rico, USA"; "Steris Isomedix Services, 1880 Industrial Drive, Libertyville 60048, Illinois, USA" and "Synergy Health Allershausen GmbH, Kesselbodenstrasse 7, D-85391 Allershausen, Germany" for sterilization activities.</p> <p>Removal of subcontractors "European Medical Contract Manufacturing B.V., Middenkampweg 17, Nijmegen, 64545 CH, Netherlands" ; "Greatbatch Medical Orthopaedics, L'Echelette 7, CH-2534 Orvin, Switzerland" and "Zimmer Surgical, Inc., 2021 Old Mountain Road, Statesville, North Carolina, 28677, USA" for manufacture activities.</p> <p>Correction of the services supplied by subcontractor "Alhenia AG, Täfernstrasse 39, CH-5405 Baden-Dättwil, Switzerland" from "manufacture" to "Other critical processes".</p> <p>Correction of subcontractor name and change of address from "Greatbatch Medical Orthopaedics, 4532 Park 30 Drive, Columbia City, IN 46725, USA" to "Greatbatch Medical, 4545 Kroemer Road, Fort Wayne, IN 46818, USA".</p> <p>Change of subcontractor name from "Moog Medical Devices Group OEM" to "iuvo Biosciences".</p>

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		<p>Change of subcontractor name from "Spire Spire Biomedical, Inc." to "N2 Biomedical LLC", and removal of "manufacture" as service supplied.</p> <p>Change of subcontractor "Sterigenics US, LLC" address from "305 Enterprise Drive, Westerville, Ohio 43081, USA" to "305 Enterprise Drive, Lewis Center, Ohio 43035-9418, USA".</p> <p>Correction of typo in subcontractor "Summit Medical LTD" address to include "Bourton" in the Industrial Park description.</p> <p>Correction of typo in subcontractor names, from "Zimmer Surgical, Inc." to "Zimmer Surgical" and from "Zimmer Switzerland Manufacturing GmbH" to "Zimmer GmbH".</p> <p>Addition of critical subcontractors "Iotron Technologies Inc., 1425 Kebet Way, Port Coquitlam, BC, V3C 6L3, Canada" and "Iotron Technologies Inc., 4394 East Park 30 Drive, Columbia City, IN 46725, USA" for the services of "Other critical processes".</p> <p>Addition of the following crucial suppliers of raw materials: "ALLVAC"; "Banner Medical Corp."; "Cannon Muskegon Corp"; "Carpenter Specialty Alloys"; "Centex Machining Inc."; "DSM Nutritional Products Inc."; "EDGE International"; "ELECTRALLOY"; "ESSCHEM CO"; "Fine Tubes Limited"; "Forge de Bologne"; "Fort Wayne Metals Research Product Corp"; "Lucite International UK LTD"; "NF &amp; M International Inc."; "Nolato Gejde AB"; "Orchid Orthopedic Solutions Oregon, Inc."; "Orchid Unique"; "Orthoplastics"; "Perryman Company"; "Precision Castparts Corp"; "Precision Metal Products Inc."; "Quadrant EPP US Inc."; "Remelt Sources, Inc."; "Rochling Engineering Plastics";</p>

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Date	Reference Number	Action
		"Sandvik Materials Technology"; "Stewart Precision Manufacturing, Inc. (CG Tech Inc)"; "Symmetry Medical Inc. – Sheffield"; "Symmetry Medical Inc. – JET"; "TIMET"; "Titanium Industries"; "VSMPO-TIRUS, US"; "Vulcanium Metals Incorporated" and "ZAPP US"
10 March 2016	8426743	Addition of the significant subcontractor "Zimmer Orthopedics Manufacturing Limited, Deerpark Industrial Estate, Oranmore, Galway, Ireland " for the activities of "Manufacture".
21 December 2016	8650353	Addition of critical subcontractors "Zhejiang Biomet Medical Products Co., Ltd., No. 980 Shenli Road, Jinhua, Zhejiang, 321016, China" and "Changzhou Biomet Medical Devices Co., Ltd., No. 235 Chuangxin Road, Export Processing Zone, Xinbei District, Changzhou, Jiangsu, 213031, China" for the activities of Assembly, Final inspection, Labelling and Packaging. Addition of activity "Crucial supplier" to "Zimmer GmbH, Sulzerallee 8, Winterthur, CH-8404, Switzerland".
17 May 2018	8694359	Addition of Millstone Medical Outsourcing as subcontractor for cleaning and packaging of metal femoral heads.
19 June 2018	8957951	Change of scope to include "Those aspects related to securing and maintaining sterility in the manufacture of orthopaedic instruments, fracture fixation devices and bone cement instruments. Those aspects related to the accuracy of metrology in the manufacture of orthopaedic instruments and fracture fixation devices"

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10 August 2018	8886502	Subcontractor name change from IUVO Biosciences to Cosmed Group Inc. for the activity of ETO sterilization.
11 March 2019	7781060	Traceable to NB 0086.
15 November 2019	9688890	Addition of manufacture to subcontractor Changzhou Biomet Medical Devices Co., Ltd. Addition of Shanghai JPYU Ion-tech. Co., Ltd. for gamma sterilisation.
23 December 2019	9757918	Addition of Zimmer GmbH as EC Rep.
18 June 2020	3118662	EU Representative added; Biomet Global Supply Chain Center B.V. & change of address for subcontractors Sterigenics US, LLC.

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Date	Reference Number	Action
18 December 2020	3110725	<p>Certificate renewal</p> <p>Scope "Bone Cement" removed and replaced with "Bone cement accessories"</p> <p>Subcontractor activity "manufacture" added to critical subcontractor "Changzhou Biomet Medical Devices Co. Ltd", "Zimmer GmbH" and "Centex machining Inc"</p> <p>Critical subcontractor added "Shanghai JPY Ion-tech Co, Lt, No. 1168, Huijin Road, Shanghai Qingpu Industrial Zone, 201707 Shanghai, People's Republic of China" for the activity of "Gamma Sterilization"</p> <p>Crucial supplier added "Ticona LLC, Celanese Engineered Materials, North American, headquarters, 8040 Dixie Highway, Florence, KY 41042, United states of America"</p> <p>Name change of the following critical subcontractor from; "Alhenia AG" TO "Orchid Orthopedics Switzerland GmbH"</p> <p>Following Crucial Supplier, critical subcontractor removed "Forge De Bologne", "Holmed Corporation"</p> <p>Name change of the following crucial supplier, critical subcontractor From; "ALLVAC" TO "ATI Speciality Materials"</p> <p>From "Esschem CO" TO "Esschem Inc"</p> <p>From "Greatbatch Medical, 4545 Kroemer Road, Fort Wayne, IN 46818, USA" TO "Viant Medical, LLC"</p> <p>From "Greatbatch Medical, 3735 North Arlingoton Ave., Indianapolis, IN 46218, USA" To "Viant AS&amp;O Holdings, LLC"</p>

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Date	Reference Number	Action
		<p>From "Iotron Technologies Inc., 1425 Kebet Way, Port Coquitlam, British Columbia, V3C 6L3, Canada" TO "Iotron industries Canada Inc."</p> <p>From "Iotron technologies Inc., 4394 East Park 30 Drive, Columbia City, Indiana, 46725" TO "Iotron Industries USA"</p> <p>From "Orchid Unique" TO "Orchid Unique DBA Orchid Bridgeport"</p> <p>From "Rochling Engineering plastics" TO "Rochling"</p> <p>From "Symmetry Medical Manufacturing (JET)" TO "Symmetry Medical Manufacturing, Inc. dba Tecomet (Lansing, MI)"</p> <p>From "Symmetry Medical Manufacturing, Inc." TO "Symmetry Medical Manufacturing, Inc. dba Tecomet (Warsaw, IN)"</p> <p>From "Synergy Health Ireland Ltd (Synergy Health – AST- Ireland)" TO "Synergy Health Ireland Ltd"</p> <p>From "VSMPO-Tirus, US" TO "VSMPO-Tirus, US Pittsburg"</p> <p>From "Zapp US" TO "ZAPP Precision Wire, Inc."</p> <p>From "Zimmer Trabecular Metal Technology, Inc." TO "Zimmer Trabecular Metal Technology, Inc. doing business as Zimmer and implex"</p> <p>Location correction for the following crucial supplier, critical subcontractor;</p> <p>From "Cannon Muskegon, 2875 Lincoln St., Muskegon, Michigan, 49443-0506, USA" TO "Cannon Muskegon Corp, 2875 Lincoln Street, Muskegon, Michigan, 49441, USA"</p>

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		<p>From "CARPENTER SPECIALTY ALLOYS, 101 West Bern Street, Muskegon, Michigan, 49441, USA" TO "CARPENTER SPECIALTY ALLOYS, 101 West Bern Street, Reading PA 19601, USA"</p> <p>From "Millstone Medical Outsourcing LLC, 580 Commerce Drive, Fall River, Massachusetts ,02720-4759, USA" TO "Millstone Medical Outsourcing LLC, 580 Commerce Drive, Fall River, Massachusetts ,02720, USA "</p> <p>From "CeramTec GmbH, Medical Products Division, CeramTec-Weg 1, 956115 Marktrechwitz, Germany" TO "CeramTec GmbH, Medical Products Division, CeramTec-Weg 1, 95615 Marktrechwitz, Germany"</p> <p>From "N2 Biomedical LLC, One Patriots Park, Bedford, Massachusetts, 01730-2396, USA" TO "N2 Biomedical LLC, One Patriots Park, Bedford, Massachusetts, 01730, USA"</p> <p>From "Nolato MediTech AB, Koppargatan 1, 2335 Lomma, SWEDEN" TO "Nolato MediTech AB, Koppargatan 13, 2335 Lomma, SWEDEN"</p> <p>From "Orchid Orthopedic Solutions Oregon, Inc, 19363 Fir Street, Oregon City, Oregon, 97045, USA" TO "Orchid Orthopedic Solutions Oregon, Inc, 13963 Fir Street, Oregon City, Oregon, 97045, USA"</p> <p>Location and name correction/change for the following crucial supplier          From: "Quadrant EPP US Inc, 2120 Fairmount Ave, Reading, Pennsylvania, 19612" TO "Mitsubishi Chemical Advanced Materials Inc, 2120 Fairmount Ave, Reading, Pennsylvania, 19605"</p>

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Date	Reference Number	Action
25 January 2021	3327528	Addition of Sterigenics Salt Lake City as a subcontractor for ETO sterilization.

**Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3**

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Date	Reference Number	Action
17 June 2022	9689444	<p>Removal of critical subcontractors "Surface Dynamics LLC" and "CeramTec GmbH" (Marktredwitz).</p> <p>Removal of crucial supplier "Electralloy".</p> <p>Removal of EU Representative "Zimmer U.K. Ltd".</p> <p>Addition of critical subcontractor "Orchid Orthopedic Solutions, LLC" for the activity "packaging".</p> <p>Addition of critical subcontractor "Surface Dynamics LLC D/B/A Lincotek Medical" for the activities "manufacture, other critical processes".</p> <p>Change of name for "Iotron Industries USA" to "Sterigenics Radiation Technologies IN, Inc".</p> <p>Change of name for "Precision Castparts Corp" to "PCC Structural, Inc".</p> <p>Change of name for "Vulcanium Metals Incorporated" to "United Performance Metals".</p> <p>Change of name for "EDGE International" to "Dragonfish, Inc. dba Edge International".</p> <p>Change of name for "Rochling" to "Röchling Industrial – Gastonia".</p> <p>Change of name for "VSMPO-Tirrus U.S." to "VSMPO-Tirrus U.S. Pittsburg".</p>

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Date	Reference Number	Action
17 June 2022	9689444	Amendment of address for "Esschem Inc." to remove "PO 1139". Amendment of name and address from "Fine Tubes Limited, Plymbridge Road, Estover, Plymouth, Devon, PL6 7LG, United Kingdom" to "Fine Tubes Ltd, Estover Works, Plymbridge Road, Estover, Plymouth, PL6 7LG, United Kingdom". Change of name for "Stewart Precision Manufacturing, Inc. (CG Tech Inc)" to "Stewart Precision Manufacturing, Inc.". Amendment of name and address for "Synergy Health Westport Ltd, (Synergy Health – AST – Westport), Lodge Road, Westport, County Mayo, F28 AF54, Ireland" to "Synergy Health Westport Ltd, Lodge Road, Westport, County Mayo, Ireland".
15 November 2022	3774701	Administrative change to certificate.

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15 November 2022

Zimmer, Inc.  
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Warsaw  
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46580  
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To whom it may concern,

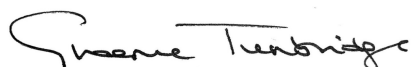
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

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 515162	93/42/EEC Annex II excluding Section 4	3774701	Administrative change to certificate.

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,



Graeme Tunbridge  
Senior Vice President, Medical Devices