



Declaration of conformity

Ref. DD 02 003 – DELTA System

Manufacturer	LimaCorporate S.p.A.
Address	Via Nazionale, 52 33038 – Villanova di S.Daniele del Friuli (UD)-ITALY
Product	DELTA System
Codes and description	see Table 1, Annex 1
First CE marked lots and first CE approval dates	see Table 2, Annex 2
Classification	Class III (according to commission directive 2005/50/EC)

We, Limacorporate S.p.A., ensure and declare with sole responsibility that the above mentioned products are in conformity with the Essential Requirements of **MDD 93/42/EEC** and following modifications (**2007/47/EC**) and they have been introduced on market according to the **D.Lgs. 24 febbraio 1997, n. 46**. Conformity is proven according to what specified in Annex II. The product's documentation is available in our head office.

Notified body n.0123 TÜV SÜD Product Service GmbH
RidlerStr. 65, 80339 München, Germany

EC certificate (Annex II (excl. II.4), section 3 of MDD 93/42/EEC)

Certificate G1 075731 0058 Rev.01

Issue date 25-10-2019

Expiry date 26-05-2024

EC design examination certificate (Annex II, section 4 of MDD 93/42/EEC)

Certificate G7 075731 0070 Rev. 00

Issue date 09-08-2019

Expiry date 26-05-2024

Villanova di S.Daniele, 25-10-2019

Regulatory Manager

Roberto Gabetta



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Annex 1

DELTA - TT	
COD.	DESCRIPTIONS
Acetabular Cups (Ti6Al4V)	
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

DELTA - PF	
COD.	DESCRIPTIONS
Acetabular Cups (Ti6Al4V + PoroTi + HA)	
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



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5551.25.700	dia. 70 mm, for Liners Size Large
5551.25.720	dia. 72 mm, for Liners Size Large
Acetabular Cups (Ti6Al4V + PoroTi)	
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
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	
COD.	DESCRIPTIONS
Acetabular Cups (Ti6Al4V + PoroTi + HA)	
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



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DELTA - ST-C

COD.	DESCRIPTIONS
ST - C Acetabular Cups (Ti6Al4V + PoroTi)	
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
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
ST - C Acetabular Cups (Ti6Al4V + PoroTi + HA)	
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

COD.	DESCRIPTIONS
Acetabular Cups (Ti6Al4V)	
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
5549.14.640	dia. 64 mm, for Liners Size Large
5549.14.660	dia. 66 mm, for Liners Size Large



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DELTA MULTIHOLE TT

COD.	DESCRIPTIONS
Acetabular Cups (Ti6Al4V)	
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

DELTA REVISION and REVISION TT

COD.	DESCRIPTIONS
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
Acetabular Cups (Ti)	
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
Hemispheric Modules (Ti6Al4V)	
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



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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

<i>COD.</i>	<i>DESCRIPTIONS</i>
Delta Liners (Biologix® Delta)	
5885.42.052	I.D. 28 mm - Size X SMALL
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 Liners (UHMWPE X-LIMA + Ti6Al4V)	
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 Liners (UHMWPE X-LIMA + Ti6Al4V)	
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 Liners (UHMWPE X-LIMA + Ti6Al4V)	
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
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 Liners (UHMWPE + Ti6Al4V)	



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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 Liners (UHMWPE + Ti6Al4V)	
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)	
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)
5886.15.620	Angled Spacer 20° Size XL+5 (Use Liner Large)
Dual mobility liner (CoCrMo)	
5885.09.040	Liner MEDIUM for mobile liner dia. 40mm
5885.09.042	Liner LARGE for mobile liner dia. 42mm
Mobile Liners (UHMWPE)	
5566.50.401	dia.40mm for head dia. 28mm
5566.50.420	dia.42mm for head dia. 28mm
Mobile Liners (LimaVit)	
5566.54.401	dia.40mm for head dia. 28mm
5566.54.420	dia.42mm for head dia. 28mm
LimaVit neutral liners (LimaVit + Ti6Al4V)	
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



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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)	
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

Table 1: Codes and descriptions

Villanova di S.Daniele, 25-10-2019

Regulatory Manager

Roberto Gabetta



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Annex 2

Product	First CE marked lot	First CE approval date
DELTA TT cups	0705513	15.05.2007
DELTA PF cups	0300319	31.01.2003
DELTA Fins cups	0601875	15.05.2006
DELTA ST-C cups	0200351	07.02.2002
DELTA One TT cups	0802292	02.04.2008
DELTA Multihole TT cups	1407714	06.08.2015
DELTA Revision and Revision TT cups	0603841	03.10.2006
DELTA Cup Accessories	0100366	15.02.2001

Table 2: First CE marked lot and first CE approval date for each product

Villanova di S.Daniele, 25-10-2019

Regulatory Manager

Roberto Gabetta

