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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 0059 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  
protheses: Femoral Heads**

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.:**

ITA1072134

**Valid from:**

2018-11-11

**Valid until:**

2023-11-10

**Date,**

2018-10-30

Stefan Preiß

TÜV SÜD  
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AA1/07.17



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## Facility(ies):

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

## Model(s):

**Femoral Modular Heads**  
**Bipolar Heads**  
**Lock Bipolar Heads**  
**Femoral Cephalic Heads**

## Parameter:

### FEMORAL MODULAR HEADS

#### Heads (BioloX<sup>®</sup> Delta) - Taper 12/14

Code	Description
5010.42.281	dia. 28 mm, S, Taper 12/14
5010.42.282	dia. 28 mm, M, Taper 12/14
5010.42.283	dia. 28 mm, L, Taper 12/14
5010.42.321	dia. 32 mm, S, Taper 12/14
5010.42.322	dia. 32 mm, M, Taper 12/14
5010.42.323	dia. 32 mm, L, Taper 12/14
5010.42.361	dia. 36 mm, S, Taper 12/14
5010.42.362	dia. 36 mm, M, Taper 12/14
5010.42.363	dia. 36 mm, L, Taper 12/14
5010.42.364	dia. 36 mm, XL, Taper 12/14
5010.42.401	dia. 40 mm, S, Taper 12/14
5010.42.402	dia. 40 mm, M, Taper 12/14
5010.42.403	dia. 40 mm, L, Taper 12/14
5010.42.404	dia. 40 mm, XL, Taper 12/14

#### Heads (CoCrMo) - Taper 12/14

Code	Description
5010.09.221	dia. 22 mm, S, Taper 12/14
5010.09.222	dia. 22 mm, M, Taper 12/14
5010.09.223	dia. 22 mm, L, Taper 12/14
5010.09.224	dia. 22 mm, XL, Taper 12/14
5010.09.281	dia. 28 mm, S, Taper 12/14
5010.09.282	dia. 28 mm, M, Taper 12/14

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5010.09.283	dia. 28 mm, L, Taper 12/14
5010.09.284	dia. 28 mm, XL, Taper 12/14
5010.09.285	dia. 28 mm, XXL, Taper 12/14
5010.09.286	dia. 28 mm, XXXL, Taper 12/14
5010.09.321	dia. 32 mm, S, Taper 12/14
5010.09.322	dia. 32 mm, M, Taper 12/14
5010.09.323	dia. 32 mm, L, Taper 12/14
5010.09.324	dia. 32 mm, XL, Taper 12/14
5010.09.325	dia. 32 mm, XXL, Taper 12/14
5010.09.326	dia. 32 mm, XXXL, Taper 12/14
5010.09.361	dia. 36 mm, S, Taper 12/14
5010.09.362	dia. 36 mm, M, Taper 12/14
5010.09.363	dia. 36 mm, L, Taper 12/14
5010.09.364	dia. 36 mm, XL, Taper 12/14
5010.09.365	dia. 36 mm, XXL, Taper 12/14
5010.09.366	dia. 36 mm, XXXL, Taper 12/14
<b>Heads (AISI 316/L) - Taper 12/14</b>	
<b>Code</b>	<b>Description</b>
5010.05.221	dia. 22 mm, S, Taper 12/14
5010.05.222	dia. 22 mm, M, Taper 12/14
5010.05.223	dia. 22 mm, L, Taper 12/14
5010.05.224	dia. 22 mm, XL, Taper 12/14
5010.05.281	dia. 28 mm, S, Taper 12/14
5010.05.282	dia. 28 mm, M, Taper 12/14
5010.05.283	dia. 28 mm, L, Taper 12/14
5010.05.284	dia. 28 mm, XL, Taper 12/14
5010.05.285	dia. 28 mm, XXL, Taper 12/14
5010.05.286	dia. 28 mm, XXXL, Taper 12/14
5010.05.321	dia. 32 mm, S, Taper 12/14
5010.05.322	dia. 32 mm, M, Taper 12/14
5010.05.323	dia. 32 mm, L, Taper 12/14
5010.05.324	dia. 32 mm, XL, Taper 12/14
5010.05.325	dia. 32 mm, XXL, Taper 12/14
5010.05.326	dia. 32 mm, XXXL, Taper 12/14
<b>Heads (FeCrNiMnMoNbN) - Taper 12/14</b>	

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Code	Description
2416.07.221	dia. 22 mm, - 2, Taper 12/14
2416.07.222	dia. 22 mm, 0, Taper 12/14
2416.07.223	dia. 22 mm, + 4, Taper 12/14
5010.07.281	dia. 28 mm, S, Taper 12/14
5010.07.282	dia. 28 mm, M, Taper 12/14
5010.07.283	dia. 28 mm, L, Taper 12/14
5010.07.284	dia. 28 mm, XL, Taper 12/14
5010.07.285	dia. 28 mm, XXL, Taper 12/14
5010.07.286	dia. 28 mm, XXXL, Taper 12/14
<b>Revision Heads (BioloX ® Delta, Ti6Al4V) - Taper 12/14</b>	
Code	Description
5010.42.021	dia. 28 mm, S, Taper 12/14
5010.42.022	dia. 28 mm, M, Taper 12/14
5010.42.023	dia. 28 mm, L, Taper 12/14
5010.42.024	dia. 28 mm, XL, Taper 12/14
5010.42.031	dia. 32 mm, S, Taper 12/14
5010.42.032	dia. 32 mm, M, Taper 12/14
5010.42.033	dia. 32 mm, L, Taper 12/14
5010.42.034	dia. 32 mm, XL, Taper 12/14
5010.42.041	dia. 36 mm, S, Taper 12/14
5010.42.042	dia. 36 mm, M, Taper 12/14
5010.42.043	dia. 36 mm, L, Taper 12/14
5010.42.044	dia. 36 mm, XL, Taper 12/14
5010.42.051	dia. 40 mm, S, Taper 12/14
5010.42.052	dia. 40 mm, M, Taper 12/14
5010.42.053	dia. 40 mm, L, Taper 12/14
5010.42.054	dia. 40 mm, XL, Taper 12/14
<b>Heads (CoCrMo) - Taper 14/16</b>	
Code	Description
5012.09.221	dia. 22 mm, S, Taper 14/16
5012.09.222	dia. 22 mm, M, Taper 14/16
5012.09.223	dia. 22 mm, L, Taper 14/16
5012.09.281	dia. 28 mm, S, Taper 14/16
5012.09.282	dia. 28 mm, M, Taper 14/16



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5012.09.283	dia. 28 mm, L, Taper 14/16
5012.09.284	dia. 28 mm, XL, Taper 14/16
5012.09.285	dia. 28 mm, XXL, Taper 14/16
5012.09.286	dia. 28 mm, XXXL, Taper 14/16
5012.09.321	dia. 32 mm, S, Taper 14/16
5012.09.322	dia. 32 mm, M, Taper 14/16
5012.09.323	dia. 32 mm, L, Taper 14/16
5012.09.324	dia. 32 mm, XL, Taper 14/16
5012.09.325	dia. 32 mm, XXL, Taper 14/16
5012.09.326	dia. 32 mm, XXXL, Taper 14/16

## BIPOLAR HEADS

Bipolar Heads (AISI 316/L, UHMWPE)	
Code	Description
5030.05.380	dia. 38 mm, for dia. 22 mm Heads
5030.05.390	dia. 39 mm, for dia. 22 mm Heads
5030.05.400	dia. 40 mm, for dia. 22 mm Heads
Bipolar Heads (CoCrMo, UHMWPE)	
Code	Description
5030.09.380	dia. 38 mm, for dia. 22 mm Heads
5030.09.390	dia. 39 mm, for dia. 22 mm Heads
5030.09.400	dia. 40 mm, for dia. 22 mm Heads

## LOCK BIPOLAR HEADS

LOCK Bipolar Heads (AISI 316/L, UHMWPE)	
Code	Description
5527.05.410	dia. 41 mm, for dia. 28 mm Heads
5527.05.420	dia. 42 mm, for dia. 28 mm Heads
5527.05.430	dia. 43 mm, for dia. 28 mm Heads
5527.05.440	dia. 44 mm, for dia. 28 mm Heads
5527.05.450	dia. 45 mm, for dia. 28 mm Heads
5527.05.460	dia. 46 mm, for dia. 28 mm Heads
5527.05.470	dia. 47 mm, for dia. 28 mm Heads
5527.05.480	dia. 48 mm, for dia. 28 mm Heads
5527.05.490	dia. 49 mm, for dia. 28 mm Heads

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5527.05.500	dia. 50 mm, for dia. 28 mm Heads
5527.05.510	dia. 51 mm, for dia. 28 mm Heads
5527.05.520	dia. 52 mm, for dia. 28 mm Heads
5527.05.530	dia. 53 mm, for dia. 28 mm Heads
5527.05.540	dia. 54 mm, for dia. 28 mm Heads
5527.05.550	dia. 55 mm, for dia. 28 mm Heads
5527.05.560	dia. 56 mm, for dia. 28 mm Heads
5527.05.570	dia. 57 mm, for dia. 28 mm Heads
<b>LOCK Bipolar Heads (CoCrMo, UHMWPE)</b>	
<b>Code</b>	<b>Description</b>
5527.09.410	dia. 41 mm, for dia. 28 mm Heads
5527.09.420	dia. 42 mm, for dia. 28 mm Heads
5527.09.430	dia. 43 mm, for dia. 28 mm Heads
5527.09.440	dia. 44 mm, for dia. 28 mm Heads
5527.09.450	dia. 45 mm, for dia. 28 mm Heads
5527.09.460	dia. 46 mm, for dia. 28 mm Heads
5527.09.470	dia. 47 mm, for dia. 28 mm Heads
5527.09.480	dia. 48 mm, for dia. 28 mm Heads
5527.09.490	dia. 49 mm, for dia. 28 mm Heads
5527.09.500	dia. 50 mm, for dia. 28 mm Heads
5527.09.510	dia. 51 mm, for dia. 28 mm Heads
5527.09.520	dia. 52 mm, for dia. 28 mm Heads
5527.09.530	dia. 53 mm, for dia. 28 mm Heads
5527.09.540	dia. 54 mm, for dia. 28 mm Heads
5527.09.550	dia. 55 mm, for dia. 28 mm Heads
5527.09.560	dia. 56 mm, for dia. 28 mm Heads
5527.09.570	dia. 57 mm, for dia. 28 mm Heads

## FEMORAL CEPHALIC HEADS

<b>Femoral Cephalic Heads (AISI 316/L) - Taper 12/14</b>	
<b>Code</b>	<b>Description</b>
5061.05.410	dia. 41.0 mm
5061.05.420	dia. 42.0 mm
5061.05.430	dia. 43.0 mm
5061.05.445	dia. 44.5 mm

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5061.05.460	dia. 46.0 mm
5061.05.475	dia. 47.5 mm
5061.05.490	dia. 49.0 mm
5061.05.510	dia. 51.0 mm
5061.05.525	dia. 52.5 mm
5061.05.540	dia. 54.0 mm
5061.05.555	dia. 55.5 mm
5061.05.570	dia. 57.0 mm