By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 621697**

Issued To: **Biomet Biologics, LLC**
f/t/a Cell Factor Technol
P.O.Box 587
56 East Bell Drive
Warsaw
Indiana
46581
USA

In respect of:

The design and manufacture of:
-sterile and non-sterile kits and components with and without ACD-A for the separation or delivery of autologous blood components for orthopedic applications.
-sterile and non-sterile kits and components with and without ACD-A for the separation or delivery of autologous bone marrow aspirate for orthopedic applications.
-sterile and non-sterile kits and components with and without ACD-A for the delivery of graft materials for orthopedic applications.

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):

Albert Roossien, Regulatory Lead

First Issued: **2015-04-15** Date: **2019-03-11** Expiry Date: **2022-10-01**

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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**
Advanced Engineering, Inc. 5299 Mishler Road Huntington Indiana 46750 USA	**Manufacture** **Packaging**
Biomet France Sarl Plateau de Lautagne Valence Cedex 9 26000 France	**Manufacture**
Biomet Orthopedics 56 East Bell Drive Warsaw Indiana 46581 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Biomet Sports Medicine P O Box 587 56 East Bell Drive Warsaw Indiana 46581 USA	**Design** **Manufacture**
Biomet UK Limited Waterton Industrial Estate Bridgend CF31 3XA United Kingdom	**Design** **Development** **EU Representative** **Gas Plasma Sterilization** **Manufacture**
Interpore Cross International 181 Technology Drive Irvine California 92618 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Sterigenics, US, LLC 305 Enterprise Drive Lewis Center Ohio 43035 USA	**Gamma Sterilization**
Sterigenics, US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Steris Isomedix Services South Facility 2500 Commerce Drive Libertyville Illinois 60048 USA	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
Steris Isomedix Services, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
15 April 2015	8242734	First Issue Certificate replaces CE 69332 due to upgrade of certificate from Annex V to Annex II Addition of sub-contractors from CE 69332. Addition of sterilisation sub-contractor (Steris Isomedix Services, South Facility, 2500 Commerce Drive, Libertyville, IL, 60048, USA) Clarification of scope to: The design and manufacture of - sterile and non-sterile kits and components for the separation or delivery of autologous blood components for bone and connective tissue applications. - sterile and non-sterile kits and components for the separation or delivery of autologous bone marrow aspirate for bone and connective tissue applications. - sterile and non-sterile kits and components for the separation and delivery of graft materials for bone and connective tissue applications.
28 May 2015	8345858	Add 'with and without ACD-A' and remove 'separation and' from 'separation and delivery of graft materials for bone and connective tissue applications' to the scope

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Date	Reference Number	Action
29 September 2017	8802363	Certificate Renewal Addition of Sterigenics (305 Enterprise Drive) to list of subcontractors for Gamma Sterilization Removal of subcontractors: Biomet 3i, Biomet Deutschland GmbH, Biomet Fairlawn, Biomet Microfixation, Biomet Spain Orthopaedics S.L, Biomet UK Limited (Murdock Road), Catheter Research, Inc, Centurion Sterilization Services, EBI, LLC and Zhejiang Biomet Medical Products. Clarification of Sterilization activities. Amended 'bone and connective tissue' to 'orthopedic' in the scope. Correction of Address for Post code and addition of 'P.O.Box 587'
Current	9751556	Traceable to NB 0086.