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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 0065 Rev. 00

Manufacturer:

Limacorporate S.p.A.

Via Nazionale, 52

33038 Villanova San Daniele del Friuli (UDINE)

ITALY

Product:

Orthopaedic Implants

Arthroprosthesis. Shoulder 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.:

ITA1178901

Valid from:

2019-07-16

Valid until:

2024-05-26

Date,

2019-07-16

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):

SMR System
SMR Resurfacing System
Glenoids

SMR system	
COD.	DESCRIPTIONS
	Finned Humeral Body with Locking Screw (Ti6Al4V)
1350.15.110	Finned Humeral Body Medium
1350.15.120	Finned Humeral Body Short
	Trauma Humeral Body with Locking Screw (Ti6Al4V)
1350.15.010	Medium
1350.15.020	Long
1350.15.030	Short
	Cemented Stems (Ti6Al4V) L. 80 mm
1306.15.120	dia. 12 mm
1306.15.140	dia. 14 mm
1306.15.160	dia. 16 mm
1306.15.180	dia. 18 mm
1306.15.200	dia. 20 mm
	Cementless Finned Stems (Ti6Al4V) L. 60 mm
1304.15.110	dia. 11 mm
1304.15.120	dia. 12 mm
1304.15.130	dia. 13 mm
	Cementless Finned Stems (Ti6Al4V) L. 80 mm
1304.15.140	dia. 14 mm
1304.15.150	dia. 15 mm
1304.15.160	dia. 16 mm



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1309.15.154	dia. 15 mm, h 150 mm
1309.15.156	dia. 15 mm, h 180 mm
1309.15.158	dia. 15 mm, h 210 mm
	Neutral Adaptor Tapers (Ti6Al4V)
1330.15.270	0 mm
1331.15.270	0 mm, Long
	Eccentric Adaptor Tapers (Ti6Al4V)
1330.15.272	+ 2 mm
1330.15.274	+ 4 mm
1330.15.276	+ 6 mm
1330.15.278	+ 8 mm
1331.15.272	+ 2 mm, Long
1331.15.274	+ 4 mm, Long
1331.15.276	+ 6 mm, Long
1331.15.278	+ 8 mm, Long
	Humeral Heads (CoCrMo)
1322.09.380	Dia. 38 mm
1322.09.382	Dia. 38 mm ECC2
1322.09.384	Dia. 38 mm ECC4
1322.09.400	Dia. 40 mm
1322.09.401	Dia 40mm H12
1322.09.402	Dia 40mm H12 ECC2
1322.09.404	Dia 40mm H12 ECC4
1322.09.420	Dia. 42 mm
1322.09.421	Dia 42mm H12
1322.09.422	Dia 42mm H12 ECC2
1322.09.424	Dia 42mm H12 ECC4
1322.09.426	Dia 42mm H12 ECC6
1322.09.440	Dia. 44 mm
1322.09.441	Dia 44mm H13
1322.09.442	Dia 44mm H13 ECC2
1322.09.444	Dia 44mm H13 ECC4
1322.09.446	Dia 44mm H13 ECC6

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1322.09.447	Dia 44mm H13 ECC7
1322.09.460	Dia. 46 mm
1322.09.461	Dia 46mm H14
1322.09.480	Dia. 48 mm
1322.09.481	Dia 48mm H15
1322.09.500	Dia. 50 mm
1322.09.501	Dia 50mm H16
1322.09.520	Dia. 52 mm
1322.09.521	Dia 52mm H17
1322.09.540	Dia. 54 mm
1322.09.541	Dia 54mm H18
1321.09.401	Dia 40mm H13
1321.09.402	Dia 40mm H13 ECC2
1321.09.404	Dia 40mm H13 ECC4
1321.09.406	Dia 40mm H13 ECC6
1321.09.407	Dia 40mm H13 ECC7
1321.09.421	Dia 42mm H13
1321.09.422	Dia 42mm H13 ECC2
1321.09.424	Dia 42mm H13 ECC4
1321.09.426	Dia 42mm H13 ECC6
1321.09.427	Dia 42mm H13 ECC7
1321.09.441	Dia 44mm H14
1321.09.461	Dia 46mm H15
1321.09.481	Dia 48mm H16
1321.09.501	Dia 50mm H17
1321.09.521	Dia 52mm H18
1321.09.541	Dia 54mm H19
1324.09.401	Dia 40mm H17
1324.09.421	Dia 42mm H17
1324.09.441	Dia 44mm H18
1324.09.461	Dia 46mm H19
1324.09.481	Dia 48mm H20
1324.09.501	Dia 50mm H21



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1322.15.500	Dia. 50 mm
1322.15.501	Dia 50mm H16
1322.15.520	Dia. 52 mm
1322.15.521	Dia 52mm H17
1322.15.540	Dia. 54 mm
1322.15.541	Dia 54mm H18
1321.15.401	Dia 40mm H13
1321.15.402	Dia 40mm H13 ECC2
1321.15.404	Dia 40mm H13 ECC4
1321.15.406	Dia 40mm H13 ECC6
1321.15.407	Dia 40mm H13 ECC7
1321.15.421	Dia 42mm H13
1321.15.422	Dia 42mm H13 ECC2
1321.15.424	Dia 42mm H13 ECC4
1321.15.426	Dia 42mm H13 ECC6
1321.15.427	Dia 42mm H13 ECC7
1321.15.441	Dia 44mm H14
1321.15.461	Dia 46mm H15
1321.15.481	Dia 48mm H16
1321.15.501	Dia 50mm H17
1321.15.521	Dia 52mm H18
1321.15.541	Dia 54mm H19
1324.15.401	Dia 40mm H17
1324.15.421	Dia 42mm H17
1324.15.441	Dia 44mm H18
1324.15.461	Dia 46mm H19
1324.15.481	Dia 48mm H20
1324.15.501	Dia 50mm H21
1324.15.521	Dia 52mm H22
1324.15.541	Dia 54mm H23
1325.15.401	Dia 40mm H18
1325.15.421	Dia 42mm H18
1325.15.441	Dia 44mm H19

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1325.15.461	Dia 46mm H20
1325.15.481	Dia 48mm H21
1325.15.501	Dia 50mm H22
1325.15.521	Dia 52mm H23
1325.15.541	Dia 54mm H24
	CTA Humeral Heads (CoCrMo)
1323.09.420	dia. 42 mm
1323.09.460	dia. 46 mm
1323.09.500	dia. 50 mm
1323.09.540	dia. 54 mm
	CTA Humeral Heads (Ti6Al4V)
1323.15.420	dia. 42 mm
1323.15.460	dia. 46 mm
1323.15.500	dia. 50 mm
1323.15.540	dia. 54 mm
	CTA Heads Adaptor for Reverse Humeral Body (Ti6Al4V)
1352.15.200	36 mm Heads Adaptor for Reverse Humeral Body
	Reverse Humeral Bodies with Locking Screw (Ti6Al4V)
1352.20.010	HA Coated Reverse Humeral Body
1352.15.050	Finned Reverse Humeral Body for Trauma
1352.15.001	Humeral Extension + 9 mm
1352.15.010	Reverse Humeral Body
1352.15.005	Reverse Humeral Body - Short
1352.15.110	Randelli Reverse Humeral Body for revision
1352.15.105	Randelli Reverse Humeral Body for revision - Short
	Reverse Liners 36 mm (UHMWPE X-LIMA)
1360.50.010	Standard
1360.50.015	+ 3 mm
1360.50.020	+ 6 mm
1361.50.010	Retentive Std.
1361.50.015	Retentive + 3 mm
1361.50.020	Retentive + 6 mm
	Reverse Liners 36 mm (UHMWPE)

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1360.50.810	Standard
1360.50.815	+ 3 mm
1360.50.820	+ 6 mm
1361.50.810	Retentive Std.
1361.50.815	Retentive + 3 mm
1361.50.820	Retentive + 6 mm
	Glenosphere 36 mm with connector (CoCrMo)
1374.09.105	Glenosphere dia. 36 mm - Small - R
1374.09.110	Glenosphere dia. 36 mm
1374.15.010	Glenosphere + Adaptor + "LTO Randelli" Screw
1376.09.025	Eccentric Glenosphere dia. 36 mm - Small - R
1376.09.030	Eccentric Glenosphere dia. 36 mm
	Glenosphere 36 mm with connector (Ti6Al4V)
1374.15.105	Glenosphere dia. 36 mm - Small - R
1374.15.110	Glenosphere dia. 36 mm
1376.15.025	Eccentric Glenosphere dia. 36 mm - Small - R
1376.15.030	Eccentric Glenosphere dia. 36 mm
	Glenosphere 36 mm (CoCrMo)
1374.09.111	Glenosphere dia. 36 mm
1376.09.031	Eccentric Glenosphere dia. 36 mm
	Glenosphere 36 mm (Ti6Al4V)
1374.15.111	Glenosphere dia. 36 mm
1376.15.031	Eccentric Glenosphere dia. 36 mm
	Reverse HP Liners 44 mm (CoCrMo)
1362.09.010	Liner dia. 44 mm - Short
1362.09.015	Liner dia. 44 mm - Medium
1362.09.020	Liner dia. 44 mm - Long
1362.09.115	Lateralizing Liner dia. 44 mm - Medium
1362.09.120	Lateralizing Liner dia. 44 mm - Long
	Reverse HP Liners 44 mm (Alumina)
1362.39.015	Ceramic Reverse Liners 44 mm - medium
1362.39.020	Ceramic Reverse Liners 44 mm - long
	Reverse Liners 38 mm (CoCrMo)

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1327.11.400	dia. 40 mm
1327.11.420	dia. 42 mm
1327.11.440	dia. 44 mm
1327.11.460	dia. 46 mm
1327.11.480	dia. 48 mm
1327.11.500	dia. 50 mm
1327.11.520	dia. 52 mm
1327.11.540	dia. 54 mm
	Resurfacing Heads FDA (CoCrMo+PoroTi)
1327.10.400	dia. 40 mm
1327.10.420	dia. 42 mm
1327.10.440	dia. 44 mm
1327.10.460	dia. 46 mm
1327.10.480	dia. 48 mm
1327.10.500	dia. 50 mm
1327.10.520	dia. 52 mm
1327.10.540	dia. 54 mm
	CTA Resurfacing Heads (CoCrMo+PoroTi+HA)
1328.11.420	dia. 42 mm
1328.11.460	dia. 46 mm
1328.11.500	dia. 50 mm
1328.11.540	dia. 54 mm
	CTA Resurfacing Heads FDA (CoCrMo+PoroTi)
1328.10.420	dia. 42 mm
1328.10.460	dia. 46 mm
1328.10.500	dia. 50 mm
1328.10.540	dia. 54 mm
	Resurfacing Stems (Ti6Al4V)
1317.15.010	11 X 32 mm



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1317.15.020

13 X 36 mm

GLENOIDS

COD.	DESCRIPTIONS
	Cemented Glenoids (UHMWPE)
1378.50.005	Small-R
1378.50.010	Standard
1378.50.020	Small
	Cemented Glenoids 3 pegs (UHMWPE X - Lima)
1379.51.005	Extra-Small
1379.51.010	Standard
1379.51.020	Small
1379.51.030	Large
	Metal back glenoid (Ti6Al4V + PoroTi + HA)
1375.20.005	Small - R
1375.20.020	Small
1375.20.010	Standard
1375.20.030	Large
	Metal back glenoid (Ti6Al4V + PoroTi FDA)
1375.21.005	Small - R
1375.21.020	Small
1375.21.010	Standard
1375.21.030	Large
	Axioma Metal Back glenoid (Ti6Al4V + PoroTi + HA)
1375.25.350	Small - R
1375.25.360	Small
1375.25.370	Standard
1375.25.380	Large
	Axioma Metal Back glenoid (Ti6Al4V + PoroTi FDA)
1375.21.350	Small - R

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1375.21.360	Small
1375.21.370	Standard
1375.21.380	Large
	TT Baseplate (Ti6Al4V)
1375.15.605	Small-R
1375.15.620	Small
1375.15.610	Standard
	Axioma TT Baseplate (Ti6Al4V)
1375.15.650	Small-R
1375.15.660	Small
1375.15.670	Standard
	Axioma TT Glenoid Peg (Ti6Al4V)
1375.14.651	S-R Short
1375.14.652	S-R Medium
1375.14.653	S-R Long
1375.14.654	S-R X-Long
1375.14.661	S/STD Short
1375.14.662	S/STD Medium
1375.14.663	S/STD Long
1375.14.664	S/STD X-Long
	Metal Back liner (UHMWPE)
1377.50.005	Small - R
1377.50.020	Small
1377.50.010	Standard
1377.50.030	Large
	L2 Metal Back liner (UHMWPE)
1377.51.050	Small - R
1377.51.060	Small
1377.51.070	Standard
1377.51.080	Large
	AXIOMA Metal Back liner (UHMWPE)
1377.50.350	Small - R
1377.50.360	Small

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1377.50.370	Standard
1377.50.380	Large