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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 0070 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: Delta System**

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.:

ITA1147644

Valid from:

2019-08-09

Valid until:

2024-05-26

Date,

2019-08-09

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):

DELTA TT cups
DELTA PF cups
DELTA Fins cups
DELTA ST-C cups
DELTA One TT cups
DELTA Multihole TT cups
DELTA Revision cups
DELTA Revision TT cups
DELTA Cup Accessories

Parameters:

DELTA TT cups

Acetabular Cups (Ti6Al4V)

Code	Description
5552.15.440	dia. 44 mm, for Liners Size Small
5552.15.460	dia. 46 mm, for Liners Size Small
5552.15.480	dia. 48 mm, for Liners Size Small
5552.15.500	dia. 50 mm, for Liners Size Medium
5552.15.520	dia. 52 mm, for Liners Size Medium
5552.15.540	dia. 54 mm, for Liners Size Large
5552.15.560	dia. 56 mm, for Liners Size Large
5552.15.580	dia. 58 mm, for Liners Size Large
5552.15.600	dia. 60 mm, for Liners Size Large
5552.15.620	dia. 62 mm, for Liners Size Large
5552.15.640	dia. 64 mm, for Liners Size Large
5552.15.660	dia. 66 mm, for Liners Size Large
5552.15.680	dia. 68 mm, for Liners Size Large
5552.15.700	dia. 70 mm, for Liners Size Large
5552.15.720	dia. 72 mm, for Liners Size Large
5552.15.740	dia. 74 mm, for Liners Size Large
5552.15.760	dia. 76 mm, for Liners Size Large

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Delta PF cups

Acetabular cup (Ti6Al4V + PoroTi + HA)

Code	Description
5551.25.440	dia. 44 mm, for Liners Size Small
5551.25.460	dia. 46 mm, for Liners Size Small
5551.25.480	dia. 48 mm, for Liners Size Small
5551.25.500	dia. 50 mm, for Liners Size Medium
5551.25.520	dia. 52 mm, for Liners Size Medium
5551.25.540	dia. 54 mm, for Liners Size Medium
5551.25.501	dia. 50 mm, for Liners Size Large
5551.25.521	dia. 52 mm, for Liners Size Large
5551.25.541	dia. 54mm, for Liners Size Large
5551.25.560	dia. 56 mm, for Liners Size Large
5551.25.580	dia. 58 mm, for Liners Size Large
5551.25.600	dia. 60 mm, for Liners Size Large
5551.25.620	dia. 62 mm, for Liners Size Large
5551.25.640	dia. 64 mm, for Liners Size Large
5551.25.660	dia. 66 mm, for Liners Size Large
5551.25.680	dia. 68 mm, for Liners Size Large
5551.25.700	dia. 70 mm, for Liners Size Large
5551.25.720	dia. 72 mm, for Liners Size Large

Acetabular cups (Ti6Al4V + PoroTi)

Code	Description
5551.21.440	dia. 44 mm, for Liners Size Small
5551.21.460	dia. 46 mm, for Liners Size Small
5551.25.480	dia. 48 mm, for Liners Size Small
5551.21.500	dia. 50 mm, for Liners Size Medium
5551.21.520	dia. 52 mm, for Liners Size Medium
5551.21.540	dia. 54 mm, for Liners Size Medium
5551.21.501	dia. 50 mm, for Liners Size Large
5551.21.521	dia. 52 mm, for Liners Size Large
5551.21.541	dia. 54 mm, for Liners Size Large

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5551.21.560	dia. 56 mm, for Liners Size Large
5551.21.580	dia. 58 mm, for Liners Size Large
5551.21.600	dia. 60 mm, for Liners Size Large
5551.21.620	dia. 62 mm, for Liners Size Large
5551.21.640	dia. 64 mm, for Liners Size Large
5551.21.660	dia. 66 mm, for Liners Size Large
5551.21.680	dia. 68 mm, for Liners Size Large
5551.21.700	dia. 70 mm, for Liners Size Large
5551.21.720	dia. 72 mm, for Liners Size Large

DELTA Fins cups

Acetabular Cups (Ti6Al4V + PoroTi + HA)	
Code	Description
5550.25.420	dia. 42 mm, for Liners Size Small
5550.25.440	dia. 44 mm, for Liners Size Small
5550.25.460	dia. 46 mm, for Liners Size Small
5550.25.480	dia. 48 mm, for Liners Size Small
5550.25.500	dia. 50 mm, for Liners Size Medium
5550.25.520	dia. 52 mm, for Liners Size Medium
5550.25.541	dia. 54 mm, for Liners Size Large
5550.25.560	dia. 56 mm, for Liners Size Large
5550.25.580	dia. 58 mm, for Liners Size Large
5550.25.600	dia. 60 mm, for Liners Size Large
5550.25.620	dia. 62 mm, for Liners Size Large
5550.25.640	dia. 64 mm, for Liners Size Large
5550.25.660	dia. 66 mm, for Liners Size Large

DELTA ST-C cups

Acetabular cups (Ti6Al4V + PoroTi)	
Code	Description
5522.21.144	dia. 44 mm, for Liners Size Small
5522.21.146	dia. 46 mm, for Liners Size Small
5522.21.148	dia. 48 mm, for Liners Size Small

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5522.21.050	dia. 50 mm, for Liners Size Medium
5522.21.052	dia. 52 mm, for Liners Size Medium
5522.21.154	dia. 54 mm, for Liners Size Large
5522.21.156	dia. 56 mm, for Liners Size Large
5522.21.158	dia. 58 mm, for Liners Size Large
5522.21.160	dia. 60 mm, for Liners Size Large
5522.21.162	dia. 62 mm, for Liners Size Large

Acetabular cups (Ti6Al4V + PoroTi + HA)	
Code	Description
5522.25.144	dia. 44 mm, for Liners Size Small
5522.25.146	dia. 46 mm, for Liners Size Small
5522.25.148	dia. 48 mm, for Liners Size Small
5522.25.050	dia. 50 mm, for Liners Size Medium
5522.25.052	dia. 52 mm, for Liners Size Medium
5522.25.154	dia. 54 mm, for Liners Size Large
5522.25.156	dia. 56 mm, for Liners Size Large
5522.25.158	dia. 58 mm, for Liners Size Large
5522.25.160	dia. 60 mm, for Liners Size Large
5522.25.162	dia. 62 mm, for Liners Size Large

DELTA One TT cups

Acetabular cups (Ti6Al4V)	
Code	Description
5549.14.440	dia. 44 mm, for Liners Size Small
5549.14.460	dia. 46 mm, for Liners Size Small
5549.14.480	dia. 48 mm, for Liners Size Small
5549.14.501	dia. 50 mm, for Liners Size Large
5549.14.521	dia. 52 mm, for Liners Size Large
5549.14.541	dia. 54 mm, for Liners Size Large
5549.14.560	dia. 56 mm, for Liners Size Large
5549.14.580	dia. 58 mm, for Liners Size Large
5549.14.600	dia. 60 mm, for Liners Size Large
5549.14.620	dia. 62 mm, for Liners Size Large

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5549.14.640	dia. 64 mm, for Liners Size Large
5549.14.660	dia. 66 mm, for Liners Size Large

DELTA Multihole TT cups

Acetabular cups (Ti6Al4V)	
Code	Description
5548.14.440	dia. 44 mm, for Liners Size Small
5548.14.460	dia. 46 mm, for Liners Size Small
5548.14.480	dia. 48 mm, for Liners Size Small
5548.14.500	dia. 50 mm, for Liners Size Large
5548.14.520	dia. 52 mm, for Liners Size Large
5548.14.540	dia. 54 mm, for Liners Size Large
5548.14.560	dia. 56 mm, for Liners Size EXTRA-LARGE
5548.14.580	dia. 58 mm, for Liners Size EXTRA-LARGE
5548.14.600	dia. 60 mm, for Liners Size EXTRA-LARGE
5548.14.620	dia. 62 mm, for Liners Size EXTRA-LARGE
5548.14.640	dia. 64 mm, for Liners Size EXTRA-LARGE
5548.14.660	dia. 66 mm, for Liners Size EXTRA-LARGE
5548.14.680	dia. 68 mm, for Liners Size EXTRA-LARGE
5548.14.700	dia. 70 mm, for Liners Size EXTRA-LARGE
5548.14.720	dia. 72 mm, for Liners Size EXTRA-LARGE
5548.14.740	dia. 74 mm, for Liners Size EXTRA-LARGE
5548.14.760	dia. 76 mm, for Liners Size EXTRA-LARGE



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DELTA Revision TT cups

Acetabular cups (Ti)

Code	Description
5533.38.050	dia. 50 mm, for Liners Size Large
5533.38.054	dia. 54 mm, for Liners Size Large
5533.38.058	dia. 58 mm, for Liners Size Large
5533.38.062	dia. 62 mm, for Liners Size Large
5533.38.066	dia. 66 mm, for Liners Size Large

Delta Revision cups

Acetabular cups (Ti + PoroTi)

5533.21.050	dia. 50 mm, for Liners Size Large
5533.21.054	dia. 54 mm, for Liners Size Large
5533.21.058	dia. 58 mm, for Liners Size Large
5533.21.062	dia. 62 mm, for Liners Size Large
5533.21.066	dia. 66 mm, for Liners Size Large

TT Hemispheric modules (Ti6Al4V)

Code	Description
5533.14.500	dia. 50 mm, Eccentricity 12 mm
5533.14.502	dia. 50 mm, Eccentricity 18 mm
5533.14.540	dia. 54 mm, Eccentricity 12 mm
5533.14.542	dia. 54 mm, Eccentricity 18 mm
5533.14.580	dia. 58 mm, Eccentricity 12 mm
5533.14.582	dia. 58 mm, Eccentricity 18 mm
5533.14.620	dia. 62 mm, Eccentricity 12 mm
5533.14.622	dia. 62 mm, Eccentricity 18 mm
5533.14.660	dia. 66 mm, Eccentricity 12 mm
5533.14.662	dia. 66 mm, Eccentricity 18 mm

DELTA Cup Accessories

BioloX®Delta Liner

Code	Description
5885.42.052	I.D. 28 mm - Size X SMALL



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5885.42.155	I.D. 32 mm - Size SMALL
5885.42.258	I.D. 36 mm - Size MEDIUM
5885.42.260	I.D. 36 mm - Size LARGE
5885.42.262	I.D. 40 mm - Size LARGE

Neutral Liner (UHMWPE X-LIMA + Ti6Al4V)	
Code	Description
5885.51.055	I.D. 28 mm - Size SMALL
5885.51.058	I.D. 28 mm - Size MEDIUM
5885.51.158	I.D. 32 mm - Size MEDIUM
5885.51.060	I.D. 28 mm - Size LARGE
5885.51.160	I.D. 32 mm - Size LARGE
5885.51.260	I.D. 36 mm - Size LARGE
5885.51.070	I.D. 28 mm - Size EXTRA-LARGE
5885.51.170	I.D. 32 mm - Size EXTRA-LARGE
5885.51.270	I.D. 36 mm - Size EXTRA-LARGE
5885.51.272	I.D. 40 mm - Size EXTRA-LARGE

Neutral Liner (UHMWPE X-LIMA + Ti6Al4V)	
Code	Description
5885.51.005	I.D. 28 mm - Size SMALL
5885.51.008	I.D. 28 mm - Size MEDIUM
5885.51.108	I.D. 32 mm - Size MEDIUM
5885.51.010	I.D. 28 mm - Size LARGE
5885.51.110	I.D. 32 mm - Size LARGE
5885.51.210	I.D. 36 mm - Size LARGE

Protruded Liner (UHMWPE X-LIMA + Ti6Al4V)	
Code	Description
5886.51.055	I.D. 28 mm - Size SMALL
5886.51.058	I.D. 28 mm - Size MEDIUM
5886.51.158	I.D. 32 mm - Size MEDIUM
5886.51.060	I.D. 28 mm - Size LARGE
5886.51.160	I.D. 32 mm - Size LARGE
5886.51.260	I.D. 36 mm - Size LARGE

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5886.51.070	I.D. 28 mm - Size EXTRA-LARGE
5886.51.170	I.D. 32 mm - Size EXTRA-LARGE
5886.51.270	I.D. 36 mm - Size EXTRA-LARGE
5886.51.272	I.D. 40 mm - Size EXTRA-LARGE

Neutral Liner (UHMWPE + Ti6Al4V)	
Code	Description
5885.50.055	I.D. 28 mm - Size SMALL
5885.50.058	I.D. 28 mm - Size MEDIUM
5885.50.060	I.D. 28 mm - Size LARGE

Protruded Liner (UHMWPE + Ti6Al4V)	
Code	Description
5886.50.055	I.D. 28 mm - Size SMALL
5886.50.058	I.D. 28 mm - Size MEDIUM
5886.50.060	I.D. 28 mm - Size LARGE

Spacers (Ti6Al4V)	
Code	Description
5885.15.310	Neutral Spacer Size S (Use Liner X Small)
5885.15.320	Neutral Spacer Size S+5 (Use Liner X Small)
5886.15.300	Angled Spacer 10° Size S (Use Liner X Small)
5886.15.310	Angled Spacer 20° Size S (Use Liner X Small)
5885.15.420	Neutral Spacer Size M+5 (Use Liner Small)
5885.15.510	Neutral Spacer Size L (Use Liner Medium)
5885.15.520	Neutral Spacer Size L+5 (Use Liner Medium)
5886.15.500	Angled Spacer 10° Size L (Use Liner Medium)
5886.15.510	Angled Spacer 20° Size L (Use Liner Medium)
5886.15.505	Angled Spacer 10° Size L+5 (Use Liner Medium)
5886.15.520	Angled Spacer 20° Size L+5 (Use Liner Medium)
5885.15.610	Neutral Spacer Size XL (Use Liner Large)
5885.15.620	Neutral Spacer Size XL+5 (Use Liner Large)
5886.15.600	Angled Spacer 10° Size XL (Use Liner Large)
5886.15.610	Angled Spacer 20° Size XL (Use Liner Large)
5886.15.605	Angled Spacer 10° Size XL+5 (Use Liner Large)

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5886.15.620

Angled Spacer 20° Size XL+5 (Use Liner Large)

Dual Mobility Liner (CoCrMo)

Code	Description
5885.09.040	Liner MEDIUM for mobile liner dia. 40mm
5885.09.042	Liner LARGE for mobile liner dia. 42mm

Mobile Liner (UHMWPE)

Code	Description
5566.50.401	dia.40mm for head dia. 28mm
5566.50.420	dia.42mm for head dia. 28mm

Mobile Liners (LimaVit)

Code	Description
5566.54.401	dia.40mm for head dia. 28mm
5566.54.420	dia.42mm for head dia. 28mm

LimaVit neutral liners (LimaVit +Ti6Al4V)

Code	Description
5885.54.055	I.D.28 mm Size SMALL
5885.54.058	I.D.28 mm Size MEDIUM
5885.54.060	I.D.28 mm Size LARGE
5885.54.070	I.D.28 mm Size EXTRA-LARGE
5885.54.155	I.D.32 mm Size SMALL
5885.54.158	I.D.32 mm Size MEDIUM
5885.54.160	I.D.32 mm Size LARGE
5885.54.170	I.D.32 mm Size EXTRA-LARGE
5885.54.258	I.D.36 mm Size MEDIUM
5885.54.260	I.D.36 mm Size LARGE
5885.54.270	I.D.36 mm Size EXTRA-LARGE
5885.54.262	I.D.40 mm Size LARGE
5885.54.272	I.D.40 mm Size EXTRA-LARGE

LimaVit protruded liners (LimaVit +Ti6Al4V)

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Code	Description
5886.54.055	I.D.28 mm Size SMALL
5886.54.058	I.D.28 mm Size MEDIUM
5886.54.060	I.D.28 mm Size LARGE
5886.54.070	I.D.28 mm Size EXTRA-LARGE
5886.54.158	I.D.32 mm Size MEDIUM
5886.54.160	I.D.32 mm Size LARGE
5886.54.170	I.D.32 mm Size EXTRA-LARGE
5886.54.260	I.D.36 mm Size LARGE
5886.54.270	I.D.36 mm Size EXTRA-LARGE
5886.54.272	I.D.40 mm Size EXTRA-LARGE