



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 13 10 75731 029

Manufacturer:**Limacorporate S.p.A.**

Via Nazionale, 52
33038 Villanova San Daniele del Friuli (UDINE)
ITALY

Product:

Orthopaedic Implants
Arthroprosthesis. Total hip joint prostheses: 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.: ITA 234614

Valid from: 2013-11-11
Valid until: 2018-11-10

Date, 2013-11-12

Hans-Heiner Junker



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

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Model(s):

Femoral Modular Heads
Bipolar Heads
Lock Bipolar Heads
Femoral Cephalic Heads

Parameters:

Femoral modular heads- Taper 12/14:
- BioloX® Delta dia. 28 mm #S-L, dia. 32 mm #S-L,
dia. 36 mm #S-XL, dia. 40 mm #S-XL
- BioloX® Forte dia. 28 mm #S-L, dia. 32 mm #S-L,
dia. 36 mm #S-L
- CoCrMo dia. 22 mm #S-XL, dia. 28 mm #S-XXXL,
dia. 32 mm #S-XXXL, dia. 36 mm #S-XXXL
- AISI 316/L dia. 22 mm #S-XL, dia. 28 mm #S-XXXL,
dia. 32 mm #S-XXXL
- FeCrNiMnMoNbN dia. 22 mm # -2 / +4, d
ia. 28 mm #S-XXXL
- Revision Heads BioloX® Delta + Ti6Al4V
dia. 28 mm #S-XL, dia. 32 mm #S-XL,
dia. 36 mm #S-XL, dia. 40 mm #S-XL
Femoral modular heads- Taper 14/16:
- BioloX® Forte dia. 32 mm #S-L
- CoCrMo dia. 22 mm #S-L, dia. 28 mm #S-XXXL, dia.
32 mm #S-XXXL
- AISI 316/L dia. 22 mm #S-L, dia. 28 mm #S-XXXL,
dia. 32 mm #S-XXXL
Adaptor Tapers from 12/14 a 14/16
AISI 316/L , Ti6Al4V, CoCrMo
Bipolar Heads
- AISI 316/L and UHMWPE dia. 38-40 mm
- CoCrMo and UHMWPE dia. 38-40 mm
LOCK Bipolar Heads
- AISI 316/L and UHMWPE dia. 41-57 mm
- CoCrMo and UHMWPE dia. 41-57 mm
Femoral Cephalic Heads - Taper 12/14
- AISI 316/L dia. 41-57 mm

Facility(ies):

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