

EC Certificate - Full Quality Assurance System

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

No.**CE 516222****Issued To:****Zimmer GmbH
Sulzerallee 8
Winterthur
8404
Switzerland**

In respect of:

See certificate scope page.

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: **2007-08-08**

Date: **2020-06-19**

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.

Certificate No: CE 516222

Certificate Scope:

The design and manufacture of orthopaedic implants for joint replacement and osteosynthesis, spinal implants for fusion and spinal implants for dynamic stabilization with and without HA coating, trial prostheses and surgical instruments supplied sterile for single use or intended for connection to active devices.

Those aspects of Annex II concerned with the conformity of the products with the metrological requirements of surgical instruments.

Those aspects of Annex II concerned with securing and maintaining sterile conditions of surgical instruments.

First Issued: **2007-08-08**Date: **2020-06-19**Expiry Date: **2024-05-26**

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List of Significant Subcontractors

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

Certificate No: **CE 516222**
 Date: **2020-06-19**
 Issued To: **Zimmer GmbH**
Sulzerallee 8
Winterthur
8404
Switzerland

Subcontractor:

Service(s) supplied

BGS Beta-Gamma-Service GmbH & Co. KG
 Industriestraße 9
 93342 Saal
 Deutschland

Other Critical Processes

Biomet GSCC B.V.
 Hazeldonk 6530
 4836 LD Breda
 The Netherlands

EU Representative

CeramTec GmbH
 Medical Products Division
 CeramTec Platz 1-9
 73207 Plochingen
 Germany

Manufacture

Diener AG
 Precision Machining
 Stationsstrasse 66
 8424 Embrach
 Switzerland

Manufacture

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Subcontractor:	Service(s) supplied
DOT GmbH Charles-Darwin-Ring 1 a Rostock 18059 Germany	Manufacture Other Critical Processes
Eurocoating S.p.A. Via Al Dos de la Roda, 60 Z.I. Cire 38057 Pergine Valsugana (TN) Italy	Other Critical Processes
Fischer Söhne AG Luzernerstrasse 105 5630 Muri Switzerland	Manufacture Other Critical Processes
Früh Verpackungstechnik AG Allmendstrasse 47 8320 Fehraltorf Switzerland	Labelling Packaging

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Subcontractor:	Service(s) supplied
LEONI Studer AG Hogenweidstrasse 2+4 4658 Däniken Switzerland	Other Critical Processes
Medicoat AG Almuesenacherstrasse 2a 5506 Mägenwil Switzerland	Other Critical Processes
Medicoat SAS 127 Avenue René Jacot Etupes 25460 France	Manufacture Other Critical Processes
Orchid Orthopedics Switzerland GmbH Täferstrasse 39 Baden-Dättwil CH-5405 Switzerland	Manufacture

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Subcontractor:

Service(s) supplied

Sterigenics Germany GmbH
 Kasteler Strasse 45
 Wiesbaden
 65203
 Germany

ETO Sterilization

Synergy Health Däniken AG
 Hogenweidstrasse 6
 Däniken
 CH-4658
 Switzerland

Radiation (Gamma Sterilization)

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

Manufacture

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Subcontractor:

Service(s) supplied

Zimmer Switzerland manufacturing GmbH
 Sulzerallee 8
 Winterthur
 CH-8404
 Switzerland

Manufacture

Zimmer Trabecular Metal Technology, Inc.
 doing business as Zimmer and Implex
 10 Pomeroy Road
 Parsippany
 New Jersey
 07054
 USA

Other Critical Processes

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Certificate History

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Date	Reference Number	Action
08 August 2007	7008116	Transfer from another notified body, certificate number G1 04 08 53422 003.
21 August 2007	7031680	Addition of "Medisize Schweiz AG, Switzerland" to the list of significant subcontractors for manufacturing and packaging activities.
22 February 2008	7165430	Extension to scope to include "trial prostheses and surgical instruments supplied sterile for single use or intended for connection to active devices". Addition of "Isotron Deutschland GmbH", Germany to the significant list of sub-contractors as sterilization sub-contractor activity. Removal of Biovision GmbH from significant list of subcontractors. Sub-contractor name change from "Studer Hard" to Leoni Studer AG Studer Hard".
31 July 2008	7242884	Change to scope removing "resorbable stem centralizers". Certificate Renewal.
29 May 2009	7216361	Addition of Eurocoating S.p.A. to the list of significant subcontractors for other critical processes.

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Date	Reference Number	Action
17 February 2011	7304212	<p>Modification of Scope: Removal of 'interference screws,' and 'supplied sterile' and addition of 'medullary plugs' and 'provisional'.</p> <p>Addition of the following subcontractor for manufacturing & other critical processes activities:</p> <p>Manufacturing: Alhenia AG, Bächler Feintech AG, BioVision GmbH, AG, Finsbury Orthopaedic Limited, Gebr. Brasseler GmbH & Co. KG (Komet Medical), Gehring CUT AG, Dieter Marquardt Medizintechnik GmbH, Mayer Medizintechnik GmbH, Medicea Technologies, Moser-Baer AG, Preciswiss AG, Putnam Plastics, Sphinx Werkzeuge AG, WSM-Präzisionsmechanik AG, and Saphirwerk Industrieprodukte AG.</p> <p>Manufacturing & Other critical processes: Semadeni AG, Samaplast AG, Sulzer Meteo AG, DOT GmbH and Fischer Söhne AG</p> <p>Other critical processes added to 'LEONI Studer Hard AG'.</p> <p>Deletion of subcontractors: Früh Verpackungs-Technik AG and Zimmer Switzerland Manufacturing GmbH.</p> <p>Change of subcontractor name from 'CeramTec AG' to 'CeramTec GmbH'</p> <p>address: 'Fabrikstrasse 23-29' to CeramTec Platz 1.9, '73207 Plochingen'.</p>
10 August 2011	7702199	<p>Extension to scope to include:</p> <p>"Those aspects of Annex II concerned with the conformity of the products with the metrological requirements of surgical instruments.</p> <p>Those aspects of Annex II concerned with securing and maintaining sterile conditions of surgical instruments."</p>

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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
09 November 2012	7910779	Removal of Subcontractors: 'Finsbury Orthopaedic Ltd', 'Leoni Studer Hard AG' and 'Deiter Marquardt Medizintechnik GmbH' Correction of Subcontractors: Name Change for 'Isotron France SAS' to 'Synergy Health Maseille SAS' Name Change for 'Isotron Deutschland GmbH' to Synergy Health Allerhausen GmbH Addition of Subcontractors: 'Leoni Struder AG, Däniken, Switzerland' for subcontractor activity E-Beam Sterilisation 'Synergy Health Däniken AG, Däniken, Switzerland' for subcontractor activity Gamma Irradiation.
18 April 2013	7969655	Addition of Metoxit AG as manufacturing subcontractor.
16 July 2013	8012514	Certificate Renewal. Removal of Preciswiss AG from the subcontractor list. Change of address of Sterigenics Germany GmbH. Removal of 'resorbable interference screws' from the scope.
09 October 2013	7986686	Addition of ebeam UHMWPE crosslinking subcontractor BGS Beta-Gamma-Service GmbH, Saal.
28 January 2015	8282338	Removal of significant subcontractor "Zimmer France Manufacturing". Addition of significant subcontractor "Medicoat SAS, 127 Avenue René Jacot, 25460 Etupes, France" for the activities of manufacture and other critical processes.

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19 June 2016	8535753	Addition of subcontractor "Früh Verpackungstechnik AG, Fehraltorf, 8320, Switzerland" for the activities of Packaging and Labelling.
27 February 2018	8843502	Addition of critical subcontractor "Medicoat AG, Almuesenacherstrasse 2a, Gewerbe Nord, 5506 Mägenwil, Switzerland" for the activity of 'Other Critical Processes'.
27 July 2018	8938893	Certificate Renewal. Scope clarification of 'spinal implants' to 'spinal implants for fusion and spinal implants for dynamic stabilisation with and without HA coating'. Addition of subcontractor: "Diener AG". Correction to subcontractor name change "Sulzer Metco AG (Switzerland)" is now "Oerlikon Metco AG". Correction to subcontractor name change "Alhenia AG" is now "Orchid Orthopedics Switzerland GmbH". Removal of subcontractors "Mayer Medizintechnik GmbH", "Synergy Health Allershausen GmbH", "Bächler Feintech AG", "Medicrea Technologies", "Biovision GmbH", "Saphirwerk Industrieprodukte AG", and "WSM-Präzisionsmechanik AG".
31 January 2019	8997751	Addition of subcontractor "Zimmer Trabecular Metal Technology, Inc.".
05 March 2019	7781060	Traceable to NB 0086.

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Date	Reference Number	Action
06 April 2020	3084349	<p>Certificate Renewal.</p> <p>Critical subcontractor administrative name change from:</p> <p>"BGS Beta-Gamma-Service GmbH & Co. KG, Industriestrasse 9, 93342 Saal an der Donau, Germany" TO "BGS Beta-Gamma-Service GmbH & Co. KG, Industriestrasse 9, 93342 Saal, Germany"</p> <p>"CeramTec AG, CeramTec Platz 1-9, D-73207 Plochingen, Germany" TO "CeramTec GmbH Medical Products Division, CeramTec Platz 1-9, 73207 Plochingen, Germany"</p> <p>"Diener AG , 8424 Embrach, Switzerland" TO "Diener AG Precision Machining, Stationsstrasse 66, 8424 Embrach, Switzerland"</p> <p>"Eurocoating S.p.A., Via Al Dos de la Roda, 60 Z.I. Cire, Cire Pergine (TN), 38057, Italy" TO "Eurocoating S.p.A., Via Al Dos de la Roda, 60 Z.I. , Cire 38057, Pergine Valsugana (TN), Italy"</p> <p>"Fischer Söhne AG, Luzernerstrasse 105, CH-5630 Muri AG, Switzerland" TO "Fischer Söhne AG, Luzernerstrasse 105, 5630 Muri, Switzerland"</p> <p>"LEONI Studer Hard AG, Hogenweidstrasse 2, CH-4658 Däniken, Switzerland" TO "LEONI Studer AG, Hogenweidstrasse 2+4, 4658 Däniken, Switzerland"</p> <p>"Medicoat AG, Almuesenacherstrasse 2a, Gewerbe Nord, 5506 Mägenwil, Switzerland" TO "Medicoat AG, Almuesenacherstrasse 2a, 5506 Mägenwil, Switzerland"</p> <p>"Orchid Orthopedics Switzerland GmbH, Täferstrasse 39, Baden-Dättwil, CH- 5405 , Switzerland" TO "Orchid Orthopedics Switzerland GmbH, Täferstrasse 39, 5405 Baden-Dättwil AG, Switzerland"</p> <p>"FRÜH VERPACKUNGSTECHNIK AG, Fehraltorf, 8320, Switzerland" TO "FRÜH VERPACKUNGSTECHNIK AG, Allmendstrasse 47, 8320 Fehraltorf, Switzerland"</p>

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Date	Reference Number	Action
		Following subcontractors are removed from the certificate: Gebr. Brasseler GmbH & Co. KG (KOMET MEDICAL), Medisize Schweiz AG, Metoxit AG, Moser-Baer AG, Samaplast AG, Semadeni AG, Sphinx Werkzeuge AG, Oerlikon Metco AG, Synergy Health Marseille SAS, Putnam plastics, Gehring Cut AG Following EU representative added to the certificate "Biomet GSCC BV, Hazeldonk 6530, 4836 LD Breda, The Netherlands".
Current	3220100	Critical subcontractor added "Zimmer Switzerland manufacturing GmbH, Sulzerallee 8, Winterthur, CH-8404, Switzerland".

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