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 ZLG-BS-244.10.08



Product Service

EC Certificate

EC Design-Examination Certificate
 Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
 (Devices in Class III)

No. G7 075731 0067 Rev. 00

Manufacturer: **Limacorporate S.p.A.**
 Via Nazionale, 52
 33038 Villanova San Daniele del Friuli (UDINE)
 ITALY

Product: **Orthopaedic Implants**
Arthroprosthesis. Total hip joint prostheses

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: ITA1202742

Valid from: 2019-08-01
Valid until: 2024-05-26

Date, 2019-08-01

Stefan Preiß
 Head of Certification/Notified Body



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Facility(ies): Limacorporate S.p.A.
 Via Nazionale, 52, 33038 Villanova San Daniele del Friuli (UDINE),
 ITALY

Model(s): **SL Self Locking Femoral Stems**
C2 Femoral stems
PLS Femoral stems
H-MAX S Femoral stems
FIT Femoral stems
Minima S Femoral stems
Master SL Femoral stems
COLLO-MIS Femoral stems

Parameters:

SL Self Locking Femoral Stems

	Partially Coated Stems – Cementless (Ti6Al4V + PoroTi) - Taper 12/14
3515.21.003	Width 4.5 mm, # 02
3515.21.005	Width 6.5 mm, # 0
3515.21.010	Width 7.5 mm, # 1
3515.21.015	Width 8.75 mm, # 1 PLUS
3515.21.020	Width 10.0 mm, # 2
3515.21.030	Width 11.5 mm, # 3
3515.21.040	Width 12.5 mm, # 4
3515.21.050	Width 13.5 mm, # 5
3515.21.060	Width 15.0 mm, # 6
3515.21.070	Width 17.5 mm, # 7
3515.21.080	Width 20.0 mm, # 8

C2 Femoral stems

	Stems - Cementless (Ti6Al4V) – Taper 12/14
4510.15.010	# 01
4510.15.020	# 0
4510.15.030	# 1
4510.15.040	# 2
4510.15.050	# 3
4510.15.060	# 4

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4510.15.070	# 5
4510.15.080	# 6
4510.15.090	# 7
4510.15.100	# 8
4510.15.110	# 9
4510.15.120	# 10
4510.15.130	# 11
4510.15.140	# 12
Lateralized Stems – Cementless (Ti6Al4V) – Taper 12/14	
4511.15.010	# 01
4511.15.020	# 0
4511.15.030	# 1
4511.15.040	# 2
4511.15.050	# 3
4511.15.060	# 4
4511.15.070	# 5
4511.15.080	# 6
4511.15.090	# 7
4511.15.100	# 8
4511.15.110	# 9
4511.15.120	# 10
4511.15.130	# 11
4511.15.140	# 12
Revision Stems – Cementless (Ti6Al4V) – Taper 12/14	
4513.15.040	# 2
4513.15.050	# 3
4513.15.060	# 4
4513.15.070	# 5
4513.15.080	# 6
4513.15.090	# 7
4513.15.100	# 8
4513.15.110	# 9

PLS Femoral stems

	Standard Stems – Cementless (Ti6Al4V) – Taper 12/14
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EC Certificate

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Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

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4610.15.010	# 1
4610.15.020	# 2
4610.15.030	# 3
4610.15.040	# 4
4610.15.050	# 5
4610.15.060	# 6
4610.15.070	# 7
4610.15.080	# 8
4610.15.090	# 9
4610.15.100	# 10
4610.15.110	# 11
Lateralized Stems – Cementless (Ti6Al4V) – Taper 12/14	
4611.15.010	# 1
4611.15.020	# 2
4611.15.030	# 3
4611.15.040	# 4
4611.15.050	# 5
4611.15.060	# 6
4611.15.070	# 7
4611.15.080	# 8
4611.15.090	# 9
4611.15.100	# 10
4611.15.110	# 11

H-MAX S Femoral stems

Standard Stems – Cementless (Ti6Al4V + HA) – Taper 12/14	
4250.20.080	# 8
4250.20.090	# 9
4250.20.100	# 10
4250.20.110	# 11
4250.20.120	# 12
4250.20.130	# 13
4250.20.140	# 14
4250.20.150	# 15
4250.20.160	# 16

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4250.20.170	# 17
4250.20.180	# 18
Lateralized Stems – Cementless (Ti6Al4V + HA) – Taper 12/14	
4251.20.080	# 8
4251.20.090	# 9
4251.20.100	# 10
4251.20.110	# 11
4251.20.120	# 12
4251.20.130	# 13
4251.20.140	# 14
4251.20.150	# 15
4251.20.160	# 16
4251.20.170	# 17
4251.20.180	# 18

FIT Femoral stems

Femoral Stems – Cementless (Ti6Al4V + PoroTi + HA) – Taper 12/14	
4211.25.010	LEFT, # 1
4211.25.020	LEFT, # 2
4211.25.030	LEFT, # 3
4211.25.040	LEFT, # 4
4211.25.050	LEFT, # 5
4211.25.060	LEFT, # 6
4211.25.070	LEFT, # 7
4211.25.110	RIGHT, # 1
4211.25.120	RIGHT, # 2
4211.25.130	RIGHT, # 3
4211.25.140	RIGHT, # 4
4211.25.150	RIGHT, # 5
4211.25.160	RIGHT, # 6
4211.25.170	RIGHT, # 7

Minima S Femoral stems

Standard Stems – Cementless (Ti6Al4V + PoroTi) – Taper 12/14	
4503.21.010	# 1
4503.21.020	# 2

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4503.21.030	# 3
4503.21.040	# 4
4503.21.050	# 5
4503.21.060	# 6
4503.21.070	# 7
4503.21.080	# 8
4503.21.090	# 9
4503.21.100	# 10
4503.21.110	# 11
4503.21.120	# 12

	Lateralized Stems – Cementless (Ti6Al4V + PoroTi) – Taper 12/14
4504.21.010	# 1
4504.21.020	# 2
4504.21.030	# 3
4504.21.040	# 4
4504.21.050	# 5
4504.21.060	# 6
4504.21.070	# 7
4504.21.080	# 8
4504.21.090	# 9
4504.21.100	# 10
4504.21.110	# 11
4504.21.120	# 12

Master SL Femoral stems

	Standard Stems – Cementless (Ti6Al4V + PoroTi) – Taper 12/14
3515.21.210	# 1
3515.21.220	# 2
3515.21.230	# 3
3515.21.240	# 4
3515.21.250	# 5
3515.21.260	# 6
3515.21.270	# 7
3515.21.280	# 8

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3515.21.290	# 9
3515.21.300	# 10
3515.21.310	# 11
3515.21.320	# 12
3515.21.330	# 13
	Standard Stems – Cementless (Ti6Al4V + PoroTi + HA) – Taper 12/14
3515.25.210	# 1
3515.25.220	# 2
3515.25.230	# 3
3515.25.240	# 4
3515.25.250	# 5
3515.25.260	# 6
3515.25.270	# 7
3515.25.280	# 8
3515.25.290	# 9
3515.25.300	# 10
3515.25.310	# 11
3515.25.320	# 12
3515.25.330	# 13
	Lateralized Stems – Cementless (Ti6Al4V + PoroTi) – Taper 12/14
3516.21.210	# 1
3516.21.220	# 2
3516.21.230	# 3
3516.21.240	# 4
3516.21.250	# 5
3516.21.260	# 6
3516.21.270	# 7
3516.21.280	# 8
3516.21.290	# 9
3516.21.300	# 10
3516.21.310	# 11
3516.21.320	# 12
3516.21.330	# 13
	Lateralized Stems – Cementless (Ti6Al4V +

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	PoroTi + HA) – Taper 12/14
3516.25.210	# 1
3516.25.220	# 2
3516.25.230	# 3
3516.25.240	# 4
3516.25.250	# 5
3516.25.260	# 6
3516.25.270	# 7
3516.25.280	# 8
3516.25.290	# 9
3516.25.300	# 10
3516.25.310	# 11
3516.25.320	# 12
3516.25.330	# 13

COLLO-MIS Femoral stems

	Stems – Cementless (Ti6Al4V + PoroTi + HA) – Taper 12/14
4201.25.010	# 1
4201.25.020	# 2
4201.25.030	# 3
4201.25.040	# 4
4201.25.050	# 5
4201.25.060	# 6
4201.25.070	# 7
4201.25.080	# 8
4201.25.090	# 9

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