

Manufacturer:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s):

BIOLOX® Femoral Heads and Cup Inserts

Intended Use:

The ic-Heads BIOLOX® are ceramic femoral heads intended for articulation with BIOLOX® delta cup inserts, polyethylene-acetabular cups, polyethylene-acetabular cup inserts or tripolar polyethylene-components as part of a total hip arthroplasty or with ic- bipolar heads CoCrMo as part of a hemi hip arthroplasty. They are connected modularly with hip stems.

The ic-Head Revision BIOLOX® delta is a femoral head consisting of a taper adapter and an ic-head BIOLOX® delta which is matched to the corresponding taper adapter. It is intended for articulation with a BIOLOX® delta cup insert, a polyethylene-acetabular cup, a polyethylene-acetabular cup insert, a tripolar polyethylene-component as part of a total hip arthroplasty or with an ic- bipolar head CoCrMo as part of a hemi hip arthroplasty. It is connected modularly with a hip stem. It is intended for use either for acetabular cup revision or femoral head exchange in cases where ceramic femoral heads must be inserted on hip stems left in situ. Furthermore, the system makes neck length corrections possible for primary hip replacements.

The BIOLOX® delta Cup Insert is intended for insertion into a modular acetabular cup to provide the articulating surface with an ic-Head BIOLOX® as part of a total hip arthroplasty.

REF Number(s):

REF-Numbers see Attachment I - III

Classification:

Class III

(Council Directive 93/42/EEC, Annex IX, rule 8, in conjunction with commission directive 2005/50/EC)

Standard(s) applied:

EN ISO 13485

Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 14971

Medical devices - Application of risk management to medical devices

EN ISO 11137-1

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11607-1

Packaging for terminally sterilized medical devices – Requirements for materials, sterile barrier systems and packaging systems

EN ISO 10993-1

Biological evaluation of medical devices – Part1: Evaluation and testing

EN ISO 14630

Non-active surgical implants - General requirements

EN ISO 21534

Non-active surgical implants - Joint replacement implants - Particular requirements

EU Declaration of Conformity

GMDN code(s) and term(s):

P 38156

Ceramic femoral head prosthesis

P 48055

Ceramic acetabular liner

We declare under our sole responsibility that the medical devices listed in the attachments are in conformity with the essential requirements of Annex I of Council Directive 93/42/EEC and have undergone the conformity assessment procedure according to Annex II of Council Directive 93/42/EEC.

Notified Body:

MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

EC Certificate of Conformity

Council Directive 93/42/EEC Annex II excluding section 4
Certificate No.: 7092GB410201201A
Validity: 01/12/2020 - 27/05/2024

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II, section 4
Certificate No.: 13214GB411190903
Validity: 03/09/2019 - 26/05/2024

Identification:

CE 0482



implantcast GmbH
Lüneburger Schanze 26 D-21614 Buxtehude
Tel.: +49 4161 744-0 Fax: +49 4161 744-200

Buxtehude, 04.12.2020
Place, date

i.V. Juliane Höppner
Head of Regulatory Affairs

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN
25872800	ic-head BIOLOX® forte taper 12/14 mm	Ø 28mm S	P 38156	4048844017392
25872805	ic-head BIOLOX® forte taper 12/14 mm	Ø 28mm M	P 38156	4048844017408
25872810	ic-head BIOLOX® forte taper 12/14 mm	Ø 28mm L	P 38156	4048844017415
25873200	ic-head BIOLOX® forte taper 12/14 mm	Ø 32mm S	P 38156	4048844017439
25873205	ic-head BIOLOX® forte taper 12/14 mm	Ø 32mm M	P 38156	4048844017446
25873210	ic-head BIOLOX® forte taper 12/14 mm	Ø 32mm L	P 38156	4048844017453
25873600	ic-head BIOLOX® forte taper 12/14 mm	Ø 36mm S	P 38156	4048844017477
25873605	ic-head BIOLOX® forte taper 12/14 mm	Ø 36mm M	P 38156	4048844017484
25873610	ic-head BIOLOX® forte taper 12/14 mm	Ø 36mm L	P 38156	4048844017491
25862800	ic-head BIOLOX® delta taper 12/14 mm	Ø 28mm S	P 38156	4048844017293
25862805	ic-head BIOLOX® delta taper 12/14 mm	Ø 28mm M	P 38156	4048844017309
25862810	ic-head BIOLOX® delta taper 12/14 mm	Ø 28mm L	P 38156	4048844017316
25863200	ic-head BIOLOX® delta taper 12/14 mm	Ø 32mm S	P 38156	4048844017323
25863205	ic-head BIOLOX® delta taper 12/14 mm	Ø 32mm M	P 38156	4048844017330
25863210	ic-head BIOLOX® delta taper 12/14 mm	Ø 32mm L	P 38156	4048844017347
25863215	ic-head BIOLOX® delta taper 12/14 mm	Ø 32mm, XL	P 38156	4048844277864
25863600	ic-head BIOLOX® delta taper 12/14 mm	Ø 36mm S	P 38156	4048844017354
25863605	ic-head BIOLOX® delta taper 12/14 mm	Ø 36mm M	P 38156	4048844017361
25863610	ic-head BIOLOX® delta taper 12/14 mm	Ø 36mm L	P 38156	4048844017378
25863615	ic-head BIOLOX® delta taper 12/14 mm	Ø 36mm XL	P 38156	4048844017385
25864000	ic-head BIOLOX® delta taper 12/14 mm	Ø 40mm K	P 38156	4048844111250
25864005	ic-head BIOLOX® delta taper 12/14 mm	Ø 40mm M	P 38156	4048844111267
25864010	ic-head BIOLOX® delta taper 12/14 mm	Ø 40mm L	P 38156	4048844111274
25864015	ic-head BIOLOX® delta taper 12/14 mm	Ø 40mm XL	P 38156	4048844111281
25864400	ic-head BIOLOX® delta taper 12/14 mm	Ø 44mm, S	P 38156	4048844111298
25864405	ic-head BIOLOX® delta taper 12/14 mm	Ø 44mm, M	P 38156	4048844111304
25864410	ic-head BIOLOX® delta taper 12/14 mm	Ø 44mm, L	P 38156	4048844111311

EU Declaration of Conformity

Attachment II

Reference number	item description	size	GMDN	GTIN
25864415	ic-head BIOLOX® delta taper 12/14 mm	Ø 44mm, XL	P 38156	4048844111328
25892800	ic-head BIOLOX® delta taper 12/14 mm	Ø 28mm	P 38156	4048844433345
25893200	ic-head BIOLOX® delta taper 12/14 mm	Ø 32mm	P 38156	4048844433352
25893600	ic-head BIOLOX® delta taper 12/14 mm	Ø 36mm	P 38156	4048844433369
25894000	ic-head BIOLOX® delta taper 12/14 mm	Ø 40mm	P 38156	4048844433376
25894400	ic-head BIOLOX® delta taper 12/14 mm	Ø 44mm	P 38156	4048844433383
25880000	taper adapter for ic-head revision BIOLOX® delta 12/14	S	P 38156	4048844420819
25880005	taper adapter for ic-head revision BIOLOX® delta 12/14	M	P 38156	4048844420833
25880010	taper adapter for ic-head revision BIOLOX® delta 12/14	L	P 38156	4048844420826
25880015	taper adapter for ic-head revision BIOLOX® delta 12/14	XL	P 38156	4048844420840
25882800	ic- head revision BioloX® delta taper 12/14 mm	28 mm S	P 38156	4048844017507
25882805	ic- head revision BioloX® delta taper 12/14 mm	28 mm M	P 38156	4048844017514
25882810	ic- head revision BioloX® delta taper 12/14 mm	28 mm L	P 38156	4048844017521
25882815	ic- head revision BioloX® delta taper 12/14 mm	28 mm XL	P 38156	4048844017538
25883200	ic- head revision BioloX® delta taper 12/14 mm	32 mm S	P 38156	4048844017545
25883205	ic- head revision BioloX® delta taper 12/14 mm	32 mm M	P 38156	4048844017552
25883210	ic- head revision BioloX® delta taper 12/14 mm	32 mm L	P 38156	4048844017569
25883215	ic- head revision BioloX® delta taper 12/14 mm	32 mm XL	P 38156	4048844017576
25883600	ic- head revision BioloX® delta taper 12/14 mm	36 mm S	P 38156	4048844017583
25883605	ic- head revision BioloX® delta taper 12/14 mm	36 mm M	P 38156	4048844017590
25883610	ic- head revision BioloX® delta taper 12/14 mm	36 mm L	P 38156	4048844017606
25883615	ic- head revision BioloX® delta taper 12/14 mm	36 mm XL	P 38156	4048844017613
25884000	ic- head revision BioloX® delta taper 12/14 mm	40 mm S	P 38156	4048844119034
25884005	ic- head revision BioloX® delta taper 12/14 mm	40 mm M	P 38156	4048844119027
25884010	ic- head revision BioloX® delta taper 12/14 mm	40 mm L	P 38156	4048844119041

EU Declaration of Conformity

Attachment III

Reference number	item description	size	GMDN	GTIN
25884015	ic- head revision BioloX® delta taper 12/14 mm	40 mm XL	P 38156	4048844119058
25884400	ic- head revision BioloX® delta taper 12/14 mm	44 mm S	P 38156	4048844119065
25884405	ic- head revision BioloX® delta taper 12/14 mm	44 mm M	P 38156	4048844119072
25884410	ic- head revision BioloX® delta taper 12/14 mm	44 mm L	P 38156	4048844117795
25884415	ic- head revision BioloX® delta taper 12/14 mm	44 mm XL	P 38156	4048844119010
02202835	BIOLOX® delta cup insert	Ø 28/35mm	P 48055	4048844257927
02202839	BIOLOX® delta cup insert	Ø 28/39mm	P 48055	4048844307462
02203239	BIOLOX® delta cup insert	Ø 32/39mm	P 48055	4048844005535
02203244	BIOLOX® delta cup insert	Ø 32/44mm	P 48055	4048844005542
02203248	BIOLOX® delta cup insert	Ø 32/48mm	P 48055	4048844005559
02203252	BIOLOX® delta cup insert	Ø 32/52mm	P 48055	4048844005566
02203644	BIOLOX® delta cup insert	Ø 36/44mm	P 48055	4048844005573
02203648	BIOLOX® delta cup insert	Ø 36/48mm	P 48055	4048844005580
02203652	BIOLOX® delta cup insert	Ø 36/52mm	P 48055	4048844005597
02204048	BIOLOX® delta cup insert	Ø 40/48mm	P 48055	4048844211998
02204052	BIOLOX® delta cup insert	Ø 40/52mm	P 48055	4048844212001

End of schedule. No additional information past this point.