

EC Certificate - Full Quality Assurance System

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

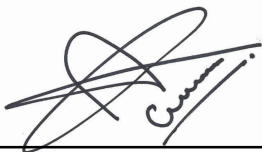
No. **CE 516222**
Issued To: **Zimmer GmbH**
Sulzerallee 8
Winterthur
8404
Switzerland

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):



Albert Roossien, Regulatory Lead

First Issued: **2007-08-08**

Date: **2019-03-05**

Expiry Date: **2023-07-31**

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Page 1 of 2

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: **2019-03-05**Expiry Date: **2023-07-31**

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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: **2019-03-05**
 Issued To: **Zimmer GmbH**
Sulzerallee 8
Winterthur
8404
Switzerland

Subcontractor:	Service(s) supplied
BGS Beta-Gamma-Services GmbH & Co KG Industriestrasse 9 93342 Saal an der Donau Germany	Other Critical Processes
CeramTec AG CeramTec-Platz 1-9 Plochingen 73207 Germany	Manufacture
Diener AG 8424 Embrach Switzerland	Manufacture
DOT GmbH Charles-Darwin-Ring 1 a Rostock 18059 Germany	Manufacture Other Critical Processes

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Subcontractor:	Service(s) supplied
Eurocoating S.p.A. Via Al Dos de la Roda, 60 Z.I. Ciré Ciré pergine (TN) 38057 Italy	Other Critical Processes
Fischer Söhne AG Luzernerstrasse 105 CH-5630 Muri AG Switzerland	Manufacture Other Critical Processes
Früh Verpackungstechnik AG Fehraltorf 8320 Switzerland	Labelling Packaging
Gebr. Brasseler GmbH & Co. KG Trophagener Weg 25 Lemgo 32657 Germany	Manufacture

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Subcontractor:	Service(s) supplied
Gehring CUT AG Alte Poststrasse 5 CH-9548 Matzingen Switzerland	Manufacture
LEONI Studer Hard AG Hogenewidstrasse 2 CH-468 Däniken Switzerland	Other Critical Processes
Medicoat AG Almuesenacherstrasse 2a Gwerbe Nord, Mägenwil 5506 Switzerland	Other Critical Processes
Medicoat SAS 127 Avenue René Jacot Etupes 25460 France	Manufacture Other Critical Processes

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Subcontractor:	Service(s) supplied
Medisize Schweiz AG Hakabstrasse 5 CH-8309 Nürensdorf Switzerland	Manufacture Packaging
Metoxit AG Emdwiesenstrasse 6 Thayngen 8240 Switzerland	Manufacture Packaging
Moser-Baer AG Spitalstrasse 7 CH-3454 Sumiswald Switzerland	Manufacture
Oerlikon Metco AG Rigackerstrasse 16 CH - 5610 Wohlen Switzerland	Manufacture

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Subcontractor:	Service(s) supplied
Orchid Orthopedics Switzerland GmbH Täferstrasse 39 Baden-Dättwil CH-5405 Switzerland	Manufacture
Putnam Plastics Corporation 130 Louisa Viens Drive Dayville Connecticut 06241 USA	Manufacture
Samaplast AG Neugrütstrasse 3 St. Margrethen CH-9430 Switzerland	Manufacture Other Critical Processes

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Subcontractor:	Service(s) supplied
Semadeni AG Taegetlistrasse 35-39 CH-3072 Ostermundigen Switzerland	Manufacture Other Critical Processes
Sphinx Werkzeuge AG Gewerberstrasse 1 CH-4552 Derendingen Switzerland	Manufacture
Sterigenics Germany GmbH Kasteler Strasse 45 Wiesbaden 65203 Germany	ETO Sterilization
Synergy Health Däniken AG Hogenweidstrasse 6 Däniken CH-4658 Switzerland	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Synergy Health Marseille SAS MIN 712 Les Arnavaux 13323 Marseille Cedex 14 France	Gamma Sterilization
Zimmer Inc. 1800 W. Center Street Warsaw Indiana 46580 USA	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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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 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' 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. Those aspects of Annex II concerned with securing and maintaining sterile conditions of surgical instruments."</p>

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09 November 2012	7910779	<p>Removal of Subcontractors: 'Finsbury Orthopaedic Ltd', 'Leoni Studer Hard AG' and 'Deiter Marquardt Medizintechnik GmbH'</p> <p>Correction of Subcontractors:</p> <p>Name Change for 'Isotron France SAS' to 'Synergy Health Maseille SAS'</p> <p>Name Change for 'Isotron Deutschland GmbH' to Synergy Health Allerhausen GmbH'</p> <p>Addition of Subcontractors:</p> <p>'Leoni Struder AG, Däniken, Switzerland' for subcontractor activity E-Beam Sterilisation</p> <p>'Synergy Health Däniken AG, Däniken, Switzerland for subcontractor activity Gamma Irradiation.</p>
18 April 2013	7969655	Addition of Metoxit AG as manufacturing subcontractor.
16 July 2013	8012514	<p>Certificate renewal.</p> <p>Removal of Preciswiss AG from the subcontractor list.</p> <p>Change of address of Sterigenics Germany GmbH.</p> <p>Removal of 'resorbable interference screws' from the scope.</p>
09 October 2013	7986686	Addition of ebeam UHMWPE crosslinking subcontractor BGS Beta-Gamma-Service GmbH, Saal.

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Date	Reference Number	Action
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.
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'.

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Date	Reference Number	Action
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."
Current	7781060	Traceable to NB 0086.

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