

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 517467
Issued To: Zimmer Surgical, Inc.
200 W Ohio Avenue
Dover
Ohio
44622
USA

In respect of:

Those aspects relating to securing and maintaining sterility in the manufacture of traction systems, orthopaedic soft goods, cassette drapes and surgical gowning.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2020-04-15**

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.

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List of Significant Subcontractors

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

Certificate No: **CE 517467**
 Date: **2020-04-15**
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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
Emerald Nonwovens Co.,Ltd 88,88/1 Moo 2 Nong Chumpon Nean Kao-Yoi Phetchaburi 76140 Thailand	ETO Sterilization

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Subcontractor:	Service(s) supplied
Microtek Medical Inc. 602 Lehmborg Road Columbus Mississippi 39702 USA	Control of Sterilization Manufacture
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	Gamma Sterilization
Sterigenics US, LLC 305 Enterprise Drive Lewis Center Ohio 43035-9418 USA	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Zimmer GmbH Sulzerallee 8 Winterthur 8404 Switzerland	EU Representative
Zimmer U.K. Ltd. 9 Lancaster Place South Marston Park Swindon Wiltshire SN3 4FP United Kingdom	EU Representative

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Date	Reference Number	Action
14 June 2007	-	First issue, transfer from another Notified Body, Certificate number TuV G2S 05 12 14780 021.
05 November 2010	7602973	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	7652708	Certificate renewal.
21 February 2014	8091688	Removal of Zimmer Surgical Inc, 2021 old mountain road site from the significant subcontractors.
26 March 2015	8294787	Scope extension for surgical gowning. Addition of Microtek Medical Inc. as a significant subcontractor.
13 May 2016	8501349	Certificate renewal. Change of significant subcontractor name from Ethox International to iuvo BioScience.

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Date	Reference Number	Action
15 March 2018	8869224	Critical supplier name changes from 'Iuvo BioScience-Erie, LLC' to 'Cosmed Group Inc.' Amended services supplied from 'Sterile Manufacture' to 'Manufacture' and 'Control of Sterilization' for subcontractor Microtek Medical Inc.
14 February 2019	7781067	Traceable to NB 0086
12 April 2019	9750440	Addition of Zimmer GmbH as EU Representative
22 August 2019	9783699	Subcontractor name change from "Sterigenics US, LLC 305 Enterprise drive, Westerville, Ohio 43081, USA" to "Sterigenics US, LLC 305 Enterprise drive Lewis Centre, Ohio 43035-9418, USA"
11 November 2019	3067894	Critical subcontractor added, "Emerald Nonwovens Co.,Ltd, 88,88/1 Moo 2, Nong Chumpon Nean, Kao-Yoi, Phetchaburi 76140, THAILAND"
13 December 2019	3108151	EU representative added ' Biomet Global Supply chain Center B.V (hereafter Biomet GSCC B.V), Hazeldonk, 6530, 4836 LD Breda, The Netherlands
Current	3053574	Certificate renewal. Admin change of subcontractor activity for Sterigenics US,LLC, 305 Enterprise Drive"; change from "Gamma Irradiation" TO "Gamma Sterilization".

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