

EC Design-Examination Certificate

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

No. **CE 545649**
Issued To: **Zimmer Inc.**
1800 W. Center Street
Warsaw
Indiana
46580
USA

In respect of:

NexGen Legacy Constrained Condylar Knee (LCCK) System

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2009-03-12**

Date: **2019-03-08**

Expiry Date: **2024-03-11**

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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.

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Supplementary Information to CE 545649

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Catalogue Number	Description
NexGen® Complete Knee Solution, Legacy® Knee - Constrained Condylar (LCCK) Femoral Component	
00-5994-013-91	Option, Size C Left
00-5994-013-92	Option, Size C Right
00-5994-014-91	Option, Size D Left
00-5994-014-92	Option, Size D Right
00-5994-015-91	Option, Size E Left
00-5994-015-92	Option, Size E Right
00-5994-016-91	Option, Size F Left
00-5994-016-92	Option, Size F Right
00-5994-017-91	Option, Size G Left
00-5994-017-92	Option, Size G Right
NexGen® Complete Knee Solution, Legacy® Knee - Constrained Condylar (LCCK) Articular Surface with Locking Screw	
00-5994-022-10	Size Striped Purple/C,D 10 mm Height for use with Femoral C,D
00-5994-022-12	Size Striped Purple/C,D 12 mm Height for use with Femoral C,D
00-5994-022-14	Size Striped Purple/C,D 14 mm Height for use with Femoral C,D
00-5994-022-17	Size Striped Purple/C,D 17 mm Height for use with Femoral C,D

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00-5994-022-20	Size Striped Purple/C,D 20 mm Height for use with Femoral C,D
00-5994-022-23	Size Striped Purple/C,D 23 mm Height for use with Femoral C,D
00-5994-022-28	Size Striped Purple/C,D 28 mm Height for use with Femoral C,D
00-5994-022-33	Size Striped Purple/C,D 33 mm Height for use with Femoral C,D
00-5994-030-10	Size Yellow/C,D 10 mm Height for use with Femoral C,D
00-5994-030-12	Size Yellow/C,D 12 mm Height for use with Femoral C,D
00-5994-030-14	Size Yellow/C,D 14 mm Height for use with Femoral C,D
00-5994-030-17	Size Yellow/C,D 17 mm Height for use with Femoral C,D
00-5994-030-20	Size Yellow/C,D 20 mm Height for use with Femoral C,D
00-5994-030-23	Size Yellow/C,D 23 mm Height for use with Femoral C,D
00-5994-030-28	Size Yellow/C,D 28 mm Height for use with Femoral C,D
00-5994-030-33	Size Yellow/C,D 33 mm Height for use with Femoral C,D
00-5994-032-10	Size Striped Yellow/E,F 10 mm Height for use with Femoral E,F
00-5994-032-12	Size Striped Yellow/E,F 12 mm Height for use with Femoral E,F
00-5994-032-14	Size Striped Yellow/E,F 14 mm Height for use with Femoral E,F
00-5994-032-17	Size Striped Yellow/E,F 17 mm Height for use with Femoral E,F
00-5994-032-20	Size Striped Yellow/E,F 20 mm Height for use with Femoral E,F
00-5994-032-23	Size Striped Yellow/E,F 23 mm Height for use with Femoral E,F

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00-5994-032-28	Size Striped Yellow/E,F 28 mm Height for use with Femoral E,F
00-5994-032-33	Size Striped Yellow/E,F 33 mm Height for use with Femoral E,F
00-5994-040-10	Size Green/E,F 10 mm Height for use with Femoral E,F
00-5994-040-12	Size Green/E,F 12 mm Height for use with Femoral E,F
00-5994-040-14	Size Green/E,F 14 mm Height for use with Femoral E,F
00-5994-040-17	Size Green/E,F 17 mm Height for use with Femoral E,F
00-5994-040-20	Size Green/E,F 20 mm Height for use with Femoral E,F
00-5994-040-23	Size Green/E,F 23 mm Height for use with Femoral E,F
00-5994-040-28	Size Green/E,F 28 mm Height for use with Femoral E,F
00-5994-040-33	Size Green/E,F 33 mm Height for use with Femoral E,F
00-5994-041-10	Size Striped Green/C,D 10 mm Height for use with Femoral C,D
00-5994-041-12	Size Striped Green/C,D 12 mm Height for use with Femoral C,D
00-5994-041-14	Size Striped Green/C,D 14 mm Height for use with Femoral C,D
00-5994-041-17	Size Striped Green/C,D 17 mm Height for use with Femoral C,D
00-5994-041-20	Size Striped Green/C,D 20 mm Height for use with Femoral C,D
00-5994-041-23	Size Striped Green/C,D 23 mm Height for use with Femoral C,D
00-5994-042-10	Size Striped Green/G 10 mm Height for use with Femoral G
00-5994-042-12	Size Striped Green/G 12 mm Height for use with Femoral G

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00-5994-042-14	Size Striped Green/G 14 mm Height for use with Femoral G
00-5994-042-17	Size Striped Green/G 17 mm Height for use with Femoral G
00-5994-042-20	Size Striped Green/G 20 mm Height for use with Femoral G
00-5994-042-23	Size Striped Green/G 23 mm Height for use with Femoral G
00-5994-042-28	Size Striped Green/G 28 mm Height for use with Femoral G
00-5994-042-33	Size Striped Green/G 33 mm Height for use with Femoral G
00-5994-050-10	Size Blue/G 10 mm Height for use with Femoral G
00-5994-050-12	Size Blue/G 12 mm Height for use with Femoral G
00-5994-050-14	Size Blue/G 14 mm Height for use with Femoral G
00-5994-050-17	Size Blue/G 17 mm Height for use with Femoral G
00-5994-050-20	Size Blue/G 20 mm Height for use with Femoral G
00-5994-050-23	Size Blue/G 23 mm Height for use with Femoral G
00-5994-051-10	Size Striped Blue/E,F 10 mm Height for use with Femoral E,F
00-5994-051-12	Size Striped Blue/E,F 12 mm Height for use with Femoral E,F
00-5994-051-14	Size Striped Blue/E,F 14 mm Height for use with Femoral E,F
00-5994-051-17	Size Striped Blue/E,F 17 mm Height for use with Femoral E,F
00-5994-051-20	Size Striped Blue/E,F 20 mm Height for use with Femoral E,F
00-5994-051-23	Size Striped Blue/E,F 23 mm Height for use with Femoral E,F

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Certificate History

Date	Reference Number	Action
12 March 2009	10102491	First issue
29 August 2013	10142946	Addition of product codes for stem extension devices
05 March 2014	10144506	Certification Renewal
16 October 2014	10150002	Approval of packaging change for select stem extensions
13 January 2015	10149952	New LDPE formulation for packaging bags implemented
11 May 2015	10154751	Addition of Zimmer Orthopedics Manufacturing Limited (Shannon) for cleaning and packaging processes for codes 00-5988-XXX-XX and 00-5994-XXX-XX
29 January 2016	10159965	Packaging change for Complete Knee Solution Stem Extension Straight Extra Long and Femoral Set Screw (CRA/LCCK)
13 July 2016	10160290	Approval of new Tyvek® 1073B packaging material for all product codes.
27 April 2017	10170403	Packaging change for product codes 00-5994-022, 030, 032, 040, 041, 042, 050, 051-28, 33

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Date	Reference Number	Action
07 June 2017	10170407	Packaging change for product codes 00-5994-042, 050, 051- 10, 12, 14, 17, 20, 23
24 November 2017	8781096	Addition of MRI conditional labelling
07 December 2017	8781846	Removal of product codes for stem extension devices - transferred to CE 523316.
Current	9631583	Renewal of Certificate Removal of the following NexGen Legacy Constrained Condylar Knee (LCCK) System product codes: 00-5994-041-28, 00-5994-041-33, 00-5994-050-28, 00-5994-050-33, 00-5994-051-28, 00-5994-051-33

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