

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, surgical saw blades and medical pneumatic systems for blood and lymphatic circulation and bone cement mixing systems.
Those aspects of Annex II related to the maintenance of sterility in the manufacture of tourniquet systems, wound drainage systems, surgical gowning.

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: **2021-03-22**

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

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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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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: **2021-03-22**
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Subcontractor:	Service(s) supplied
Biomet Global Supply chain Center B.V (hereafter Biomet GSCC B.V) Hazeldonk 6530 4836 LD Breda The Netherlands	EU Representative
Cosmed Group Inc. 2205 East 33rd Street Erie Pennsylvania 16510 USA	ETO Sterilization
Cosmed Group, Inc. d/b/a Cosmed of NJ 19 Park Drive Franklin New Jersey 07416 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Emerald Nonwovens Co.,Ltd 88,88/1 Moo 2 Nong Chumpon Nuan Kao-Yoi Phetchaburi 76140 Thailand	ETO Sterilization
Genesis Plastic Welding, Inc 720 E. Broadway Fortville Indiana 46040 USA	Manufacture
IIMAK Mexicana, S. de R.L. de C.V. Ave. Mike Allen 1220, Edificio 5 Parque Industrial Reynosa Reynosa Tamaulipas C.P. 88780 Mexico	Manufacture

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Microtek Medical Inc. 602 Lehmborg Road Columbus Mississippi 39702 USA	Control of Sterilization Manufacture
Orchid Unique DBA Orchid Bridgeport 6688 Dixie Hwy Bridgeport Michigan 48722 USA	Manufacture
Sterigenics US, LLC 305 Enterprise Drive Lewis Center Ohio 43035-9418 USA	Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	Radiation (Gamma Sterilization)
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	Radiation (Gamma Sterilization)
Synergy Health AST, SRL B13.1 Street 4, Avenue 1 El Coyal Free Zone El Coyal Alajuela 20102 Costa Rica	ETO Sterilization

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Subcontractor:**Service(s) supplied**

Viant Costa Rica, S.A.
Parque Zona Franca Metropolitana
Edificio 2C
Barreal de Heredia
40101
Costa Rica

Manufacture

Zimmer GmbH
Sulzerallee 8
Winterthur
8404
Switzerland

EU Representative

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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 (Venton 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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Page 1 of 5

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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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Page 2 of 5

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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.
12 April 2019	9750440	Addition of Zimmer GmbH as EC Representative
22 August 2019	9783654	Addition of critical subcontractor, "iiMAK Mexicana, S. de R.L. de C.V, Av, Mike Allen No.1220, Edificio 5, Parque Industrial Reynosa, Reynosa, Tamaulipas. MEXICO CP.88780" for the activity of "manufacture". Critical subcontractor name change from, "MedPlast Medical inc" to "Viant Costa Rica, S.A". Removal of the following critical subcontractor, "Sterigenics US, LLC, 7775 south quincy street, Willowbrook Illinois, 60527, USA".

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Page 3 of 5

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13 December 2019	3105984	ETO sterilisation subcontractor added 'Synergy Health AST, SRL, B13.1 street 4, Avenue 1, El Coyol Free Zone, El Coyol, Alajuela , 20102'. EU representative added 'Biomet Global Supply chain Center B.V (hereafter Biomet GSCC B.V), Hazeldonk, 6530, 4836 LD Breda, The Netherlands'. Addition to scope 'Those aspects of Annex II related to the maintenance of sterility in the manufacture of tourniquet systems and wound drainage systems.'
15 April 2020	3053572	Certificate renewal. Scope removed " post-operative auto transfusion".
20 October 2020	3308533	Critical Subcontractor added 'Cosmed Group, Inc. d/b/a Cosmed of NJ, 19 Park Drive, Franklin, NJ 07416, United States of America" for the activity of 'ETO Sterilization"

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Page 4 of 5

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Current	3384838	Following scope added "Surgical gowning" Following critical subcontractors added: "Emerald Nonwovens Co., Ltd, 88,88/1 Moo 2, Nong Chumpon Nean, Kao-Yoi, Phetchaburi, 76140, Thailand" for the activity of "ETO Sterilization" "Microtek Medical Inc., 602 Lehmberg Road, Columbus, Mississippi, 39702, USA" for the activity of "Control of Sterilization" and "Manufacture" Administrative change from, "Sterigenics US, LLC, 10811 Withers Cove" TO "Sterigenics US, LLC, 10811 Withers Cove". Removal of the following EU representative; "Zimmer U.K. Ltd."