

Certificate

Full Quality Assurance



No. CE 515162

Issued to:

Zimmer Inc.
1800 W. Center Street
Warsaw
Indiana
46580
USA

In respect of:

Design, development and manufacture of joint replacement implants, fracture fixation devices, bone cement, trial prostheses and instruments for use with active devices.

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

David W. Ford, Executive Director, Healthcare and Testing Services

First Issued: 13 Aug 2007

Date: 10 Feb 2011

Expiration Date: 26 Feb 2016

Page: 1 of 1

Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

raising standards worldwide™



List of Significant Subcontractors

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

Certificate No. **CE 515162**
Date: **10 Feb 2011**
Issued to: **Zimmer Inc.**
Warsaw
USA

Subcontractor	Service(s) supplied
Alhenia AG Täferstrasse 39 CH-5405 Baden-Dättwil Switzerland	Manufacture
European Medical Contract Manufacturing B.V. Middenkampweg 17 6545 CH Nijmegen Netherlands	Manufacture
Isotron Westport Ltd Lodge Road Westport County Mayo Ireland	Gamma Sterilization
Zimmer Orthopedics Manufacturing Limited Shannon Industrial Estate Shannon Co Clare Ireland	Manufacture

Certificate

List of Significant Subcontractors

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

Certificate No. **CE 515162**
Date: **10 Feb 2011**
Issued to: **Zimmer Inc.**
Warsaw
USA

Subcontractor	Service(s) supplied
Zimmer U.K. Ltd. 9 Lancaster Place South Marston Park Swindon Wiltshire United Kingdom SN3 4FP	EU Representative
Greatbatch Medical Orthopaedics 4532 Park 30 Drive Columbia City IN 46725 USA	Manufacture
Greatbatch Medical Orthopaedics 3735 North Arlington Ave. Indianapolis IN 46218 USA	Manufacture
Greatbatch Medical Orthopaedics L'Echelette 7 CH-2534 Orvin Switzerland	Manufacture

Certificate

List of Significant Subcontractors

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

Certificate No. **CE 515162**
Date: **10 Feb 2011**
Issued to: **Zimmer Inc.**
Warsaw
USA

Subcontractor	Service(s) supplied
Holmed Corporation 40 Norfolk St. South Easton MA 02375 USA	Manufacture
Summit Medical Limited Industrial Estate Bourton-on-the-Water United Kingdom GL54 2HQ	Manufacture
Pioneer Surgical Technology 375 River Park Circle Marquette Michigan 49855 USA	Manufacture
Zimmer Switzerland Manufacturing GmbH Sulzerallee 8 Winterthur Switzerland CH-8404	Manufacture

Page: 3 of 6

raising standards worldwide™



List of Significant Subcontractors

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

Certificate No. **CE 515162**
Date: **10 Feb 2011**
Issued to: **Zimmer Inc.**
Warsaw
USA

Subcontractor	Service(s) supplied
Zimmer Surgical, Inc. 200 W Ohio Avenue Dover Ohio USA 44622-0010	Manufacture
Zimmer Surgical, Inc. 2021 Old Mountain Road Statesville North Carolina USA 28677	Manufacture
Ethox International Medical Manufacturing Corporation 2205 East 33rd Street Erie Pennsylvania 16510 USA	ETO Sterilization
Sterigenics US, LLC 305 Enterprise Drive Westerville OH 43081 USA	Gamma Sterilization

List of Significant Subcontractors

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

Certificate No. **CE 515162**
Date: **10 Feb 2011**
Issued to: **Zimmer Inc.**
Warsaw
USA

Subcontractor	Service(s) supplied
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	Gamma Sterilization
Zimmer Manufacturing B.V. Route #1, K.M. 123.4 Turpeaux Industrial Park Mercedita Puerto Rico 00715	Manufacture
Ceramtec GmbH Medical Applications Division CeramTec Platz 1-9 D-73207 Plochingen Germany	Manufacture
Symmetry Medical USA, Inc. 486 West 350 North Warsaw IN 46582-7721 USA	Manufacture

List of Significant Subcontractors

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

Certificate No. **CE 515162**
Date: **10 Feb 2011**
Issued to: **Zimmer Inc.**
Warsaw
USA

Subcontractor	Service(s) supplied
Steris Isomedix Services 1880 Industrial Drive Libertyville 60048 Illinois USA	ETO Sterilization Gamma Sterilization
Zimmer Trabecular Metal Technology, Inc 10 Pomeroy Road Parsippany 07054 New Jersey USA	Manufacture

Visiškas kokybės užtikrinimas

Nr. CE 515162

Išduotas:

Zimmer Inc.
1800 W. Centro g.
Warsaw
Indiana
46580
JAV

Dėl:

Projektavimo, sąnario implantų kūrimas ir gamyba, įtaisai lūžiams gydyti, kaulų cementas, bandomieji protezai ir instrumentai naudojami su aktyviais įrengimais.

mūsų tyrimų pagal Tarybos direktyvų reikalavimus 93/42/EEC, priedas II, skyrius 3.2.
Didžiosios Britanijos institucijų vardu, notifikuotojo įstaiga aukščiau minėtos direktyvos
(Notifikuotosios įstaigos numeris 0086)

/parašas/

Deividas W, Vikdantysis direktorius, sveikatos priežiūros ir bandymų paslaugos

Išduotas: 2007 rugpjūčio 13.

Data: 2011 lapkričio 10 d.

Galioja iki: 2016 lapkričio 26 d.

Puslapis 1 iš 1

Patvirtinimo sąlygos

Šio sertifikato galiojimas yra sąlyga, kad kokybės sistema prižiūrima taip kaip reikalauja Direktyva.

Šis patvirtinimas neapima produktų, sukurtų ir/arba gaminamų trečiųjų kompanijų, besinaudojančių šios sertifikavimo kompanijos dokumentais, nebent įvykdytas išskirtinis susitarimas su BSi.

keliame aukštus standartus pasauliniu mastu

Sertifikatas

Svarbių subrangovų sąrašas

Sertifikato Nr. CE 515162

Data: 2011 vasario 10 d.

Išduota: Zimmer Inc.
Warsaw
JAV

Subrangovai	Paslaugos
Alhenia AG Tafernstrasse 39 CH-5405 Baden-Dattwill Šveicarija	Gamyba
Europos medicinos sutartis Gamyba B.V Middenkamweg 17 6545 CH Nijmegen Nyderlandai	Gamyba
Isotron Westport Ltd Lodge Road Westport Country Mayo Airija	Gama sterilizacija
Zimmer Ortopedija Manufacturing Limited Shannon Industrial Estate Shannon Co Clare Airija	Gamyba

Sertifikatas

Svarbių subrangovų sąrašas

Sertifikato Nr. CE 515162

Data: 2011 vasario 10 d.

Išduota: Zimmer Inc.
Warsaw
JAV

Subrangovai	Paslaugos
Zimmer U.K. Ltd. 9 Lancaster Place Pietų Marston Park Svindonas, Wiltshire SN3 4FP Jungtinė Karalystė	Atstovas ES
Greatbatch Medical Orthopedics 4532 Park 30 Drive Kolumbijos Miestas IN 46725 JAV	Gamyba
Greatbatch Medical Orthopedics 3735 Šiaurės Arlington alėja Indianapolis IN 46218 JAV	Gamyba
Greatbatch Medical Orthopedics L'Echelette 7 CH-2534 Orvin Šveicarija	Gamyba

Sertifikatas

Svarbių subrangovų sąrašas

Sertifikato Nr. CE 515162

Data: 2011 vasario 10 d.

Išduota: Zimmer Inc.
Warsaw
JAV

Subrangovai	Paslaugos
Holmed Koropracija 40 Norfolk g. Pietų įstonas MA 02375 JAV	Gamyba
Summit Medical Limited Industrial Estate Bourton-on-the-Water Jungtinės Karalystės GL54 2HQ	Gamyba
Pioneer Surgical Technology 375 River Park Circle Marquette Mičiganas 49855 JAV	Gamyba
Zimmer Šveicarija Manufacturing GmbH Sulzerallee 8 Vinterturas Šveicarija CH-8404	Gamyba

Sertifikatas

Svarbių subrangovų sąrašas

Sertifikato Nr. CE 515162

Data: 2011 vasario 10 d.

Išduota: Zimmer Inc.
Warsaw
JAV

Subrangovai	Paslaugos
Zimmer Surgical, Inc. 200W Ohio Alėja Doveris Ohio JAV 44622-0010	Gamyba
Zimmer Surgical, Inc. 2021 Old Mountain Road Statesvilis Šiaurės Karolina JAV 28677	Gamyba
Ethox International Medical Manufacturing Corporation 2205 Rytų 33 gatvė Erie Pensilvanija 16510 JAV	ETO sterilizacija
Sterigenics US, LLC 305 Enterprise Drive Westerville OH 43081 JAV	Gamma sterilizacija

Sertifikatas

Svarbių subrangovų sąrašas

Sertifikato Nr. CE 515162

Data: 2011 vasario 10 d.

Išduota: Zimmer Inc.
Warsaw
JAV

Subrangovai	Paslaugos
Sterigenic US, LLC 1003 Lakeside Drive Gurnee Ilinojus 60031 JAV	Gamma sterilizacija
Zimmer Manufacturing B.V Route #1, K.M. 123.4 Turpeaux Industrial Park Mercedita Puerto Rikas 00715	Gamyba
Ceramtec GmbH Medical Applications Division CeramTec Platz 1-9 D-73207 Plochingen Vokietija	Gamyba
Symmetry Medical JAV, Inc. 486 vakarų 350 šiaurės Warsaw IN 46582-7721 JAV	Gamyba

Sertifikatas

Svarbių subrangovų sąrašas

Sertifikato Nr. CE 515162

Data: 2011 vasario 10 d.

Išduota: Zimmer Inc.
Warsaw
JAV

Subrangovai

Steris Isomedix Services
1880 Industrial Drive
Libertyville 60048
Ilinojus
JAV

Paslaugos

ETO sterilizacija
Gamma sterilizacija

Zimmer Tubecular Metal
Technologija, Inc
10 Pomerov Road
Parsippany
Naujasis Džersis
JAV

Gamyba