

EC Certificate - Full Quality Assurance System

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

No. CE 00520
Issued To: **Biomet UK Limited**
Waterton Industrial Estate
Bridgend
CF31 3XA
United Kingdom

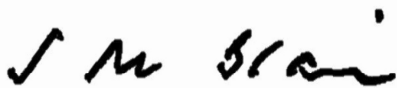
In respect of:

Design, development and manufacture of hip, knee, shoulder and upper and lower extremity orthopaedic joint replacement implants, and their associated accessories and instruments and trial orthopaedic joint replacement devices, femoral endoprostheses, osteosynthesis devices, spinal reconstruction devices, reusable and sterile single-use surgical instruments intended for connection to active devices.

Those aspects of Annex II related to the obtaining of sterility in the assembly of orthopaedic surgical instrument kits following Article 12 of the directive.

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):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **1995-02-28**

Date: **2017-07-26**

Expiry Date: **2022-07-31**

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

List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
ABSSAC Limited Unit E1A Enterprise Centre Enterprise Way Evesham WR11 1GS United Kingdom	Crucial Supplier
Allegheny Technologies Ltd Granby Avenue Garretts Green Birmingham B33 0SP United Kingdom	Crucial Supplier
Apex (Guangzhou) Tools & Orthopedics Co. No. 25, Yonghua Road Yonghe, GETDD Guangzhou // Guangdong 511356 China	Manufacture

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Subcontractor:	Service(s) supplied
Aragogamma Ctra. Granollers-Cardedeu, Km.3.5 Les Franqueses del Vallés Barcelona 08520 Spain	Sterilization
ATC Ltd 17 Perrywood Business Park Honeycrock Lane Redhill Surrey RH1 5JQ United Kingdom	Manufacture
ATI Metals PO Box 5030 Ashcraft Avenue Monroe North Carolina 28111-5030 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
Biomet 3i Dental Ibérica (VLC) c/ Islas Baleares, 50 Pol. Ind. Fuente del Jarro Paterna Valencia 46988 Spain	Manufacture
Biomet Deutschland GmbH Gustav-Krone-Str 2 14167 Berlin Germany	Design Manufacture
Biomet Fairlawn 20-01 Pollitt Drive Fairlawn New Jersey 07410 USA	Crucial Supplier

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Biomet France Sarl Plateau de Lautagne Valence 26000 France	Design Manufacture
Biomet Orthopedics PO Box 587 56 East Bell Drive Warsaw Indiana 46581 USA	Design Manufacture
Biomet Spain Orthopaedics S.L. Calle Islas Baleares 50 PG Fuente de Jarro 46988 Paterna Valencia Spain	Design Manufacture

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Subcontractor:	Service(s) supplied
Biomet UK Limited Murdock Road Dorcan Industrial Estate Swindon SN3 5HY United Kingdom	Design Development
Cambioceramics Zervkedreef 6 Leiden 2333 CK The Netherlands	Crucial Supplier
Carpenter Technology UK Ltd Adams Way Arden Forest Ind. Est. Springfield Business Park Alcester B49 6PU United Kingdom	Crucial Supplier

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CeramTec GmbH Medical Products Division CeramTec-Weg 1 95615 Marktredwitz Germany	Manufacture
Ceramtec GmbH Medical Technology Division CeramTec Platz 1-9 D-73207 Plochingen Germany	Manufacture
Changzhou Biomet Medical Devices Co., Ltd 235 Chuangxin Road Export Processing Zone, Xinbei Changzhou, Jiangsu 213031 China	Manufacture Packaging

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Subcontractor:	Service(s) supplied
DKSH AG PO Box 888 Wiesenstrasse 8 Zurich 8034 Switzerland	Crucial Supplier
DOT GmbH Charles-Darwin-Ring 1 a 18059 Rostock Germany	Manufacture
Ensinger Limited Wilfried Way Tonyrefail Mid Glamorgan CF39 8JQ United Kingdom	Crucial Supplier

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Subcontractor:	Service(s) supplied
Eurocoating SPA Via Al Dos De La Roda Cire Pergine 38057 Italy	Crucial Supplier
Invibio Ltd Invibio Technology Centre Hillhouse International Thornton Cleveleys Lancashire FY5 4QD United Kingdom	Crucial Supplier
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	Sterilization

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Subcontractor:	Service(s) supplied
Jossi Orthopaedics Ltd. Alte Landstrasse 54 Islikon CH-8546 Switzerland	Manufacture
Orchid Orthopaedic Solutions Parkway Close Parkway Industrial Estate Sheffield S9 4WH United Kingdom	Crucial Supplier Manufacture
Powder Alloy Corporation 101 Northeast Drive Loveland Ohio 45140 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
Quadrant EPP GMBH Max-Planck-Str. 11 Vreden NRW 48691 Germany	Crucial Supplier
Sanatmetal Orthopaedic & Traumatologic Equipment Manufacturer Ltd. Faiskola u. 5. 3300 Eger Hungary	Manufacture
SHANGHAI JPY ION-TECH. CO., LTD. NO.1168, Huijin Rd Shanghai Qingpu Industrial Zone 201707 Shanghai China	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Sulzer Metco UK Ltd (Now Oerlikon Metco) Suflex Estate Risca NP11 6YD United Kingdom	Crucial Supplier
Symmetry Medical Sheffield Beulah Road Sheffield S6 2AN United Kingdom	Manufacture
SYNERGY HEALTH MARSEILLE MIN 712 Les Arnavaux 13323 Marseille Cédex 14 France	Gamma Sterilization

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Synergy Health Sterilisation UK Ltd Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom	Sterilization
Synergy Health Sterilisation UK Ltd Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	Sterilization
United Orthopedic Corporation 12F, No. 80, Sec. 1, Chenggong Road Yonghe Dist New Taipei City 23452 Taiwan	Manufacture

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Subcontractor:	Service(s) supplied
United Orthopedic Corporation No. 16, Luke 1st Rd Luzhu Dist Kaohsiung City 82151 Taiwan	Manufacture
United Orthopedic Corporation No. 57, Park Avenue 2, Science Park Hsinchu City 30075 Taiwan	Manufacture
Vista Optics Cheshire Science Park Gorse Lane Widnes WA8 0RP United Kingdom	Crucial Supplier

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Subcontractor:	Service(s) supplied
VSMPO Tirus Ltd Unit 12, The I.O. Centre Nash Road Redditch B98 7AS United Kingdom	Crucial Supplier
X-Medics Scandinavia Sankt Knuds Vej 11 KLD. TH. Frederiksberg 1903 Denmark	Crucial Supplier
Zapp (GB) Ltd The Thorncliffe Distribution Centre Chapeltown Sheffield S35 2PW United Kingdom	Crucial Supplier

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Subcontractor:

Service(s) supplied

Zhejiang Biomet Medical Products
Co. Ltd.
980 Shenli Road
Jinhua
Zhejiang
321016
China

Manufacture

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Date	Reference Number	Action
28 February 1995	-	First Issue
17 February 1997	-	Swindon site now classified as a sub-contractor
09 September 1997	-	Post code change to address and Isotron (Swindon) added to the scope
09 October 1998	-	Company name change to Biomet Merck Ltd and Biomet Inc (Warsaw) added to sub-contractor list
04 February 1999	-	Biomet Merck (Berlin), Industria Quirurgicas de Levante S.A. (Valencia); Merck Biomaterial France (France) and Andarick QC added to the list of sub-contractors
01 August 2002	-	Scope change and 5 year renewal
14 May 2004	-	Change of company name to Biomet UK Limited
17 February 2005	-	"Wound drainage systems and associated operating room supplies" removed from the scope and made correction to an expiry date
21 March 2005	-	Addition of Isotron Plc (Reading) to list of sub-contractors
19 October 2005	-	Addition of icotec AG to the list of sub-contractors
25 May 2007	-	Certificate renewal Removal of "Andarick QC" from the list of significant sub-contractors Addition of "CeramTec AG" and "DOT GmbH" as manufacturing sites to the list of significant subcontractors. Clarification of scope

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28 August 2007	-	Addition of subcontractor activity "Gas Plasma Sterilization" for Swindon site
27 November 2008	7286777	Addition of CeramTec AG Marktrechwitz to the list of significant subcontractors for manufacturing
18 February 2009	7324523	Certificate correction including the addition of Biomet Orthopedics to the list of significant subcontractors for manufacture and design
18 March 2009	7328545	Addition of Zhejiang Biomet Medical Products Co., Ltd as a significant subcontractor for manufacture
30 November 2009	7444071	Change of address to Zhejiang Biomet Medical Products Co., Ltd
20 May 2011	7649662	Addition of two significant subcontractors, Apex (Guangzhou) Tools & Orthopedics, Guangzhou, China and Changzhou Biomet Medical Devices Co., Ltd., Jiangsu, China for manufacture activities.
02 August 2011	7687546	Addition of significant subcontractor, Sanatmetal Manufacturer of Orthopedic and Traumatologic Products for Manufacturing activities.

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Date	Reference Number	Action
18 July 2012	7858412	Certificate renewal Name change of Isotron limited to "Synergy Health Sterilisation UK limited" Name change of Ceramtec GmbH, Medical Applications Division to "Ceramtec GmbH, Medical Technology Division" Name change of CeramTecAG, Medical Applications Division to "CeramTecAG, Medical Technology Division" Addition of "Straits Orthopaedics (MFG) SDN. BHD, 2 Lengkok Teluk Kumbar 1, Jalan Teluk, Bayan Lepas, 11920 Penang, Malaysia" to the list of significant subcontractors for Manufacture Addition of "Symmetry Medical Sheffield, Beulah Road, Sheffield, S6 2AN, United Kingdom" to the list of significant subcontractors for Manufacture. Addition of "ATC Ltd, 17 Perrywood Business Park, Honeycrock Lane, Redhill, Surrey, RH1 5JQ, UK" to the list of significant subcontractors for Manufacture.

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Date	Reference Number	Action
30 October 2012	7908538	Certificate Reissue. Extension to Scope to include "Those aspects of Annex II related to the obtaining of sterility in the assembly of orthopaedic surgical instrument kits following Article 12 of the directive." Addition of the following significant subcontractors: "United Orthopedic Corporation, No. 57, Park Avenue 2, Science Park, Hsinchu City 30075, Taiwan, R.O.C" for manufacture. "United Orthopedic Corporation, 12F, No. 80, Sec. 1, Chenggong Road, Yonghe Dist, New Taipei City 23452 Taiwan, R.O.C" for manufacture. "United Orthopedic Corporation, No. 16, Luke 1st Rd, Luzhu Dist, Kaohsiung City 82151, Taiwan, R.O.C" for manufacture. "SHANGHAI JPY ION-TECH.CO.,LTD., NO.1168, Huijin Rd, Shanghai, Qingpu Industrial Zone, 201707 Shanghai, PEOPLE'S REPUBLIC OF CHINA" for Gamma Sterilization.
3 July 2013	8013081	Addition of Sub contractor for Manufacturing: Biomet 3i Dental Ibérica (VLC), C/ Islas Balearus, 50, Pol. Ind. Fuente del Jarro, Paterna, Valencia, Spain, 46988
14 April 2014	8108242	Addition of significant subcontractor Jossi Orthopaedics for manufacturing Removal of manufacturing activity from the Biomet UK Limited subcontractor site

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01 August 2014	8108737	Addition of packaging as an activity for Changzhou Biomet Medical Device co. Ltd.
07 September 2015	8410228	Addition of Steris Isomedix Services, Inc. (North Facility) and Aragogamma S.A. for sterilization and Biomet Fairlawn as a crucial supplier. Removal of Straits Orthopaedics as significant subcontractor Removal of Andarik QC as significant subcontractor due to error this was kept on the certificate.
05 October 2015	8416518	Addition of Orchid Bio-Coat to list of subcontractors as manufacturer. 'Orchid Bio-Coat, 23149 Commerce Drive, Farmington Hills, Michigan, 48335, USA' is used as a HA coating subcontractor.

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Date	Reference Number	Action
Current	8717655	Renewal. Clarification of details for Biomet France (zipcode), Steris Isomedix (name) and Ceramtec (name and address). Addition of crucial suppliers: Allegheny Technologies Ltd, Cambioceramics, Carpenter Technology UK Ltd, DKSH AG, Invivio Ltd, Quadrant EPP GMBH, Sulzer Metco UK Ltd (Now Oerlikon Metco), X-medics Scandinavia, Zapp (GB) Ltd, ATI Metals, Vista Optics, Eurocoating SPA, ABSSAC LIMITED, Ensinger Limited, Powder Alloy Corporation, VSMPO Tirus Ltd, Addition of significant sub-contractors: Orchid Orthopedic Solutions Ltd – manufacture and crucial supplier Synergy Health Marseille – gamma sterilisation Removal of significant sub-contractor Orchid Bio-Coat.