

EC Certificate - Full Quality Assurance System

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

No.**CE 77316****Issued To:**

**DePuy Mitek
A Johnson & Johnson Company
325 Paramount Drive
Raynham
Massachusetts
02767
USA**

In respect of:

The design, development and manufacture of absorbable and non absorbable tissue fixation devices, anchors, fasteners, orthopaedic screws, orthopaedic washers, sutures, drill bits, reamers and orthopaedic implant accessories, RF surgical equipment and sterile electrodes, powered accessories, fluid management and tissue debridement systems and accessories for suction and irrigation for use in arthroscopy.

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: **2003-11-15**

Date: **2021-05-21**

Expiry Date: **2023-11-14**

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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.

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List of Significant Subcontractors

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

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Date: **2021-05-21**
Issued To: **DePuy Mitek
A Johnson & Johnson Company
325 Paramount Drive
Raynham
Massachusetts
02767
USA**

Subcontractor:**Service(s) supplied**

Advantis Medical, Inc
DBA Avalign Cases and Trays
2121 Southtech Drive, Ste 600
Greenwood
IN
46143
USA

Manufacture

Apex Resource Technologies
17 Downing Three – Building 1
Pittsfield
Massachusetts
01201
USA

Manufacture

BGS Beta-Gamma-Service GmbH & Co KG
Fritz-Kotz-Strasse 16
Wiehl
51674
Germany

Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
Cam Bioceramics B.V. Zernikedreef 6 Bio Science Park 2333 CL Leiden The Netherlands	Crucial Supplier
China Biotech Corporation No. 10, 33 rd., Road, Taichung Industrial Park, Taichung, Taiwan	Radiation (Gamma Sterilization)
Classic WireCut Co., Inc 28210 Constellation Road Valencia California 91355 USA	Manufacture Packaging Radiation (Gamma Sterilization)

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Subcontractor:

Service(s) supplied

Confluent Medical Technologies Inc
 60 Commerce Drive
 Warwick
 RI
 02886
 USA

Manufacture

DePuy Ireland UC
 Loughbeg
 Ringaskiddy
 Co. Cork
 Ireland

EU Representative

DePuy Orthopaedics, Inc
 50 Scotland Boulevard
 Bridgewater
 Massachusetts 02324
 USA

Final Inspection

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Subcontractor:**Service(s) supplied**

DSM Biomedical B.V.
Urmonderbaan 22
6167 RA Geleen
The Netherlands

Crucial Supplier

DSM Biomedical Inc.
5750 Martin Luther King Jr. Highway
Greenville
North Carolina
27834
USA

Crucial Supplier

Ethicon Inc
655 Ethicon Circle
Cornelia
Georgia
30531
USA

Manufacture

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Subcontractor:

Service(s) supplied

Ethicon Inc
 3348 Pulliam Street
 San Angelo
 Texas
 76905
 USA

Other Critical Processes
Packaging

Ethicon, LLC
 Highway 183 Km 8.3
 San Lorenzo 00754
 Puerto Rico
 USA

Manufacture

Foster West Corporation
 4336 Losee Rd
 Suite 7
 North Las Vegas
 Nevada
 89030
 USA

Crucial Supplier

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Subcontractor:	Service(s) supplied
Gyrus Medical Limited Fortran Road St Mellons Cardiff CF3 0LT United Kingdom	Manufacture
Harmac Medical Products, Inc 2201 Bailey Avenue Buffalo New York 14211-1797 USA	Manufacture
Harmac Medical Products, Inc. H3 de Tijuana, S. de RL de CV Calle Maquiladoras No. 320-A Col.Ciudad Industrial Nueva Tijuana CP 22500 Mexico	Manufacture

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Subcontractor:

Service(s) supplied

Hemodia Maghreb
 23-25 rue Ibn El Jazzar
 Sidi Daoued La Marsa
 2046
 Tunisia

Manufacture

Hemodia SAS
 85 Rue du Chene Vert
 Labège
 31670
 France

Manufacture

Henke-Sass, Wolf GmbH
 Keltenstrasse 1
 78532 Tuttlingen
 Germany

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 Massachusetts
 02767
 USA**

Subcontractor:

Service(s) supplied

Invibio
 3A Caledon CT
 Greenville
 South Carolina
 29615
 USA

Crucial Supplier

Isomedix Operations, Inc.
 1435 Isomedix Place
 El Paso
 Texas
 79936
 USA

Radiation (Gamma Sterilization)

Isomedix Operations, Inc.
 1000 S. Sarah Place
 Ontario
 California
 91761
 USA

Radiation (Gamma Sterilization)

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02767
USA

Subcontractor:

Service(s) supplied

Isomedix Operations, Inc.
 435 Whitney Street
 Northborough
 Massachusetts
 01532
 USA

Radiation (Gamma Sterilization)

Johnson & Johnson do Brasil Industria
 e Comercio de Produtos para Saude Ltda
 Rod. Presidente Dutra – KM 154
 Sao Jose dos Campos
 Sao Paulo
 12240-908
 Brasil

Manufacture

J-Pac LLC
 25 Centre Road, Somersworth
 New Hampshire 03878
 USA

Manufacture

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Subcontractor:

Service(s) supplied

Kimball Electronics
 Poland sp. z.o.o.
 ul. Poznanska 1/C
 62-080
 Tarnowo Podgorne,
 Poland

Manufacture

Lake Region Medical
 6420 Zane Avenue North
 Brooklyn Park
 Minnesota
 55429
 USA

Crucial Supplier

Medistri S.A.
 Route de L'Industrie 96
 1564 Domdidier
 Switzerland

ETO Sterilization

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Subcontractor:

Service(s) supplied

Medos SARL
 Puits Godet 20
 Neuchâtel CH-2000
 Switzerland

Final Inspection
Manufacture

New Deantronics Taiwan Ltd
 12F, No51, Sec 4, Chong Yang Road
 Tu Cheng District
 New Taipei City
 23675
 Taiwan

Manufacture

NG Instruments, Inc.
 Dba Avalign Cutting Instruments
 4643 North State Road 15
 Warsaw
 Indiana
 46582
 USA

Manufacture

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 USA**

Subcontractor:

Service(s) supplied

Orchid Unique
 DBA Orchid Bridgeport
 6688 Dixie Hwy
 Bridgeport
 Michigan
 48722
 USA

Manufacture

Paragon Medical Inc.
 125 W 1000 South
 Smithfield
 Utah
 84335
 USA

Manufacture

Plastibell Mar-Lee USA
 180 Authority Drive
 Fitchburg
 Massachusetts
 01420
 USA

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 USA**

Subcontractor:	Service(s) supplied
Plexus Corporation 2400 Millbrook Drive Buffalo Grove Illinois 60089 USA	Manufacture
Professional Contract Sterilization, Inc 40 Myles Standish Boulevard Taunton Massachusetts 02780-1026 USA	ETO Sterilization
Providien Device Assembly, LLC Ferrocarriil 17030 Interior 16 &17 Colonia Ninos Heroes Este Tijuana CP. 22120 Mexico	Manufacture

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Subcontractor:

Service(s) supplied

Purac
 Arkelsedijk 46
 Gorinchem,
 NL-4200 AA
 The Netherlands

Crucial Supplier

Sor-Van Radiation Ltd.
 Kiryat Soreq
 PO Box 214
 Yavne 8180000
 ISRAEL

Radiation (Gamma Sterilization)

Sterigenic Belgium (Petit-Rechain) SA
 Zoning Industriel de Petit Rechain
 Avenue Andre Ernst 21
 Verviers, Liege
 B-4800
 Belgium

ETO Sterilization

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 USA**

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	ETO Sterilization
Steris Applied Sterilisation Technologies (Formerly Synergy Health Sterilisation UK Ltd) Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	Radiation (Gamma Sterilization)
Symmetry Medical Manufacturing, Inc 486 West 350 North Warsaw Indiana 46582 USA	Manufacture

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 USA**

Subcontractor:	Service(s) supplied
Synergy Health Daniken AG Hogenweidstrasse 6 Daniken CH-4658 Switzerland	Radiation (Gamma Sterilization)
Synthes GmbH Industriestrasse 28 CH-2545 Selzach Switzerland	Final Inspection
Systagenix Wound Management Limited (an affiliate of Systagenix Wound Management Manufacturing Limited) Gargrave North Yorkshire BD23 3RX United Kingdom	Manufacture

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USA

Subcontractor:

Service(s) supplied

TAG Medical Products Corporation Ltd
 Kibbutz Gaaton
 2513000
 ISRAEL

Manufacture

Teleflex Medical OEM
 1295 Main Street
 PO Box 219
 Coventry
 CT 06238
 United States

Manufacture

Tessy Plastics
 488 State Route 5 west
 Elbridge
 New York
 13060
 USA

Crucial Supplier

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02767
USA

Subcontractor:

Service(s) supplied

Top Clean Injection
 ZI Les Torrents
 Peschadoires
 63920
 France

Manufacture
Other Critical Processes
Packaging

Trokamed GmbH
 Kleine Breite 17
 78187 Geisingen
 Germany

Manufacture

Venusa de Mexico S.A. de C.V.
 A Lake Region Medical Company
 Calle Hertz 1525-6
 Parque Industrial J. Bermudez
 Ciudad Juarez
 Chihuahua
 32470
 Mexico

Manufacture

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USA

Subcontractor:

Service(s) supplied

Viant AS&O Holdings, LLC
 45 Lexington Drive
 Laconia
 New Hampshire
 03246
 USA

Final Inspection
Manufacture
Packaging

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Date	Reference Number	Action
15 November 2003	-	First issue- Transfer from TUV
23 August 2004	-	Addition of RF surgical equipment and sterile electrodes to scope and addition of Gyrus Medical Ltd subcontractor
16 December 2004	-	Addition of sub-contractors
4 February 2005	-	Addition of Ethicon Inc (San Angelo, Texas) as a subcontractor
2 June 2005	-	Addition of subcontractors Ethicon SARL and CSSR to align with CE 77321
19 July 2005	-	Change of ETO sterilisation cycle at subcontractor PCS Inc affecting CE 77326, CE 77323, CE 77320, CE 77328 and CE 77321. Addition of subcontractors Ethicon Inc and TAG Medical Products to align with CE 77321, and change of Legal Manufacturing address.
07 September 2005	-	Alignment with certificate CE 77322, Addition of Steris Corporation/Isomedix Services as a subcontractor for sterilisation.
2 December 2005	-	Addition of Sterigenics (Belgium) ETO sterilization subcontractor
24 April 2006	-	Change to sub-contractor name from DePuy Mitek Utah to Paragon Medical, Inc. Addition of Advantis Medical, Symmetry Medical and J-Pac LLC as sub-contractors for manufacture

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Date	Reference Number	Action
19 September 2006	-	Addition of "Studer Draht - Und Kabelwerk AG as Gamma Sterilization sub-contractor
05 June 2007	-	Addition of 'Gyrus ACMI' in Mexico as a significant subcontractor for manufacture and 'Sterigenics' for sterilization
09 April 2008	7194772	Removal of "ExoJet" from the certificate's scope. Addition of Lacey Manufacturing, New Deantronics Ltd., and Hemodia SAS to the significant list of subcontractors for manufacturing. Addition of China Biotech Corporation, Bioster S.p.A. "24068 Seriate (BG) Italy", Bioster S.p.A. "24050 Calcinato (BG) Italy", and IONISOS to the significant list of subcontractors for sterilization.
03 September 2008	7272968	Addition of Medistri SA to the list of significant subcontractors for sterilization
07 October 2008	7165101	Scope extension to include "Cartilage Autograft Implantation System (CAIS) and powered accessories" to certificate and addition of 3 new significant sub contractors <ul style="list-style-type: none"> a) Concordia Manufacturing Ltd, RI 02816, for manufacturing b) J&J Medical, Ethicon, BD23 3RX for manufacturing c) Steris Isomedix Services, Inc. Northborough, MA 01532, for Gamma Sterilization

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Date	Reference Number	Action
13 November 2008	7282553	Certificate renewal and addition of Steris Corporation Isomedix Services, Vega Alt to the significant list of sub contractors for Gamma Sterilization
18 November 2008	7293925	Addition of Ethicon LLC in San Lorenzo for manufacturing sub contractor activity
05 August 2009	7341024	Addition of subcontractors; 'Apex Resource Technologies' for Manufacture, 'Sor-Van Irradiation Ltd' for Sterilization and 'DePuy International Ltd' for EU Representative Change of name for subcontractors; From 'Studer Draht-Und Kabelwerk AG' to 'LEONI Struder AG', from 'J&J Medical Ethicon' to 'Systagenix Wound Management Limited', from 'Ethicon SARL' to 'Depuy Mitek SARL' Change of address of 'Concordia Manufacturing LLC' to 'Warwick, RI 02886'
27 November 2009	7457465	Addition of subcontractor; 'BGS Beta-Gamma-Service GmbH & Co. KG' for Gamma Sterilisation

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Date	Reference Number	Action
29 July 2010	7523326	<p>Scope extension to include "fluid management systems and accessories for suction and irrigation for use in arthroscopy"</p> <p>Addition of subcontractors:</p> <p>Manufacture & EU Representative: Future Medical Systems (FMS), Saint Jeannet, France</p> <p>Manufacture: Del Mar Dedicall Devices, S.A. de C.V., Mexico STE Cofat SARL, Sidi Daoued La Marsa, Tunisia Accellent, Inc., New Hampshire, USA Sopro-Comeg GmbH, Tuttlingen, Germany Plexus Service Corporation, Illinois, USA</p> <p>Packaging & Other Critical Processes: Medical Packaging, Vaulx-EN-Velin, France</p> <p>Manufacture, Packaging & Other Critical Processes: Top Clean Injection, Peschadoires, France</p> <p>Sterilisation: Sterigenics SAS, Anse, France Sterigencis SAS, Rantigny, France Sterylene, Gien, France</p>

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Date	Reference Number	Action
		Isotron Ltd. SN2 8XS, UK Change of address for subcontractors: New Deantronics Ltd. to " 12F, No.51, Sec 4, Chong Yang Road, Taipei Country, Taiwan" Paragon Medical Inc. to " 125 E 1000 South, Utah, USA."
21 September 2010	7582221	Addition of Kimball Electronics Poland sp. z o.o., Poland as manufacturing site.
23 February 2011	7635658	Addition of subcontractors; 'Venusa de Mexico S.A de C.V an Accellent Company' for Manufacture and 'STERIS Isomedix Services' for Sterilisation. Correction to addresses of: <ul style="list-style-type: none"> • Depuy Mitek SARL • CSSR. S.A. • Sterigenics Belgium • Medistri SA

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Date	Reference Number	Action
28 June 2011	7676405	<p>Change to address for three significant subcontractors</p> <p>From: Gyrus ACMI, Inc Parque Industrial Angostua, Carretera Saltillo, Zacatecas Km. 4.5, C.P. 25315 Saltillo, Coahuila, Mexico.</p> <p>To: MANUFACTURAS ZAPALINAME SA De CV, Dept. Gyrus ACMI Nave 28, Carretera Saltillo-Zacatecas KM 4.5, Parque Industrial La Angostura, Saltillo, MEXICO C.P. 25315.</p> <p>From: Kimball Electronics, Poland sp. Z.o.o, Ul. Marcelinska 92/94, Ul. 60-324 Poznan Poland.</p> <p>To: Kimball Electronics Poland sp. z.o.o, ul. Poznanska 1/C, 62-080 Tarnowo Podgorne, Poland.</p> <p>From: DePuy Mitek, A Johnson & Johnson Company, 50 Scotland Boulevard, Massachusetts 02324, USA.</p> <p>To: DePuy Mitek, A Johnson & Johnson Company, 50 Scotland Boulevard, Bridgewater, Massachusetts 02324, USA.</p>
26 April 2012	7828531	<p>Addition of significant subcontractor, Trokamed GmbH, Geisingen, for Manufacturing activities</p> <p>Change of name to significant subcontractor, from Isotron Plc to Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Swindon).</p> <p>Removal of significant subcontractor, Future Medical Systems S.A.</p>

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 77316**
 Date: **2021-05-21**
 Issued To: **DePuy Mitek
 A Johnson & Johnson Company
 325 Paramount Drive
 Raynham
 Massachusetts
 02767
 USA**

Date	Reference Number	Action
20 December 2012	7919259	<p>Addition of significant subcontractors;</p> <ol style="list-style-type: none"> 'Harmac Medical Products, Inc., 2201 Bailey Avenue, Buffalo, NY 14211-1797, USA for the activity of manufacture. 'Integra Biotechnical LLC, 2755 Dos Aarons Way, Suite B, Vista, California 92081, USA for the activity of manufacture 'Integra Biotechnical, S.A. de C.V., Calle Cipres No. 5A, 7, 8, 9, 12, 15, Centro Industrial Las Brisas, Tijuana, Baja California 22320, Mexico' for the activity of manufacture 'STERIS Isomedix Services, 43425 Business Park Drive, Temecula, California, 92590, USA' for the activity of sterilization <p>Address change for the the subcontractor 'Classic Wire Cut Co.,Inc' to '28210 Constellation Road, Valencia CA 91355, USA'</p> <p>Name changes for significant subcontractors:</p> <ol style="list-style-type: none"> 'Concordia Manufacturing, LLC' to 'Biomedical Structures LLC' 'LEONI Studer AG' to 'Synergy Health Däniken AG' 'DePuy Mitek SARL' to 'Medos SARL'

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12 June 2013	8003098	<p>Addition of the significant subcontractor:</p> <ol style="list-style-type: none"> 'Johnson & Johnson do Brasil Industria, e Comercio de Produtos para Saude Ltda., Rod. Presidente Dutra - KM 154, Sao Jose dos Campos, Sao Paulo, 12240-908, Brasil' for the activity of manufacture. 'Sterigenics US, LLC, 687 S. Wanamaker Avenue, Ontario, California, 91761, USA' for the activity of sterilization 'DePuy Orthopaedics, Inc, 50 Scotland Boulevard, Bridgewater, Massachusetts 02324, USA' for the activity of Packaging <p>Removal of the significant subcontractor:</p> <ol style="list-style-type: none"> DePuy Mitek, A Johnson & Johnson Company, 50 Scotland Boulevard, Bridgewater, Massachusetts 02324, USA for the activity of Manufacture Integra Biotechnical LLC, 2755 Dos Aarons Way, Suite B, Vista, California 92081, USA for the activity of Manufacture

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Date	Reference Number	Action
		Change of Address for significant subcontractor: Integra Biotechnical, S.A. de C.V. from 'Calle Cipres No. 5A, 7, 8, 9, 12, 15, Centro Industrial Las Brisas, Tijuana, Baja California 22320, Mexico' to 'Avenida Ferrocarril #17030 Interior 16 & 17, Col. Ninos Heroes Este C.P. 22120, Tijuana, Baja California, Mexico'
29 October 2013	8032585	Renewal of certificate Removal of the significant subcontractor: "Ethox International", "Del Mar Medical Devices S.A. de C.V", "Medical Packaging" & "DePuy Mitek" Clarification of Address for significant subcontractors: "Gyrus Medical Ltd", "Venusa de Mexico S.A de C.V", "TAG Medical Products Corporation Ltd", "Hemodia SAS", "BGS Beta-Gamma-Service GmbH & Co KG" & "MANUFACTURAS ZAPALINAME SA de CV." Change of Name for significant subcontractors: "Hemodia Maghreb" from "STE Cofact SARL"

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Date	Reference Number	Action
		"Symmetry Medical Manufacturing, Inc" from "Symmetry Medical USA, Inc." "STERIS Isomedix Services" from "Steris Corporation Sterilization Isomedix Services" Change from Packaging to Final inspection for activity supplied by "DePuy Orthopaedics, Inc., MA"
20 January 2015	8224958	Addition of significant subcontractors; 1. Teleflex Medical, 1295 Main Street, PO Box 219, Coventry 06238, USA, for Manufacturing. 2. CAM Implants, Zernikedreef 6, Leiden, 2333CL, Netherlands as a Crucial Supplier 3. Foster West, 4336 Losee Rd, Suite 8, North Las Vegas, Nevada, USA as a Crucial Supplier 4. Invibio, 3A Caledon CT, Greenville, South Carolina, 29615, USA as a Crucial Supplier 5. Corbion, Arkelsedijk 46, 4206 Ac, Gorinchem, Netherlands as a Crucial Supplier

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Date	Reference Number	Action
		6. Mar-Lee Companies, 180 Authority Drive, Fitchburg, Massachusetts, 01420, USA, For Manufacturing 7. Harmac Medical Products, Inc., H3 de Tijuana, S. de RL de CV, Calle Maquiladoras No. 320-A, Col. Ciudad Industrial, Nueva Tijuana, CP 22500, Mexico, for Manufacturing 8. DSM Biomedical Inc., 5900 M.L. King Jr. Highway, Greenville, North Carolina, 27834, USA, as a Crucial Supplier 9. DSM Biomedical B.V., Koestraat 1, Geleen, 6167 RA, Netherlands as a Crucial Supplier.
28 May 2015	8336129	Change of Name for significant subcontractors: "Lake Region Medical" from "Accellent, Inc" "Venusa de Mexico S.A. de C.V a Lake Region Medical Company" from "Venusa de Mexico S.A. de C.V an Accellent Company"
10 May 2016	8488281	Addition of subcontractors: 1. MediVision Inc. 4883 E. La Palma Ave Suite 503, Anaheim, California 92807, USA, For Manufacturing 2. Steris Isomedix Services 1000 S. Sarah Place, Ontario, California 91761 USA, for Sterilization Change to address for subcontractor Sterigenics Belgium (Petit-Rechain) SA

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Date	Reference Number	Action
26 September 2016	8486112	Addition of significant subcontractor 'Tessy Plastics, Box 160, Route 5, West Elbridge, NY 13060, USA' for the activity of Crucial Supplier
17 August 2017	8730299	Change of subcontractor name from "Biomedical Structures, LLC" to "Confluent Medical Technologies, Inc."
08 June 2018	8901990	Scope amended to remove 'cartilage autograft implantation system (CAIS)' Removal of: Bioster S.p.A. (Seriante) Bioster S.p.A (Calciate) CSSR. S.A. IONISOS (Dagneux) Sterigenics SAS (Rantigny) Sterigenics SAS (Anse) Sterigenics US LLC (Fort Worth, TX) STERIS Isomedix Services (Vega Alta) STERIS Isomedix Services (Temecula) STERIS Isomedix Services (Whippany) Sterylene. Subcontractor Changes:

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Date	Reference Number	Action
		Ethicon, Inc (San Angelo, TX) – remove "ETO Sterilisation" China Biotech Corporation - change activity from "Sterilisation" to "Gamma Sterilisation" Medistri SA - change activity from "Sterilisation" to "ETO Sterilisation" Sor-Van Irradition Ltd - change activity from "Sterilisation" to "Gamma Sterilisation" Sterigenics US, LLC (Ontario) - change activity from "Sterilisation" to "ETO Sterilisation" STERIS Isomedix Services (Ontario) - change activity from "Sterilisation" to "Gamma Sterilisation" STERIS Isomedix Services (El Paso) - change activity from "Sterilisation" to "Gamma Sterilisation" Synergy Health Sterilisation UK (Swindon) - change activity from "Sterilisation" to "Gamma Sterilisation"
08 November 2018	9647228	Certificate renewal. Change of scope from "fluid management systems" to "fluid management and tissue debridement systems". Removal of "absorbable adhesion devices, fluidjet based surgical system" from the scope. Change of name of "Advantis Medical, Inc" to "Advantis Medical, Inc DBA Avalign Cases and Trays"; "CAM Implants" to "CAM Bioceramics B.V."; "Corbion" to Purac"; "Foster West" to "Foster

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		<p>West Corporation "; "Integra Biotechnical, S.A. de C.V " to "Providien Device Assembly, LLC "; "Johnson & Johnson do Brasil Industria" to "Johnson & Johnson do Brasil Industria"; "Mar-Lee Companies" to "Plastibell Mar-Lee USA"; "New Deantronics Ltd" to "New Deantronics Taiwan Ltd"; "Sor-Van Irradiation Ltd" to "Sor-Van Radiation Ltd."; "Sterigenics US LLC and Steripro Laboratories " to "Sterigenics US LLC"; "STERIS Isomedix Services" at Ontario, El Paso and Northborough to "Isomedix Operations, Inc"; "Synergy Health Sterilisation UK Ltd (Synergy Health – AST – Swindon)"; "Steris Applied Sterilisation Technologies (Formerly Synergy Health Sterilisation UK Ltd)"; "Systagenix Wound Management Limited" to "Systagenix Wound Management Limited (an affiliate of Systagenix Wound Management Manufacturing Limited)"; "Teleflex Medical" to "Teleflex Medical OEM"; "Venusa de Mexico S.A. de C.V. An Accellent Company" to "Venusa de Mexico S.A. de C.V. A Lake Region Medical Company"</p> <p>Address revision for Apex Resource Technologies, DSM Biomedical B.V., DSM Biomedical Inc., Foster West Corporation, Hemodia Maghreb, Hemodia SAS, Providien Device Assembly, LLC, New Deantronics Taiwan Ltd, Sterigenic Belgium (Petit-Rechain) SA, Sterigenics US, LLC, Synergy Health Daniken AG, TAG Medical Products Corporation Ltd, Teleflex Medical OEM, Tessy Plastics.</p>

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Date	Reference Number	Action
		Addition of Henke-Sass, Wolf GmbH, NG Instruments, Inc., Orchid Unique. For activity of Manufacture Removal of Lacey Manufacturing Company LLC, Manufacturas Zapaliname SA de CV Addition of Packaging and Gamma Sterilisation activities for Classic WireCut Co., Inc Addition of Packaging and Final Inspection activities for Lake Region Medical Addition of Final Inspection activity for Medos SARL.
28 February 2019	7781003	Traceable to NB 0086
20 November 2020	3297046	Addition of Crucial Supplier Lake Region Medical (Brooklyn Park, MN) and change of name of subcontractor Lake Region Medical at 45 Lexington Drive, Laconia NH to Viant AS&O Holdings, LLC
21 May 2021	3443490	Change of EU Representative from DePuy International Limited to DePuy Ireland UC.

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
18 July 2022	3602458	Addition of subcontractor: Synthes GmbH Removal of the following subcontractors: <ul style="list-style-type: none">- Sopro-Comeg GmbH- MediVision Inc.

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18 July 2022

DePuy Mitek
A Johnson & Johnson Company
325 Paramount Drive
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Massachusetts
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USA

To whom it may concern,

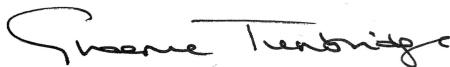
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

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 77316	93/42/EEC Annex II excluding Section 4	3602458	Addition of subcontractor: Synthes GmbH Removal of the following subcontractors: <ul style="list-style-type: none">- Sopro-Comeg GmbH- MediVision Inc.

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