

EC Certificate - Full Quality Assurance System

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

No. CE 02461
Issued To: **Biomet Orthopedics**
56 East Bell Drive
P.O Box 587
Warsaw
Indiana
46581
USA

In respect of:

See certificate scope page.

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: **1999-10-16**

Date: **2021-04-23**

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

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Page 1 of 2

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Certificate No: CE 02461

Certificate Scope:

The design, development and manufacture of hip, knee, shoulder and upper extremity orthopedic joint replacement prostheses, internal fixation implants and associated accessories, instrumentation and trial orthopedic replacement devices; reusable and sterile single-use surgical instruments intended for connection to active devices.

The design and development of image processing software for simulation of femoroacetabular impingement.

Those aspects of Annex II related to the metrology in the design and manufacture of orthopaedic surgical planning software.

Those aspects of Annex II relating to the accuracy of metrology in the design and manufacture of surgical instruments.

Those aspects of Annex II relating to the securing and maintaining sterility in the manufacture of sterile OR supplies and sterile instruments.

First Issued: **1999-10-16**Date: **2021-04-23**Expiry Date: **2024-05-26**

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Page 2 of 2

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List of Significant Subcontractors

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Subcontractor:	Service(s) supplied
3D Systems, Inc. 5381 South Alkire Circle Littleton Colorado 80127 USA	Manufacture
Advanced Engineering, Inc. 5299 Mishler Road Huntington Indiana 46750 USA	Manufacture Packaging
APS Materials Inc Unit 26A Waterford Ind Est Cork Road Waterford C. Waterford Ireland	Other Critical Processes

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Subcontractor:	Service(s) supplied
APS Materials, Inc 4011 Riverside Drive Dayton OH 45405 USA	Other Critical Processes
Biomet Deutschland GmbH Gustav-Krone-Strasse 2 14167 Berlin Germany	Manufacture
Biomet Fairlawn 20-01 Pollitt Drive Fairlawn New Jersey 07410 USA	Manufacture

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Subcontractor:	Service(s) supplied
Biomet France Sarl Plateau de Lautagne Valence 26000 France	Design Manufacture
Biomet Global Supply Chain Center B.V. Hazeldonk 6530 4836 LD Breda The Netherlands	EU Representative
Biomet Global Supply Chain Center B.V. – Clinical Graphics Molengraaffsingel 10 2629 JD Delft The Netherlands	Design

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Subcontractor:	Service(s) supplied
Biomet Microfixation also trading as Walter Lorenz Surgical, Inc. 1520 Tradeport Drive Jacksonville Florida 32218 USA	Design Manufacture
Biomet Spain Orthopaedic SL c/Islas Baleares 50. P.I. Fuente Del Jarro. Paterna Valencia E-46988 Spain	Manufacture

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Subcontractor:	Service(s) supplied
Biomet Sports Medicine also trading as Biomet Sports Medicine, Inc. 56 East Bell Drive PO Box 587 Warsaw Indiana 46581 USA	Manufacture
Biomet UK Healthcare Ltd Dorcan One Hundred Murdock Rd Swindon SN3 5HY United Kingdom	Design Development
Biomet UK Limited also trading as Biomet UK Healthcare Ltd. Waterton Industrial Estate Bridgend CF31 3XA United Kingdom	Design Development EU Representative Gas Plasma Sterilization 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	Manufacture Packaging
Cosmed Group Inc. 2205 East 33rd Street Erie Pennsylvania 16510 USA	ETO Sterilization
Eurocoating S.p.A. Via Al Dos de la Roda, 60 Z.I. Cire 38057 Pergine Valsugana (TN) Italy	Other Critical Processes

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Subcontractor:	Service(s) supplied
Interpore Cross International 181 Technology Drive Irvine California 92618 USA	Manufacture
Iotron Industries Canada Inc. 1425 Kebet Way Port Coquitlam British Columbia V3C 6L3 Canada	Other Critical Processes
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	Other Critical Processes Radiation (Gamma Sterilization)
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	Radiation (Gamma Sterilization)
Millstone Medical Outsourcing LLC 580 Commerce Drive Fall River Massachusetts 02720 USA	Labelling Packaging

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Subcontractor:	Service(s) supplied
N2 Biomedical, LLC One Patriots Park Bedford Massachusetts 01730 USA	Manufacture
Orchid Orthopedic Solutions (Oregon) 13963 Fir Street Oregon City Oregon 97045 USA	Manufacture
Orchid Orthopedic Solutions LLC 23149 Commerce Drive Farmington Hills Michigan 48335-2723 USA	Manufacture

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Subcontractor:	Service(s) supplied
Paragon Medical, Inc. 8 Matchett Drive Pierceton Indiana 46562 USA	Manufacture
rms Company 8600 Evergreen Boulevard Minneapolis Minnesota 55433 USA	Manufacture
Selenium Medical 40 rue de Chef de Baie Zone industrielle de Chef de baie La Rochelle 17000 France	Packaging

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Subcontractor:	Service(s) supplied
SHANGHAI JPY ION-TECH.CO., LTD. No. 1168, Huijin Rd. Shanghai Qingpu Industrial Zone. 201707 Shanghai People's Republic of China	Radiation (Gamma Sterilization)
Sterigenics UK Ltd Cotes Park Estate Alfreton DE55 4NJ United Kingdom	ETO Sterilization
Sterigenics US, LLC 7775 South Quincy Street Willowbrook Illinois 60527 USA	ETO Sterilization

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Subcontractor:

Service(s) supplied

Sterigenics US, LLC
344 Bonnie Circle
Corona
California
92880
USA

Radiation (Gamma Sterilization)

Sterigenics US, LLC
5725 W. Harold Gatty Drive
Salt Lake City
Utah
84116
USA

ETO Sterilization

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

Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
STERIS Applied Sterilization Technologies ULC 184 Crown Court Whitby Ontario L1N 7B1 Canada	Other Critical Processes
Structure Medical LLC 505 Production Avenue Madison Alabama 35758 USA	Manufacture
Surface Dynamics, LLC 3110 Stage Post Drive Suite 101 Bartlett Tennessee 38133 USA	Other Critical Processes

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Subcontractor:	Service(s) supplied
Synergy Health Däniken AG Hogenweidstrasse 6 Däniken CH-4658 Switzerland	Radiation (Gamma Sterilization)
Synergy Health Ede BV (Location AST Ede) Morsestraat 3 Ede 6716 AH The Netherlands	Radiation (Gamma Sterilization)
Synergy Health Sterilisation UK Ltd Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom	Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
Synergy Health Sterilisation UK Ltd Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	Radiation (Gamma Sterilization)
Synergy Health Westport Ltd Lodge Road Westport County Mayo Ireland	Radiation (Gamma Sterilization)
Zhejiang Biomet Medical Products Co., Ltd No. 980 Shenli Road Jinhua Zhejiang 321016 China	Manufacture

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Subcontractor:	Service(s) supplied
Zimmer Inc. 1800 W. Center Street Warsaw Indiana 46580 USA	Manufacture
Zimmer Orthopedics Manufacturing Limited Building 2 East Park Shannon Industrial Estate Co. Clare Ireland	Manufacture
Zimmer Orthopedics Manufacturing Limited Deerpark Industrial Estate Oranmore Galway Ireland	Control of Sterilization Manufacture Packaging

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Date	Reference Number	Action
16 October 1999	-	First issue
15 May 2000	-	Change of Biomet Orthopedics, Inc's address details
13 August 2002	-	Sterile acrylic bone cements added to scope
21 May 2003	-	CSS (Chicago) deleted from list of sub-contractors. Centurion sterilisation services added on the list of subcontractors
02 July 2004	-	Removed Sterigenics and Griffith Micro Science's sterilisation services and added Centurion Sterilisation Services which was inadvertently missed off of the previous issue. Extended scope to include 'reusable surgical instruments which can be connected to an active medical device' and 'trial orthopaedic implants'. 5 year certificate renewal

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Date	Reference Number	Action
09 August 2007	-	Certificate renewal, scope clarification and addition of the following subcontractors: <ul style="list-style-type: none"> • Biomet UK Limited, Swindon and Bridgend • EBI, L.P. also trading as Biomet Spine, Biomet Trauma, • Biomet Osteobiologics • Implant Innovations Inc. also trading as Biomet 3i • Interpore Cross International • Biomet Deutschland GmbH • Biomet France Sarf • Biomet Spain Orthopaedic SL • Biomet Cementing Technologies, Sweden • Zhejiang Biomet Medical Products Co., Ltd, China • Sterigenics, Corona
16 February 2009	7273625	Company name change from "Biomet Orthopedics, Inc." to "Biomet Orthopedics". Subcontractor name adjustments in line with company name change. Addition of EU Representative subcontractor activity to Biomet UK Bridgend.

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Date	Reference Number	Action
16 September 2010	7481598	Addition of Manufacturing subcontractors: Changzhou Biomet Medical Devices Co., Ltd. China, and Biomet Sports Medicine, IN 46581, USA. Addition of Packaging subcontractor: Millstone Medical Outsourcing, LLC, MA 02720 USA. Addition of Sterilization subcontractor: Isotron Ltd. Marcus Close & Isotron Ltd Moray Road UK and Steris Isomedix Services, MA 01532 USA. Minor postal code modification from 46582 to 46581 and addition of PO Box 587. Removal of: Biomet Sports Medicine, Redding, USA, Biomet Sports Medicine, Ontario, USA and Biomet Cementing Technologies

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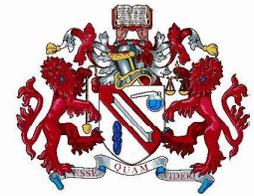
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Date	Reference Number	Action
30 June 2011	7699830	Addition of the following subcontractors: <ul style="list-style-type: none"> • Greatbatch Medical Orthopaedics, 10000 Wherle Drive, Clarence, NY 14031, USA. For Manufacture Activity. • RMS,8600 Evergreen Boulevard, Minneapolis, MN 55433, USA. For Manufacture Activity. • Huntsville Medical Products, Also dba FMI Medical 505 Production Avenue, Madison, Alabama 35758 USA. For Manufacture Activity. • AB Medical Technologies Inc, 6704 Lockheed Drive Redding, CA 96002,USA. For Manufacture Activity.
2 August 2012	7858968	Certificate Renewal Change the name of 'Isotron Ltd' and 'Isotron Limited' to 'Synergy Health Sterilisation UK Ltd' Removal of significant subcontractor 'Beam One' Scope Minor clarification.

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Date	Reference Number	Action
12 March 2014	7945802	Addition of sub-contractor: <ul style="list-style-type: none"> • Orchid BioCoat for Manufacturing • Catheter Research, Inc., D.B.A. Thomas Medical, Inc. for Manufacturing • Millstone Medical Outsourcing, LLC for Manufacturing and Packaging • Paragon Medical, Inc. for Manufacturing • Medical Modeling, Inc for Manufacturing Change of address for Sub contractor: AB Medical Technologies, Inc. to 20272 Skypark Drive Redding, California 96002

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Date	Reference Number	Action
14 November 2014	8135617	<p>Extension to scope to include "those aspects of Annex II related to the metrology in the design and manufacture of orthopaedic surgical planning software" and "aspects of the accuracy of metrology in the design and manufacture of surgical instruments".</p> <p>Addition of the following significant subcontractors: Steris Isoemdx RTC (South Facility), Advanced Engineering, Inc. and Eurocoating S.p.A.</p> <p>Change of address for Biomet UK limited (Waterton Industrial Estate).</p> <p>Addition of following activities for Biomet UK limited: design, development and Gas Plasma Sterilization.</p> <p>Removal of manufacture and Gas Plasma Sterilization activities for Biomet UK Limited (Murdock Road, Dorcan Industrial Estate).</p>
06 July 2015	8360383	<p>Addition of significant sub-contractors Synergy Health Ede B.V., Selenium Medical, N2 Biomedical and Steris Isomedix Services. Remove 'South Wales' from Biomet UK address.</p>
05 October 2015	8416518	<p>Addition of Orchid Bio-Coat at '23149 Commerce Drive, Farmington Hills, MI 48335' as manufacturer to list of subcontractors</p> <p>'Orchid Bio-Coat, 23149 Commerce Drive, Farmington Hills, Michigan, 48335, USA' is used as a HA coating subcontractor.</p>

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11 November 2015	8405625	Addition of Sterigenics as subcontractor for 'Other Critical Processes' Addition of activity 'Other Critical Processes' to Steris in Whitby.
29 November 2016	8647049	Significant subcontractor additions [Orchid Orthopedic Solutions, Oregon; Zimmer Inc., Warsaw; ZOM Ltd.; Iotron Industries Canada Inc.; Sterigenics, Lewis Center, OH; Synergy Health Westport Ltd.; Synergy Health Daniken AG; iuvo BioScience;] 'Gamma Sterilization' service added to Sterigenics, Gurnee, IL location in support of Design Dossier Review (EQ 10163046 SMO 8524900)
11 August 2017	8746977	Certificate Renewal Addition of Packaging activity for Changzhou Biomet Medical Devices Co., Ltd. Clarification of Sterilization type for: Centurion Sterilization Services, Steris Isomedix RTC, Steris Isomedix Services (1880 Industrial Drive), Steris Isomedix Services (435 Whitney Street) Change of Subcontractor names: Biomet 3i also trading as Implant Innovations to Biomet 3i also trading as Implant Innovations Inc Biomet France Sarl to Biomet France

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		Biomet Sports Medicine Also trading as Arthrotek, Inc. to Biomet Sports Medicine Also trading as Biomet Sports Medicine, Inc. Biomet UK Limited to Biomet UK Limited Also trading as Biomet UK Healthcare Ltd Catheter Research, Inc. D.B.A. Thomas Medical, Inc. to CatCenturion Sterilization Services A Division of Tri-State Hospital Supplyheter Research, Inc. D.B.A. Thomas Medical to Centurion Medical Products Corporation EBI, LLC. Doing business as Biomet Spine & Bone Healing Technologies doing business as Biomet Spine doing business as Biomet Bone Heali Osteobiologics to EBI, LLC. Db a Biomet Spine & Bone Healing Technologies db a Biomet Spine db a Biomet Bone Healing Technologies Greatbatch Medical Orthopaedics to Greatbatch Medical Huntsville Medical Products Also db a FMI Medical to Structure Medical LLC iuvo Biosciences to iuvo BioScience – Erie, LLC Medical Modeling Inc. to 3D Systems, Inc. N2 Biomedical to N2 Biomedical LLC Sterigenics to Sterigenics US, LLC (1003 Lakeside Drive, 305 Enterprise Drive and 344 Bonnie Circle)

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Date	Reference Number	Action
		<p>Steris Isomedix RTC, Steris Isomedix Services, Inc. and Steris Isomedix Services (435 Whitney Street) to Isomedix Operations, Inc. Steris Isomedix Services to Isomedix Corporation (Canada) Synergy Health Ede B.V. to Synergy Health AST, Ede Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Swindon) to STERIS Applied Sterilization Technologies Synergy Health Westport Ltd to Synergy Health Westport Ltd (Synergy Health - AST -Westport)</p> <p>Changes to address for subcontractors: Biomet France, Biomet Spain Orthopaedic SL, Biomet UK Limited (Dorcan), Catheter Research, Inc. D.B.A. Thomas Medical, Eurocoating S.p.A., 3D Systems, Inc., Orchid BioCoat, Sterigenics US, LLC (305 Enterprise Drive), Isomedix Operations, Inc. (2500 Commerce Drive), Synergy Health AST, Ede and STERIS Applied Sterilization Technologies Removal of Subcontractor Orchid BioCoat (21249 Bridge Street) Extension to scope to include: 'Those aspects of Annex II relating to the securing and maintaining sterility in the manufacture of sterile OR supplies and sterile instruments.'</p>

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16 August 2017	8796885	Addition of subcontractor "Zimmer Orthopedics Manufacturing Limited, Deerpark Industrial Estate, Oranmore, Galway, Ireland" for the activities of manufacture, packaging and control of sterilization
27 July 2018	8998300	Other critical processes added for Isomedix (Libertyville, IL)
29 November 2018	9628056	Addition of subcontractor Surface Dynamics
15 March 2019	7781060	Traceable to NB 0086.
10 October 2019	8992719	Addition of critical subcontractor APS Materials. Reinstatement of critical subcontractor Zimmer Orthopedics Manufacturing Limited, Galway.
17 January 2020	3089707	Addition of Sterigenics UK Limited to list of subcontractors for ETO sterilization.
29 June 2020	3045225	Certificate renewal Scope elements removed "lower extremity", "resorbable implants", "sterile acrylic bone cements", "oral, facial and cranial implants" EU Representative added "Biomet Global Supply Chain Center B.V, Hazeldonk 6530, 4836 LD Breda, The Netherlands" New critical subcontractors added "Shanghai JPY Ion-Tech Co., LTD, No.1168, Huijin Rd., Shanghai Qingpu Industrial Zone, 201707 China, PEOPLES REPUBLIC OF CHINA" for the activity "Gamma Sterilization", "APS Materials Inc, Unit 26A Waterford Ind Est, Cork Road, Waterford, Co. Waterford, Ireland" for the activity "Other Critical Processes"

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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 02461**
 Date: **2021-04-23**
 Issued To: **Biomet Orthopedics**
56 East Bell Drive
P.O Box 587
Warsaw
Indiana
46581
USA

Date	Reference Number	Action
		Location correction for the following critical subcontractors: From "Changzhou Biomet Medical Devices Co., Ltd, No. 235 Chuangxin Road, Export Processing Zone Xinbei, Changzhou, Jiangsu, 213031, China" TO " "Changzhou Biomet Medical Devices Co., Ltd, No. 235 Chuangxin Road, Export Processing Zone Xinbei District, Changzhou, Jiangsu, 213031, China" From "Biomet Fairlawn, 20-01 Pollitt, Fairlawn, New Jersey 07410, USA" TO "Biomet Fairlawn, 20-01 Pollitt Drive, Fairlawn, New Jersey 07410, USA" From "Biomet UK Limited, Murdock Road, Dorcan Industrial Estate, Swindon SN3 5HY, United Kingdom" TO "Biomet UK Healthcare Ltd, Dorcan One Hundred, Murdock Road, Swindon, SN3 5HY, United Kingdom" From "Eurocoating S.p.A, Via Al Dos de la Roda, 60 Z.I. Cire, Cire Pergine (TN), 38057, Italy" TO "Eurocoating S.p.A, Via Al Dos de la Roda, 60 Z.I. Cire 38057 Pergine Valsugana (TN), Italy" 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"

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Date	Reference Number	Action
		<p>From "Orchid Bio-coat, 23149 Commerce Drive Farmington Hills, Michigan 48335, USA" TO "23149 Commerce Drive Farmington Hills, Michigan 48335-2723 USA"</p> <p>From "Paragon Medical, Inc., 8 Matchett Industrial park Drive, Pierceton, Indiana, 46562, USA" TO "Paragon Medical, Inc., 8 Matchett Drive, Pierceton, Indiana, 46562, USA"</p> <p>From "Sterigenics US, LLC, 305 Enterprise Drive, Lewis Center, Ohio 43035, USA" TO "305 Enterprise Drive, Lewis Center, Ohio 43035-9418, USA"</p> <p>From "Steris Isomedix, RTC., South Facility, 2500 Commerce Drive, Libertyville, Illinois, 60048, USA" TO "2500 Commerce Drive, Libertyville, Illinois, 60048, USA"</p> <p>From "Synergy Health Ede BV, Morsestraat 3, 6716 AH Ede, The Netherlands" TO "Morsestraat 3, Ede, 6716 AH, The Netherlands"</p> <p>From "Medical Modeling Inc., 17301 W. Colfax Avenue, Suite 300, Golden, Colorado, 80401, USA" TO "3D Systems, Inc. 5381 South Alkire Circle Littleton, Colorado 80127 USA"</p> <p>Subcontractor change from "Medical Modeling Inc., 17301 W. Colfax Avenue, Suite 300, Golden, Colorado 80401, USA" TO "3D Systems, Inc. 5381 South Alkire Circle, Littleton, Colorado 80127, USA"</p>

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Date	Reference Number	Action
		<p>Removal of the following critical subcontractors "AB Medical Technologies, Inc.", "Biomet 3i also trading as Implant Innovations, Inc.", "Catheter Research, Inc. DBA. Thomas Medical, Inc", "EBI,LLC. ", "GreatBatch Medical products", "Millstone Medical Outsourcing, LLC, 8836 Polk Lane, Suite 100, Olive, Branch, Mississippi, 38654", Sterigenics, 1003 Lakeside Drive,Gurnee IL, 60031 USA", " Orchid BioCoat, 21249 Bridge street, Southfield, Michigan, 48034, USA"</p> <p>Activity "Packaging" added to critical subcontractor "Changzhou Biomet Medical Devices Co., Ltd"</p> <p>Activity "manufacture" removed from subcontractor "Steris Isomedix Services, 184 Crown Court, Whitby Ontario, L1N 7B1, Canada"</p> <p>Name correction for the following critical subcontractors:</p> <p>From "Biomet Sports Medicine also trading as Arthrotek, Inc." TO "Biomet Sports Medicine also trading as Biomet Sports Medicine, Inc"</p> <p>From "Biomet UK Limited" TO "Biomet UK Limited also trading as Biomet UK Healthcare Ltd."</p> <p>From "Centurion Sterilization services, A division of Tri-State Hospital Supply " TO "Centurion Medical Products Corporation"</p> <p>From "Huntsville medical products also dba FMI medical" TO "Structure Medical LLC"</p>

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Date	Reference Number	Action
		From "iuvo Bioscience - Erie, LLC" TO "Cosmed Group Inc." From "Orchid Bio-Coat" TO "Orchid Orthopedic Solutions LLC " From "Sterigenics, 344 Bonnie Circle, Corona, California, 92880 USA" TO "Sterigenics US, LLC" From "Steris Isomedix, RTC." TO "Isomedix Operations, Inc." From "Sterigenics, 305 Enterprise Drive, Lewis Center, Ohio 43035, USA" TO "Sterigenics US, LLC" From "Steris Isomedix Services, 184 Crown Court, Whitby Ontario, L1N 7B1, Canada " TO "STERIS Applied Sterilization Technologies ULC" From " Steris Isomedix Services, 435 Whitney Street, Nothrborough Massachusetts, 01532, USA" TO "Isomedix Operations, Inc." From "Steris Isomedix Services, Inc., North Facility, 1880 Industrial Drive, Libertyville, Illinois, 60048, USA" TO "Isomedix Operations, Inc." From "Surface Dynamics" TO "Surface Dynamics, LLC" From "Synergy Health Ede BV" TO "Synergy Health Ede BV (Location AST Ede)" From "Synergy Health Sterilisation UK Ltd (Synergy Health – AST-Reading)" TO "Synergy Health Sterilisation UK Ltd" From "Synergy Health Sterilisation UK Ltd (Synergy Health – AST-Swindon)" TO "Synergy Health Sterilisation UK Ltd"

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Date	Reference Number	Action
15 December 2020	3102134	Update of activities for Millstone Medical Outsourcing LLC, Massachusetts to include "Labelling".
25 February 2021	3166012	Addition of Sterigenics US LLC, Salt Lake City & Sterigenics US, LLC, Willowbrook to list of subcontractors for EtO sterilisation.
23 April 2021	3421953	Extension of scope to include "The design and development of image processing software for simulation of femoroacetabular impingement". Addition of critical subcontractor "Biomet Global Supply Chain Center B.V. – Clinical Graphics, Molengraaffsingel 10, 2629 JD Delft, The Netherlands" for the activity of "design".
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
18 March 2022	3635545	Addition of subcontractor "Synergy Health Sterilisation UK Ltd." (Daventry) for the activity "Radiation (Gamma Sterilization)". Removal of subcontractor "Synergy Health Sterilisation UK Ltd" (Swindon).
01 June 2022	3141340	Reviewed for the use of eIFU for MRI safety information. Assessed per EU No. 207/2012

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Date	Reference Number	Action
23 August 2022	3512004	Removal of the significant subcontractor Centurion Medical Products Corporation (Howell, MI, USA) for EtO Sterilization

23 August 2022

Biomet Orthopedics
56 East Bell Drive
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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 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 02641	93/42/EEC Annex II excluding Section 4	3512004	Removal of the significant subcontractor Centurion Medical Products Corporation (Howell, MI, USA) for EtO Sterilization

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