

# 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 and wound drainage 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: **2020-10-20**

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

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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.

# 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: **2020-10-20**  
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**USA**

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

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Genesis Plastic Welding, Inc 720 E. Broadway Fortville Indiana 46040 USA	<b>Manufacture</b>
IIMAK Mexicana, S. de R.L. de C.V. Ave. Mike Allen 1220, Edificio 5 Parque Industrial Reynosa Reynosa Tamaulipas C.P. 88780 Mexico	<b>Manufacture</b>
Orchid Unique DBA Orchid Bridgeport 6688 Dixie Highway Bridgeport Michigan 48722 USA	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics US, LLC 10811 Whithers Cover Park Drive Charlotte North Carolina 28278 USA	<b>Radiation (Gamma Sterilization)</b>
Sterigenics US, LLC 305 Enterprise Drive Lewis Center Ohio 43035-9418 USA	<b>Radiation (Gamma Sterilization)</b>
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	<b>Radiation (Gamma Sterilization)</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Synergy Health AST, SRL B13.1 Street 4, Avenue 1 El Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	<b>ETO Sterilization</b>
Viant Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal de Heredia 40101 Costa Rica	<b>Manufacture</b>
Zimmer GmbH Sulzerallee 8 Winterthur 8404 Switzerland	<b>EU Representative</b>

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

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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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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
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.
12 April 2019	9750440	Addition of Zimmer GmbH as EC Representative
22 August 2019	9783654	Addition of critical subcontractor, "iMAK 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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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".
Current	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"