

Nr. 12101-504

18.03.2016

**CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE**

Prin prezentul, **BC „Mobiabancă – Groupe Societe Generale” S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280**, deține următoarele conturi curente la BC "Mobiabancă-Groupe Societe Generale" S.A., Filiala, 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.



Dumitru Popa
Director filială „Stejaur”



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BC „Mobiabancă – Groupe Societé Générale” SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 100260006089
Sediul Central:
bd. Ștefan cel Mare și Sfânt 81a
MD-2012, Chișinău, Moldova

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1007600044280

Data înregistrării

30.07.2007

Data eliberării

30.07.2007

Bordeianu Tatiana, registrator de stat

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

semnătura

MD 0067985





AGENȚIA SERVICIILOR PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS din Registrul de stat al persoanelor juridice

Nr. 531861 data 19.09.2023

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**

Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1007600044280**

Data înregistrării de stat: **30.07.2007**

Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 2. Comerțul cu ridicata al parfumurilor și produselor cosmetice**
- 3. Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă**
- 4. Intermedieri pentru vânzarea unui asortiment larg de mărfuri**
- 5. Alte tipuri de comerț cu amănuntul în magazine nespecializate**
- 6. Alte tipuri de comerț cu ridicata**
- 7. Închirierea altor mașini și echipamente**

Capitalul social: **5400 lei,**

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociații:

1. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%**

Beneficiar efectiv:

1.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **19.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461498

OXIVIT MED

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chişinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
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Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION

HIP HEADS

PRODUCT-GROUP:
PRIMARY AND REVISION ARTHROPLASTY

RISK-CLASS: III

LOCATION: HIP

REV.10, DATE: 04.12.2017

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IC-HEADS

DESIGN DESCRIPTION



FIGURE 1 IC-HEAD
CoCrMo

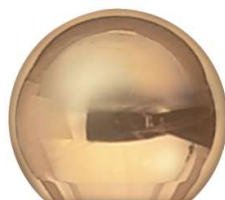


FIGURE 2 IC-HEAD
TITANIUM



FIGURE 4 IC-HEAD
BIOLOX® FORTE



FIGURE 3 IC-HEAD
BIOLOX® DELTA

The ic-heads are spherical modular femoral heads for the connection with the hip stems of the implantcast company. The heads are available in various sizes and neck lengths to match the individual patients' anatomy. The head sizes with the longest neck length provide a collar.

The ic-heads articulate with either with a monoblock acetabular cup, a liner of a modular acetabular cup, a bipolar head or a dual mobility head such as EcoFit® 2M.

The heads are available in various materials.



FIGURE 5 TAPER ADAPTER FOR IC-HEAD REVISION BIOLOX® DELTA 12/14 AND IC-HEAD REVISION BIOLOX® DELTA

Among the various ic-heads, there are also available ic-heads revision BioloX® delta in a range of sizes. It consists of a titanium alloy sleeve (taper adapter) and an ic-head BioloX® delta with a conical bore, which is matched to the taper adapter. The taper adapter is attached to the stem taper.

NECK LENGTHS

For ic-head CoCrMo and ic-head titanium:

Four neck lengths (short, medium, long and extra-long) are available in diameter 22mm to adjust neck length. Six neck lengths (S, M, L, XL, XXL and XXXL) are available in diameter 28, 32 and 36 mm to adjust neck length.

The short (S) neck lengths provide a neck length 3.5 mm / 4 mm shorter than the standard neutral medium (M) length (0 mm) while the long (L) neck length provides +3.5 mm / +4 mm and the extra-long (XL) provides +7.0 mm / +8 mm in neck length. The XXL neck lengths provide a neck length +10.5 mm / +12 mm and the XXXL provides +14 / +16 mm in neck length.

The 22 mm diameter heads have a neck base / collar in all neck length sizes as do all of the XL-length heads in all diameters.

TABLE 1 NECK LENGTHS OF IC-HEADS CoCrMo / TITANIUM

IC-HEADS CoCrMo / TITANIUM		
NECK LENGTH	OFFSET	
	OD 28 mm	OD 22 / 32 / 36 mm
S	-3.5 mm	-4 mm
M	0 mm	0 mm
L	+3.5 mm	+4 mm
XL	+7.0 mm	+8 mm
	OD 28 mm	OD 32 / 36 mm
XXL	+10,5 mm	+12,0 mm
XXXL	+ 14,0 mm	+16,0 mm

OD = OUTER DIAMETER

For ic-head BIOLOX® delta and forte:

TABLE 2 NECK LENGTHS OF IC-HEADS DELTA / FORTE

IC-HEADS BIOLOX® DELTA / FORTE		
NECK LENGTH	OFFSET	
	OD 28 mm	OD 22 / 32 / 36 / 40* / 44* mm
S	-3.5 mm	-4 mm
M	0 mm	0 mm
L	+3.5 mm	+4 mm
XL*	NOT AVAILABLE	+8 mm (+7 mm FOR BIOLOX® DELTA, 32mm)

OD = OUTER DIAMETER, * = AVAILABLE ONLY FOR DELTA

For taper adapter for ic-head revision BIOLOX® delta:

The ic-head revision BIOLOX® delta system consists of a BIOLOX® delta femoral head with 28 to 44 mm diameter and a metal sleeve (taper adapter) for one of the following dimensions:

S = - 3.0 mm

M = 0 mm

L = + 4.0 mm

XL = + 7.0 mm

COLLAR

The following tables show dimensions of the collar (if available), taper contact lengths and head space distances.

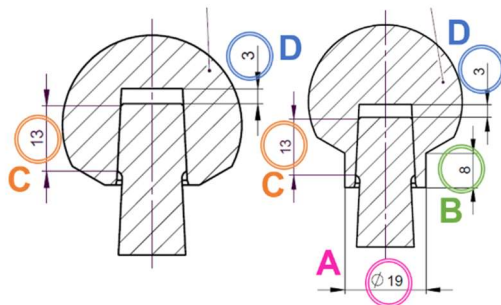


FIGURE 6 (EXAMPLE) SPECIFICATIONS FOR:
LEFT: COLLARLESS HEAD
RIGHT: COLLARED HEAD

A: COLLAR DIAMETER
B: COLLAR LENGTH
C: TAPER CONTACT LENGTH
D: HEAD SPACE DISTANCE

For ic-head CoCrMo and ic-head titanium:

Except for the ic-heads with \varnothing 22mm, all ic-heads with neck lengths S, M, L are collarless.
All ic-heads with neck lengths XL, XXL, XXXL and ic-heads \varnothing 22mm with neck lengths S, M, L have collars.

The following tables show dimensions of the collar (if available), taper contact lengths and head space distances for ic-heads CoCrMo and ic-heads titanium.

TABLE 3 SPECIFICATIONS OF THE COLLARLESS IC-HEADS

SIZE		COLLARLESS IC-HEADS	
OD [MM]	NECK LENGTH	TAPER CONTACT LENGTH [MM] (C)	HEAD SPACE DISTANCE [MM] (D)
28	S	13	1,6
28	M	13	1,6
28	L	9,5	1,6
32, 36	S	13	1,6
32, 36	M	13	3
32, 36	L	10,8	3

OD = OUTER DIAMETER

TABLE 4 SPECIFICATIONS OF THE COLLARED IC-HEADS

SIZE		COLLARED IC-HEADS			
OD [MM]	NECK LENGTH	COLLAR DIAMETER [MM] (A)	COLLAR LENGTH [MM] (B)	TAPER CONTACT LENGTH [MM] (C)	HEAD SPACE DISTANCE [MM] (D)
22	S	18	7.8	13	1,4
22	M	18	11.8	13	1,4
22	L	18	15.8	13	1,4
28	XL	19	7	13	1,6
28	XXL	19	10.5	13	1,6
28	XXXL	19	14	13	1,6
32,36	XL	19	8	13	3
32,36	XXL	19	12	13	3
32,36	XXXL	19	16	13	3

OD = OUTER DIAMETER

For ic-head BIOLOX® forte, ic-head BIOLOX® delta and ic-head revision BIOLOX® delta:

ic-heads BIOLOX® forte, ic-heads BIOLOX® delta and ic-heads revision BIOLOX® delta are collarless.

The following tables show the taper contact lengths and head space distances for ic-heads BIOLOX® products.

TABLE 5 SPECIFICATIONS OF THE IC-HEADS BIOLOX® FORTE

IC-HEADS BIOLOX® FORTE (COLLARLESS)			
SIZE		TAPER CONTACT LENGTH [MM]	HEAD SPACE DISTANCE [MM]
OD [MM]	NECK LENGTH		
28	S	11.8	2.2
28	M	12.6	3.9
28	L	10	4.5
32	S	11.8	2.3
32	M	13	3.9
32	L	10.1	4.5
36	S	13	3.5
36	M	13	6.5
36	L	10.2	6.5

TABLE 6 SPECIFICATIONS OF THE IC-HEADS BIOLOX® DELTA

IC-HEADS BIOLOX® DELTA (COLLARLESS)			
SIZE		TAPER CONTACT LENGTH [MM]	HEAD SPACE DISTANCE [MM]
OD [MM]	NECK LENGTH		
28	S	11.8	2.2
28	M	12.3	3.9
28	L	9.8	3.9
32	S	11.8	2.3
32	M	13	3.9
32	L	9.8	3.9
32	XL	8.3	8.3
36	S	13	3.5
36	M	13	6.3
36	L	10.2	6.3
36	XL	8.2	8.7
40, 44	S	12.8	5.3
40, 44	M	11.7	7.4
40, 44	L	8.9	7.4
40, 44	XL	8.1	8.3

TABLE 7 SPECIFICATIONS OF TAPER ADAPTER FOR IC-HEAD REVISION BIOLOX® DELTA

TAPER ADAPTER FOR IC-HEADS REVISION BIOLOX® DELTA (COLLARLESS)			
SIZE		TAPER CONTACT LENGTH [MM]	HEAD SPACE DISTANCE [MM]
OD [MM]	NECK LENGTH		
-	S	12.5	0.8
-	M	11.7	1.2
-	L	8.6	3.7
-	XL	7.1	6.7

SURFACE FINISH, SPHERICITY AND COATING

All ic-heads have a highly polished surface ($R_a \leq 0.05 \mu\text{m}$) and a roundness (sphericity) of 0.01 or 0.02 μm .

For ic-head CoCrMo and ic-head titanium:

The ic-heads titanium have an additional TiN coating. The specifications of this coating are given below.

TABLE 8 COATING SPECIFICATIONS

SPECIFICATIONS OF TIN-COATING	
CHARACTERISTICS	VALUE
COATING THICKNESS	5.5 ± 1.5 µm
POROSITY	/
AVERAGE ROUGHNESS RA	< 0.05 µm
AVERAGE ROUGHNESS RT	/
TENSILE STRENGTH	≥ 22 MPa
SHEAR STRENGTH	/

For ic-head BIOLOX® forte, ic-head BIOLOX® delta and ic-head revision BIOLOX® delta:

The taper adapter for ic-head revision Biolox® delta is uncoated. The inner surface of the taper adapter has roughness Rz6.3 and the outer surface has between Rz6 to Rz20. The roundness of the taper adapter is 0.08 µm.

MORSE STYLE 12/ 14 TAPER

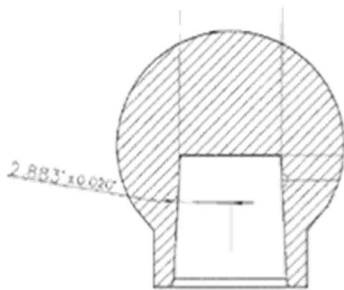


FIGURE 7 FEMORAL HEAD TAPER ANGLE

The femoral heads have a female 12/14 taper to mate with the male 12/14 taper of all implantcast hip stems. The female taper surface has a roughness of Ra ≤ 0.8 µm. The taper angle is 2.883° ± 0.020° measured from one end of the taper to the centreline.

The cone angle of the taper adapter for ic-head revision Biolox® delta is 5,767° ± 0,042° (5° 46'0'' ± 0°2'30'') measured from one end to the other end of the taper.

MATERIALS

The ic-heads CoCrMo are manufactured from wrought Cobalt-Chrome-Molybdenum alloy conforming to ISO 5832-12 while the ic-head Titanium are made of TiAl₆V₄ alloy acc. to ISO 5832-3.

The ic-heads Biolox® forte are made of Aluminum Oxide meeting the requirements of ISO 6474-1 and the ic-heads Biolox® delta are manufactured from a mixed ceramic of high-purity alumina matrix with zirconia reinforcement acc. to ISO 6474-2.

The taper adapter for the ic-head revision Biolox® delta is wrought TiAl₆V₄ alloy complying with ISO 5832-3 and ASTM F136.

SIZES AND DIMENSIONS

The ic-heads are available in 22 mm, 28 mm, 32 mm, and 36 mm outer diameter sizes and have a highly polished surface to articulate with the corresponding 22 mm, 28 mm, 32 mm, or 36 mm inside diameter sizes of the PE and ceramic liners of the modular acetabular cups, the monoblock all polyethylene acetabular cups, the bipolar heads or dual mobility heads.

The ic-heads BioloX® delta and the ic-heads revision BioloX® delta are also available in 40 mm and 44 mm outer diameter sizes in addition.

The sizes of the respective head are given in the table below.

TABLE 9 IC-HEADS SIZES AND DIMENSIONS

IC-HEAD	OUTER DIAMETER	NECK LENGTH
ic-head CoCrMo	22 mm	S, M, L, XL
	28 mm, 32 mm, 36 mm	S, M, L, XL, XXL, XXXL
ic-head titanium	28 mm, 32 mm, 36 mm	S, M, L, XL, XXL, XXXL
ic-head BioloX® forte	28 mm, 32 mm, 36 mm	S, M, L
ic-head BioloX® delta	28 mm	S, M, L
	32 mm, 36 mm, 40 mm, 44 mm	S, M, L, XL
ic-head revision BioloX® delta (with its corresponding taper adapter)	28 mm, 32 mm, 36 mm, 40 mm, 44 mm	S, M, L, XL

IC-BIPOLAR HEAD

DESIGN DESCRIPTION



FIGURE 8 IC-BIPOLAR HEAD
CoCrMo

The ic-bipolar heads serve as a hemiarthroplasty that articulates directly with the natural (non-replaced) acetabulum on the outer side and with a femoral head on the inner side. Bipolar femoral heads are used in cases where the femoral head requires replacement but the acetabulum does not.

The ic-bipolar head consists of three components: the metal outer shell, the inner shell made of UHMWPE and the retaining ring. The latter is inserted into a slot of the inner shell to prevent luxation of the ball from the shell. The inner shell is attached to the outer shell by press fit.

SURFACE FINISH AND SPHERICITY

The bipolar heads have a polished surface finish of Ra of 0.05 μm and a roundness (sphericity) of 0.01 μm .

MATERIALS

The outer shell of the bipolar heads are manufactured from wrought Cobalt-Chrome-Molybdenum alloy conforming to ISO 5832-4 while the inner shell (inlay) and the retaining ring are made of UHMWPE according to ISO 5834-2.

SIZES AND DIMENSIONS

The bipolar heads are available in two inner diameters (22mm, 28 mm) matching the outer diameters of the ic-heads and 24 outer diameter sizes. The sizes of the respective head are given in the table below.

TABLE 10 IC-BIPOLAR HEADS SIZES AND DIMENSIONS

INNER DIAMETER	OUTER DIAMETER
22 mm	38 mm
	39 mm
	40 mm
	41 mm
	42 mm
28 mm	43 mm
	44 mm
	45 mm
	46 mm
	47 mm
	48 mm
	49 mm
	50 mm
	51 mm
	52 mm
	53 mm
	54 mm
	55 mm
	56 mm
	57 mm
	58 mm
	59 mm
60 mm	
62 mm	

IC- UNIPOLAR HEAD

DESIGN DESCRIPTION



FIGURE 9 IC-UNIPOLAR HEAD
TAPER 12/14

Contrary to the ic- bipolar head the design of the ic- unipolar head doesn't provide dual mobility. Unipolar heads have a fixed head which is available in various head diameters to accommodate for the acetabulum size of the patient. The ic-Unipolar head is combined with an implantcast hip stem and articulates with the natural acetabulum.

SURFACE FINISH AND SPHERICITY

The ic- unipolar heads have a polished surface finish of Ra of 0.05 μm and a roundness (sphericity) of 0.01 μm .

MATERIALS

The ic-Unipolar head is made of a wrought high nitrogen stainless steel according to ISO 5832-9.

SIZES AND DIMENSIONS

The ic- unipolar heads are given in 13 sizes:

TABLE 11 IC-UNIPOLAR HEADS SIZES AND DIMENSIONS

OUTER DIAMETER												
40mm	42mm	44mm	46mm	47mm	48mm	49mm	50mm	51mm	52mm	54mm	56mm	58mm

DOCUMENT REVISION HISTORY

DATE	REVISION	CHANGES	AUTHOR	COMMENTS
22.01.2009	1	----	J. Höppner	in German
18.08.2010	2	----	A. Kerber	in German
03.09.2012	3	- Table presentation	A. Kerber	in German + in English
27.02.2014	4	- Table presentation: ic-head titanium only	A. Kerber	in German
05.05.2014	5	- Design, layout - German->English	J. Höppner	----
21.07.2015	6	----	J. Höppner	in English
11.02.2016	7	----	I. Fateev	In English
20.09.2016	8	- Added neck length XXL, XXXL for ic-heads	I. Fateev	in English
12.06.2017	9	- Changes in "neck length": added collar sizes in section "ic-heads" - Added: - Table of contents - Revision History	S. Schlüter	in English
04.12.2017	10	- Added "ic-head revision BIOLOX® delta". - Changes in the section "collar" of "ic-heads" - The sections "surface finish and sphericity" and "coatings / surfaces" are combined to a section "surface finish, sphericity and coating". - Changes in layout	S. Schlüter	In English ÄA18-028

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

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



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.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

For the placing on the market of class III medical devices covered by this certificate, an additional EC design examination certificate according to Annex II, section 4 of Council Directive 93/42/EEC is required.

Effective date: 2020-12-01

Expiry date: 2024-05-27

Report No.: 7092FS12F

Process No.: QS – 7092

Certificate No.: 7092GB410201201A

Hamburg, 2020-12-01



MEDCERT Certification Body
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 7092

Certificate No.: 7092GB410201201A

List of locations included in the scope of certificate

**Alter Postweg 10b
21614 Buxtehude
Germany**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 7092

Certificate No.: 7092GB410201201A

List of products / product categories included in the scope of certificate

- **Primary endoprosthesis**
- **Tumor endoprosthesis**
- **Revision endoprosthesis**
- **Instruments (rasps, handles, reamer, drills, sawblades)**
- **Trial prostheses**
- **Metal augments**

– End of list –

This appendix is integral part of the above-referenced certificate.
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MEDCERT Identification Number: 0482

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ZLG-BS-237.10.15

Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany**

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2021-12-23
Expiry date: 2024-01-02

Report No.: 7092IA13F
Procedure No.: QS – 7092
Certificate No.: 7092GB445211223

Hamburg, 2021-12-23



MEDCERT Certification Body
Lorenz Runge

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To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a management systems certification body
accredited by DAkkS.

Appendix of certificate

Procedure No.: QS – 7092
Certificate No.: 7092GB445211223

Activities and products/services in the scope of certification

Design and development, manufacturing, final inspection, and distribution of

- Primary endoprosthesis
- Tumor endoprosthesis
- Revision endoprosthesis
- Instruments (rasps, handles, reamer, drills, sawblades)
- Trial prostheses
- Metal augments

Locations in the scope of certification

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

implantcast GmbH
Alter Postweg 10b
21614 Buxtehude
Germany

This appendix is integral part of the above-referenced certificate.
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MEDCERT is a management systems certification body
accredited by DAkkS.

TO WHOM IT MAY CONCERN

01/09/2023

Certificate of sterilisation

Hereby, we, **implantcast GmbH**, placed in Lüneburger Schanze 26, D-21614 Buxtehude, Germany, manufacturer and exporter of primary endoprosthesis and instruments confirm that the implant components (femoral stems, ic-heads, caps...) **are sterilised and supplied sterile by the implantcast GmbH**. The product is sterile unless the packaging is damaged or opened and the "Use before" date has not expired. "Use before" date indicates the guaranteed sterility, which is up to 5 years. Please observe the "Use before" date on the product label. If the date has expired, sterility can no longer be guaranteed and the product should not be used.



Vadim Lioubitski
Export Manager
C.I.S. countries



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

