bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 517465**

Issued To: **Zimmer Surgical, Inc.**
200 W Ohio Avenue
Dover
Ohio
44622
USA

In respect of:

The design and manufacture of burn care products, tourniquet systems, wound debridement and wound drainage systems, post-operative auto transfusion, surgical saw blades and medical pneumatic systems for blood and lymphatic circulation and bone cement mixing systems.

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: **2007-06-14** Date: **2019-04-12** Expiry Date: **2021-05-14**

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EC Certificate - Full Quality Assurance System

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:

Certificate No:	**CE 517465**
Date:	**2019-04-12**
Issued To:	**Zimmer Surgical, Inc.** **200 W Ohio Avenue** **Dover** **Ohio** **44622** **USA**

Subcontractor:	**Service(s) supplied**
Cosmed Group Inc. 2205 East 33rd Street Erie Pennsylvania 16510 USA	**ETO Sterilization**
Genesis Plastic Welding, Inc 720 E. Broadway Fortville Indiana 46040 USA	**Manufacture**
Medplast Medical Inc Parque Zona Franca Metropolitana Edificio 2C Barreal de Heredia 40101 Costa Rica	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Orchid Unique DBA Orchid Bridgeport 6688 Dixie Highway Bridgeport Michigan 48722 USA	**Manufacture**
Sterigenics US, LLC 305 Enterprise Drive Lewis Center Ohio 43035-9418 USA	**Gamma Sterilization**
Sterigenics US, LLC 10811 Withers Cove Park Dr Charlotte North Carolina 28278 USA	**Gamma Sterilization**

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

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	**ETO Sterilization**
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	**Gamma Sterilization**
Zimmer GmbH Sulzerallee 8 8404 Winterhur Switzerland	**EU Representative**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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Certificate No:	**CE 517465**
Date:	**2019-04-12**
Issued To:	**Zimmer Surgical, Inc.** **200 W Ohio Avenue** **Dover** **Ohio** **44622** **USA**

Subcontractor:	**Service(s) supplied**
Zimmer U.K. Ltd. 9 Lancaster Place South Marston Park Swindon Wiltshire SN3 4FP United Kingdom	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 517465**

Date: **2019-04-12**

Issued To: **Zimmer Surgical, Inc.**
200 W Ohio Avenue
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Date	Reference Number	Action
4 June 2007	-	First issue, transfer from another Notified Body, Certificate number TuV G1 06 05 14780 024.
05 November 2010	7602973	Scope modification, removal of 'Uterine Distension Systems. Change of company name from 'Zimmer OSP' to 'Zimmer Surgical, Inc.' Addition of 'Zimmer U.K. Ltd.', as EU rep. to significant list of subcontractors. Slight change to company address, removal of 0010 from postal code.
13 May 2011	7652704	Certificate renewal
08 March 2013	7957845	Addition of 'ATEK Medical, LLC (Vention Medical Costa Rica), Edificio 1E and 7A, 300 Este Cenada, Zona Franca Metropolitana, Heredia, Barreal de Heredia, 40101, Costa Rica' for manufacture activity
21 February 2014	8091688	Removal of Zimmer Surgical Inc, 2021 old mountain road site from the significant subcontractors
29 July 2015	8375881	Addition of Sterigenics Illinois site for ETO sterilisation

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Date	Reference Number	Action
13 May 2016	8501349	Certificate renewal. Change of significant subcontractor name from Ethox International to iuvo BioScience. Change of name (to Vention Medical Costa Rica, S.A.) and address of significant subcontractor ATEK Medical, LLC.
15 December 2017	8877547	Re-instatement of scope for wound debridement systems after suspension. Suspension Period: 2017.11.27. to 2017.12.15.
15 March 2018	8869224	Critical supplier name changes from 'Iuvo BioScience-Erie, LLC' to 'Cosmed Group Inc' and 'Vention Medical Costa Rica, S.A.' to 'Medplast Medical Inc.'
07 August 2018	8852849	Addition of "surgical saw blades and medical pneumatic systems for blood and lymphatic circulation" to scope of registration. Addition of significant subcontractors "Genesis Plastic Welding, Inc", "Orchid Unique, DBA Orchid Bridgeport" and "Sterigenics US. LLC".
30 August 2018	8852849	Administrative correction to SMO in history section for above entry

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Date	Reference Number	Action
28 November 2018	9648430	Addition of significant subcontractor "Sterigenics US, LLC, 1700 College Blvd, West Memphis, Arkansas, 72301, USA" for "Gamma Sterilization" Change of address for significant subcontractor Sterigenics – Ohio site from "Westerville" to "Lewis Center" Update to subcontractor activities for Sterigenics – Ohio and North Carolina sites from "Gamma Irradiation" to "Gamma Sterilization" to be consistent with Sterigenics – West Memphis site.
14 February 2019	7781067	Traceable to NB 0086.
Current	9750440	Addition of Zimmer GmbH as EC Representative