

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, 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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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.

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List of Significant Subcontractors

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

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Subcontractor:

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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Subcontractor:	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	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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Subcontractor:

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
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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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
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
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
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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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	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
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
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
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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Subcontractor:	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

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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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
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
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
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
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

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

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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	Renewal of certificate. Removal of subcontractors "Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614, USA"; "Edwards Lifesciences Technologies S�arl, State Road 402, Km 1.4, Industrial Park, 00610-1577 A�asco, 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. 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. Correction of the services supplied by subcontractor "Alhenia AG, T�ferstrasse 39, CH-5405 Baden-D�ttwil, Switzerland" from "manufacture" to "Other critical processes".

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Date	Reference Number	Action
		<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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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".