

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 515162**
 Date: **21 December 2016**
 Issued To: **Zimmer Inc.**
1800 W. Center Street
Warsaw
Indiana
46580
USA

Date	Reference Number	Action
		Tubes Limited"; "Forge de Bologne"; "Fort Wayne Metals Research Product Corp"; "Lucite International UK LTD"; "NF & 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"; "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".

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		<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> <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</p>

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		Sub contractor name change: from 'Isotron Westport Ltd' to 'Synergy Health Westport Limited'
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.
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, Täferstrasse 39, CH-5405 Baden-Dättwil, Switzerland" from "manufacture" to "Other critical processes".</p>

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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>

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

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Subcontractor:

Service(s) supplied

Zimmer Trabecular Metal
 Technology, Inc.
 10 Pomeroy Road
 Parsippany
 New Jersey
 07054
 USA

Manufacture

Zimmer U.K. Ltd.
 9 Lancaster Place
 South Marston Park
 Swindon
 Wiltshire
 SN3 4FP
 United Kingdom

EU Representative

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Subcontractor:	Service(s) supplied
Zimmer Orthopedics Manufacturing Limited Deerpark Industrial Estate Oranmore Galway Ireland	Manufacture
Zimmer Orthopedics Manufacturing Limited Building 2 East Park Shannon Industrial Estate Co. Clare Ireland	Manufacture
Zimmer Surgical 200 W Ohio Avenue Dover Ohio 44622 USA	Manufacture

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Subcontractor:	Service(s) supplied
Zhejiang Biomet Medical Products Co., Ltd No. 980 Shenli Road Jinhua Zhejiang 321016 China	Assembly Final Inspection Labelling Packaging
Zimmer GmbH Sulzerallee 8 Winterthur 8404 Switzerland	Crucial Supplier Manufacture
Zimmer Manufacturing B.V. Route #1, K.M. 123.4 Turpeaux Industrial Park Mercedita 00715 Puerto Rico	Manufacture

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Subcontractor:

Service(s) supplied

VSMPO-TIRUS, US
 401 Riverport Drive
 Leetsdale
 Pennsylvania
 15056
 USA

Crucial Supplier

Vulcanium Metals Incorporated
 3045 Commercial Avenue
 Northbrook
 Illinois
 60062
 USA

Crucial Supplier

ZAPP US
 475 International Circle
 Summerville
 South Carolina
 29483
 USA

Crucial Supplier

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Subcontractor:	Service(s) supplied
Synergy Health Westport Limited Lodge Road Westport County Mayo Ireland	Gamma Sterilization
TIMET 100 Titanium Way Toronto Ohio 43964 USA	Crucial Supplier
Titanium Industries 18 Green Pond Road Rockaway New Jersey 07866 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
Symmetry Medical, Inc. (Sheffield) Beulah Road Sheffield S6 2AN United Kingdom	Crucial Supplier
Synergy Health Däniken AG Hogen Weidstrasse 6 Däniken CH-4658 Switzerland	Gamma Sterilization
Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Offaly Ireland	ETO Sterilization

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Subcontractor:	Service(s) supplied
Surface Dynamics 231 Northland Blvd. Cincinnati Ohio 45246 USA	Manufacture Other critical processes
Symmetry Medical Manufacturing, Inc. 486 West 350 North Warsaw Indiana 46582-7721 USA	Manufacture
Symmetry Medical, Inc. (JET) 5212 Aurelius Road Lansing Michigan 48911 USA	Crucial Supplier

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Service(s) supplied

Sterigenics US, LLC
 7775 South Quincy
 Willowbrook
 Illinois
 60527
 USA

ETO Sterilization

Stewart Precision Manufacturing, Inc.
 (CG Tech Inc)
 12631 N. 3rd. Ave.
 Phoenix
 Arizona
 85027
 USA

Crucial Supplier

Summit Medical Ltd
 Bourton Industrial Park
 Bourton-on-the-Water
 Gloucestershire
 GL54 2HQ
 United Kingdom

Manufacture

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Subcontractor:

Service(s) supplied

Sandvik Materials Technology
 982 Griffin Pond Road
 Clarks Summit
 Pennsylvania
 18411
 USA

Crucial Supplier

Sterigenics US, LLC
 1003 Lakeside Drive
 Gurnee
 Illinois
 60031
 USA

Gamma Sterilization

Sterigenics US, LLC
 305 Enterprise Drive
 Lewis Center
 Ohio
 43035-9418
 USA

Gamma Sterilization

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Service(s) supplied

Quadrant EPP US Inc.
 2120 Fairmount Ave
 Reading
 Pennsylvania
 19612
 USA

Crucial Supplier

Remelt Sources, Inc.
 1650 Mineral Springs Rd
 Darlington
 South Carolina
 29540
 USA

Crucial Supplier

Rochling Engineering Plastics
 903 Gastonia Technology Parkway
 Dallas
 North Carolina
 28034
 USA

Crucial Supplier

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Subcontractor:	Service(s) supplied
Pioneer Surgical Technology 375 River Park Circle Marquette Michigan 49855 USA	Manufacture
Precision Castparts Corp 13340 S.E. 84th Clackamas Oregon 97015 USA	Crucial Supplier
Precision Metal Products Inc. 850 West Bradley Avenue El Cajon California 92020 USA	Crucial Supplier

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Subcontractor:

Service(s) supplied

Orchid Unique
 6688 Dixie Hwy
 Bridgeport
 Michigan
 48722
 USA

Crucial Supplier

Orthoplastics
 Grove Mill
 Todmorden Road
 Bacup
 Lancashire
 OL13 9EF
 United Kingdom

Crucial Supplier

Perryman Company
 149 South Johnson Road
 Houston
 Pennsylvania
 15342
 USA

Crucial Supplier

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Subcontractor:

Service(s) supplied

NF & M International Inc.
 1729 Pennsylvania Avenue
 Monaca
 Pennsylvania
 15061
 USA

Crucial Supplier

Nolato Gejde AB
 Koppargatan 1
 Lomma
 23435
 Sweden

Crucial Supplier

Orchid Orthopedic Solutions Oregon, Inc.
 19363 Fir Street
 Oregon City
 Oregon
 97045
 USA

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Service(s) supplied

Lucite International UK Ltd
 Horndale Avenue
 Newton
 Aycliffe
 County Durham
 DL5 6YE
 United Kingdom

Crucial Supplier

Micropulse
 5865 East State Road 14
 Columbia City
 Indiana
 46725
 USA

Manufacture

N2 Biomedical LLC
 One Patriots Park
 Bedford
 Massachusetts
 01730-2396
 USA

Other critical processes

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Service(s) supplied

Iotron Technologies Inc.
 1425 Kebet Way
 Port Coquitlam
 British Columbia
 V3C 6L3
 Canada

Other critical processes

Iotron Technologies Inc.
 4394 East Park 30 Drive
 Columbia City
 Indiana
 46725
 USA

Other critical processes

iuvo Biosciences
 2205 East 33rd Street
 Erie
 Pennsylvania
 16510
 USA

ETO Sterilization

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Subcontractor:	Service(s) supplied
Greatbatch Medical 3735 North Arlington Ave. Indianapolis Indiana 46218 USA	Manufacture
Greatbatch Medical 4545 Kroemer Road Fort Wayne Indiana 46818 USA	Manufacture
Holmed Corporation 40 Norfolk St. South Easton Massachusetts 02375 USA	Manufacture

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Subcontractor:	Service(s) supplied
Fine Tubes Limited Plymbridge Road Estover Plymouth Devon PL6 7LG United Kingdom	Crucial Supplier
Forge de Bologne BP 28 - Rue d'Oradour sur Glane Chaumontel F-95270 France	Crucial Supplier
Fort Wayne Metals Research Product Corp 9609 Ardmore Ave. Fort Wayne Indiana 46809 USA	Crucial Supplier

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Subcontractor:

Service(s) supplied

EDGE International
 330 Leo Street
 Dayton
 Ohio
 45404
 USA

Crucial Supplier

ELECTRALLOY
 175 Main Street
 Oil City
 Pennsylvania
 16301
 USA

Crucial Supplier

ESSCHEM CO
 4000 Columbia Avenue
 Linwood
 Pennsylvania
 19061
 USA

Crucial Supplier

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Service(s) supplied

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

Assembly
Final Inspection
Labelling
Packaging

DSM Nutritional Products Inc.
 45 Waterview Boulevard
 Parsippany
 New Jersey
 07054
 USA

Crucial Supplier

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Subcontractor:	Service(s) supplied
Centex Machining Inc. 1513 Sam Bass Rd Round Rock Texas 78681 USA	Crucial Supplier
CeramTec GmbH CeramTec-Weg 1 95615 Marktredwitz Germany	Manufacture
CeramTec GmbH Medical Applications Division CeramTec Platz 1-9 D-73207 Plochingen Germany	Manufacture

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Service(s) supplied

Banner Medical Corp.
 494 E Lies Rd.
 Carol Stream
 Illinois
 60188
 USA

Crucial Supplier

Cannon Muskegon Corp
 2875 Lincoln St.
 Muskegon
 Michigan
 49441
 USA

Crucial Supplier

Carpenter Specialty Alloys
 101 West Bern Street
 Reading
 Pennsylvania
 19601
 USA

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Service(s) supplied

Alhenia AG
 Täferstrasse 39
 Baden-Dättwil
 CH-5405
 Switzerland

Other critical processes

ALLVAC
 2020 Ashcraft Ave.
 Monroe
 North Carolina
 28110-5030
 USA

Crucial Supplier

APS Materials, Inc.
 4011 Riverside Drive
 Dayton
 Ohio
 45405
 USA

Other critical processes

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

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

**Zimmer Inc.
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In respect of:

Design, development and manufacture of joint replacement implants, fracture fixation devices, bone cement, trial prostheses and instruments for use with active 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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **13 August 2007**

Date: **21 December 2016**

Expiry Date: **26 February 2021**

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