

Anexa nr. 1

*La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE*

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 2 din 7 iunie 2023

Solicitantul **SRL "Oxivit-med"**, cu sediul **mun. Chisinau, MD-2020, str-la**
(adresa)

Studentilor 6B, tel./fax: **079954795**, e-mail oxivit.medical@gmail.com,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor
categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție
pe piață a:

1. **Proteza pentru articulatii:cupa acetabulara necimentata HA, model
EcoFit®**

Se anexează următoarele acte:

- a) declarația de conformitate CE emisă de producător;**
- b) certificatul de conformitate CE ;**
- c) Actul prin care producatorul isi desemneaza reprezentantul;**

Data _____

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către
solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **SRL "Oxivit-med"**, cu sediul **mun. Chisinau, MD-2020, str-la Studentilor 6B,** (adresa)

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Proteza pentru articulatii:cupa acetabulara necimentata HA, model EcoFit®

Sunt autentice și corespund realității.

_____, **Director**
Numele, prenumele și funcția

Semnătura _____

Data _____

We, **implantcast GmbH**, based in Germany, 21614 Buxtehude, Lüneburger Schanze 26,
(manufacturer) (address)

assign OXIVIT-MED SRL, based in Republic of Moldova, mun. Chisinau, MD-2020, str-la. Studentilor 6B,
(authorized representative) (address)

as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.


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

Manufacturer:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s):

Acetabular Cups and Cup Inserts

Intended Use:

The EcoFit® Cups (1) are acetabular components intended to be used in combination with an acetabular cup insert to replace the natural acetabulum in total hip arthroplasty. The EcoFit® Cups are intended for cementless, press-fit fixation.

(1) EcoFit® cup, EcoFit® cup HA, EcoFit® NH cup, EcoFit® NH cup HA, EcoFit® cup EPORE®, EcoFit® cup EPORE® NH, EcoFit® cup EPORE® multi-hole, EcoFit® cup EPORE® / TCP, EcoFit® cup EPORE® / TCP NH, EcoFit® cup EPORE® / TCP multi-hole

The Ceraco® Cup ROM is an acetabular component intended to be used in combination with an acetabular cup insert to replace the natural acetabulum in total hip arthroplasty. The Ceraco® Cup ROM is intended for cementless, press-fit fixation.

The EcoFit® SC Screw Cup is an acetabular component intended to be used in combination with an acetabular cup insert to replace the natural acetabulum in total hip arthroplasty. The EcoFit® SC Screw Cup is intended for cementless, screw-in fixation.

PE Insert 0°, PE Insert 10°, implacross® E PE Insert 0°, implacross® E PE Insert 10°, implacross® PE Insert 0° and implacross® PE Insert 10° are acetabular cup inserts intended to articulate with a femoral head prosthesis.

EcoFit® Inserts are acetabular cup inserts intended to articulate with the convex (outer) spherical surface of the 2M polyethylene head (EcoFit® 2M Head / 2M implacross® E Head) in Dual Mobility Total Hip Arthroplasty.

The PE – Cups Mueller II are hemi-spherical monoblock acetabular cups for total hip arthroplasty. They are intended for cemented fixation.

REF Number(s):

REF-Numbers see Attachment I - XIII

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 11135-1	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the 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 – Part 1: 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 34076	Polyethylene acetabulum prosthesis
P 43167	Acetabular shell
P 43168	Non-constrained polyethylene acetabular liner
P 48056	Metallic acetabular liner
P 56710	Acetabulum prosthesis apical hole plug

We declare under our sole responsibility that the medical devices listed in the attachment(s) 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.: 13191GB411210118A
Validity: 18/01/2021 – 27/05/2024

Identification:

CE 0482


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

Buxtehude, 22.01.2021
Place, date

i.V. Juliane Höppner
Abteilungsleitung / Head of Regulatory Affairs

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN
02802037	PE insert 0°	Ø 28/37mm	P 43168	4048844006440
02802039	PE insert 0°	Ø 28/39mm	P 43168	4048844006457
02802041	PE insert 0°	Ø 28/41mm	P 43168	4048844006464
02802044	PE insert 0°	Ø 28/44mm	P 43168	4048844108694
02802048	PE insert 0°	Ø 28/48mm	P 43168	4048844006471
02802052	PE insert 0°	Ø 28/52mm	P 43168	4048844006488
02803441	PE insert 0°	Ø 32/41mm	P 43168	4048844006860
02803444	PE insert 0°	Ø 32/44mm	P 43168	4048844006877
02803448	PE insert 0°	Ø 32/48mm	P 43168	4048844006884
02803452	PE insert 0°	Ø 32/52mm	P 43168	4048844006891
02804448	PE insert 0°	Ø 36/48mm	P 43168	4048844006938
02804452	PE insert 0°	Ø 36/52mm	P 43168	4048844006945
02802137	PE insert 10°	Ø 28/37mm	P 43168	4048844006495
02802139	PE insert 10°	Ø 28/39mm	P 43168	4048844006501
02802141	PE insert 10°	Ø 28/41mm	P 43168	4048844006518
02802144	PE insert 10°	Ø 28/44mm	P 43168	4048844108700
02802148	PE insert 10°	Ø 28/48mm	P 43168	4048844006525
02802152	PE insert 10°	Ø 28/52mm	P 43168	4048844006532
02803141	PE insert 10°	Ø 32/41mm	P 43168	4048844006815
02803144	PE insert 10°	Ø 32/44mm	P 43168	4048844006822
02803148	PE insert 10°	Ø 32/48mm	P 43168	4048844006839
02803152	PE insert 10°	Ø 32/52mm	P 43168	4048844006846
02804548	PE insert 10°	Ø 36/48mm	P 43168	4048844006952
02804552	PE insert 10°	Ø 36/52mm	P 43168	4048844006969
02333239	implacross® E PE insert 0°	Ø 32/39mm	P 43168	4048844206857
02333244	implacross® E PE insert 0°	Ø 32/44mm	P 43168	4048844206864

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Attachment II

Reference number	item description	size	GMDN	GTIN
02333248	implacross® E PE insert 0°	Ø 32/48mm	P 43168	4048844206871
02333252	implacross® E PE insert 0°	Ø 32/52mm	P 43168	4048844206888
02333644	implacross® E PE insert 0°	Ø 36/44mm	P 43168	4048844206895
02333648	implacross® E PE insert 0°	Ø 36/48mm	P 43168	4048844206901
02333652	implacross® E PE insert 0°	Ø 36/52mm	P 43168	4048844206918
02262835	implacross® E PE insert 10°	Ø 28/35 mm	P 43168	4048844326784
02343239	implacross® E PE insert 10°	Ø 32/39mm	P 43168	4048844206925
02343244	implacross® E PE insert 10°	Ø 32/44mm	P 43168	4048844206932
02343248	implacross® E PE insert 10°	Ø 32/48mm	P 43168	4048844206949
02343252	implacross® E PE insert 10°	Ø 32/52mm	P 43168	4048844206956
02343644	implacross® E PE insert 10°	Ø 36/44mm	P 43168	4048844206963
02343648	implacross® E PE insert 10°	Ø 36/48mm	P 43168	4048844206970
02343652	implacross® E PE insert 10°	Ø 36/52mm	P 43168	4048844206987
02232837	implacross® PE insert 0°	Ø 28/37mm	P 43168	4048844006440
02232839	implacross® PE insert 0°	Ø 28/39mm	P 43168	4048844005610
02232841	implacross® PE insert 0°	Ø 28/41mm	P 43168	4048844006464
02232844	implacross® PE insert 0°	Ø 28/44mm	P 43168	4048844108717
02232848	implacross® PE insert 0°	Ø 28/48mm	P 43168	4048844005634
02232852	implacross® PE insert 0°	Ø 28/52mm	P 43168	4048844005641
02233239	implacross® PE insert 0°	Ø 32/39mm	P 43168	4048844197124
02233241	implacross® PE insert 0°	Ø 32/41mm	P 43168	4048844006860
02233244	implacross® PE insert 0°	Ø 32/44mm	P 43168	4048844005665
02233248	implacross® PE insert 0°	Ø 32/48mm	P 43168	4048844005672
02233252	implacross® PE insert 0°	Ø 32/52mm	P 43168	4048844005689
02233644	implacross® PE insert 0°	Ø 36/44mm	P 43168	4048844005696
02233648	implacross® PE insert 0°	Ø 36/48mm	P 43168	4048844005702
02233652	implacross® PE insert 0°	Ø 36/52mm	P 43168	4048844005719

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Attachment III

Reference number	item description	size	GMDN	GTIN
02242835	implacross® PE insert 10°	Ø 28/35 mm	P 43168	4048844257934
02242837	implacross® PE insert 10°	Ø 28/37mm	P 43168	4048844006495
02242839	implacross® PE insert 10°	Ø 28/39mm	P 43168	4048844005733
02242841	implacross® PE insert 10°	Ø 28/41mm	P 43168	4048844006518
02242844	implacross® PE insert 10°	Ø 28/44mm	P 43168	4048844108724
02242848	implacross® PE insert 10°	Ø 28/48mm	P 43168	4048844005757
02242852	implacross® PE insert 10°	Ø 28/52mm	P 43168	4048844005764
02243239	implacross® PE insert 10°	Ø 32/39mm	P 43168	4048844197131
02243241 *	implacross® PE insert 10°	Ø 32/41mm	P 43168	4048844006815
02243244	implacross® PE insert 10°	Ø 32/44mm	P 43168	4048844005788
02243248	implacross® PE insert 10°	Ø 32/48mm	P 43168	4048844005795
02243252	implacross® PE insert 10°	Ø 32/52mm	P 43168	4048844005801
02243644	implacross® PE insert 10°	Ø 36/44mm	P 43168	4048844005818
02243648	implacross® PE insert 10°	Ø 36/48mm	P 43168	4048844005825
02243652	implacross® PE insert 10°	Ø 36/52mm	P 43168	4048844005832
02203844	EcoFit® insert TiN	Ø 38/44 mm	P 48056	4048844363697
02204248	EcoFit® insert TiN	Ø 42/48 mm	P 48056	4048844363703
02204652	EcoFit® insert TiN	Ø 46/52 mm	P 48056	4048844363710
02233844	EcoFit® insert	Ø 38/44 mm	P 48056	4048844388577
02234248	EcoFit® insert	Ø 42/48 mm	P 48056	4048844388584
02234652	EcoFit® insert	Ø 46/52 mm	P 48056	4048844388591
02809140	insert for Ceraco® dysplasia- cup 10°	Ø 22 / 40+42mm	P 43168	4048844077518
02809144	insert for Ceraco® dysplasia- cup 10°	Ø 22 / 44+46mm	P 43168	4048844077532
02809148	insert for Ceraco® revision- cup 10°	Ø 28 / 48+50mm	P 43168	4048844007355

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Attachment IV

Reference number	item description	size	GMDN	GTIN
02809152	insert for Ceraco® revision- cup 10°	Ø 28 / 52+54mm	P 43168	4048844007362
02809156	insert for Ceraco® revision- cup 10°	Ø 28 / 56+58mm	P 43168	4048844007379
02809160	insert for Ceraco® revision- cup 10°	Ø 32 / 60+62mm	P 43168	4048844007386
02809164	insert for Ceraco® revision- cup 10°	Ø 32 / 64+66mm	P 43168	4048844007393
02809168	insert for Ceraco® revision- cup 10°	Ø 32 / 68+70mm	P 43168	4048844007409
02200046	EcoFit® cup cementless incl. central hole cover	Ø 46mm	P 43167	4048844005368
02200048	EcoFit® cup cementless incl. central hole cover	Ø 48mm	P 43167	4048844005375
02200050	EcoFit® cup cementless incl. central hole cover	Ø 50mm	P 43167	4048844005382
02200052	EcoFit® cup cementless incl. central hole cover	Ø 52mm	P 43167	4048844005399
02200054	EcoFit® cup cementless incl. central hole cover	Ø 54mm	P 43167	4048844005405
02200056	EcoFit® cup cementless incl. central hole cover	Ø 56mm	P 43167	4048844005412
02200058	EcoFit® cup cementless incl. central hole cover	Ø 58mm	P 43167	4048844005429
02200060	EcoFit® cup cementless incl. central hole cover	Ø 60mm	P 43167	4048844005436
02200062	EcoFit® cup cementless incl. central hole cover	Ø 62mm	P 43167	4048844005443
02200064	EcoFit® cup cementless incl. central hole cover	Ø 64mm	P 43167	4048844005450
02200066	EcoFit® cup cementless incl. central hole cover	Ø 66mm	P 43167	4048844005467
02200068	EcoFit® cup cementless incl. central hole cover	Ø 68mm	P 43167	4048844005474
02200346	EcoFit® cup HA cementless incl. central hole cover	Ø 46mm	P 43167	4048844130954
02200348	EcoFit® cup HA cementless incl. central hole cover	Ø 48mm	P 43167	4048844130961
02200350	EcoFit® cup HA cementless incl. central hole cover	Ø 50mm	P 43167	4048844130978
02200352	EcoFit® cup HA cementless incl. central hole cover	Ø 52mm	P 43167	4048844130985
02200354	EcoFit® cup HA cementless incl. central hole cover	Ø 54mm	P 43167	4048844130992
02200356	EcoFit® cup HA cementless incl. central hole cover	Ø 56mm	P 43167	4048844131005
02200358	EcoFit® cup HA cementless incl. central hole cover	Ø 58mm	P 43167	4048844131012
02200360	EcoFit® cup HA cementless incl. central hole cover	Ø 60mm	P 43167	4048844131029
02200362	EcoFit® cup HA cementless incl. central hole cover	Ø 62mm	P 43167	4048844131036
02200364	EcoFit® cup HA cementless incl. central hole cover	Ø 64mm	P 43167	4048844131043

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Attachment V

Reference number	item description	size	GMDN	GTIN
02200366	EcoFit® cup HA cementless incl. central hole cover	Ø 66mm	P 43167	4048844131050
02200368	EcoFit® cup HA cementless incl. central hole cover	Ø 68mm	P 43167	4048844131067
02200146	EcoFit® NH cup cementless incl. central hole cover	Ø 46mm	P 43167	4048844100339
02200148	EcoFit® NH cup cementless incl. central hole cover	Ø 48mm	P 43167	4048844100346
02200150	EcoFit® NH cup cementless incl. central hole cover	Ø 50mm	P 43167	4048844100353
02200152	EcoFit® NH cup cementless incl. central hole cover	Ø 52mm	P 43167	4048844100360
02200154	EcoFit® NH cup cementless incl. central hole cover	Ø 54mm	P 43167	4048844100377
02200156	EcoFit® NH cup cementless incl. central hole cover	Ø 56mm	P 43167	4048844100384
02200158	EcoFit® NH cup cementless incl. central hole cover	Ø 58mm	P 43167	4048844100391
02200160	EcoFit® NH cup cementless incl. central hole cover	Ø 60mm	P 43167	4048844100407
02200162	EcoFit® NH cup cementless incl. central hole cover	Ø 62mm	P 43167	4048844100414
02200164	EcoFit® NH cup cementless incl. central hole cover	Ø 64mm	P 43167	4048844100421
02200166	EcoFit® NH cup cementless incl. central hole cover	Ø 66mm	P 43167	4048844100438
02200168	EcoFit® NH cup cementless incl. central hole cover	Ø 68mm	P 43167	4048844100445
02200446	EcoFit® NH cup HA cementless incl. central hole cover	Ø 46mm	P 43167	4048844134433
02200448	EcoFit® NH cup HA cementless incl. central hole cover	Ø 48mm	P 43167	4048844134440
02200450	EcoFit® NH cup HA cementless incl. central hole cover	Ø 50mm	P 43167	4048844134457
02200452	EcoFit® NH cup HA cementless incl. central hole cover	Ø 52mm	P 43167	4048844134464
02200454	EcoFit® NH cup HA cementless incl. central hole cover	Ø 54mm	P 43167	4048844134471
02200456	EcoFit® NH cup HA cementless incl. central hole cover	Ø 56mm	P 43167	4048844134488
02200458	EcoFit® NH cup HA cementless incl. central hole cover	Ø 58mm	P 43167	4048844134495
02200460	EcoFit® NH cup HA cementless incl. central hole cover	Ø 60mm	P 43167	4048844134501
02200462	EcoFit® NH cup HA cementless incl. central hole cover	Ø 62mm	P 43167	4048844134518
02200464	EcoFit® NH cup HA cementless incl. central hole cover	Ø 64mm	P 43167	4048844134525
02200466	EcoFit® NH cup HA cementless incl. central hole cover	Ø 66mm	P 43167	4048844134532
02200468	EcoFit® NH cup HA cementless incl. central hole cover	Ø 68mm	P 43167	4048844134549

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Attachment VI

Reference number	item description	size	GMDN	GTIN
20610046	Ceraco® cup ROM cementless incl. central hole cover	Ø 46mm	P 43167	4048844099077
20610048	Ceraco® cup ROM cementless incl. central hole cover	Ø 48mm	P 43167	4048844099084
20610050	Ceraco® cup ROM cementless incl. central hole cover	Ø 50mm	P 43167	4048844099091
20610052	Ceraco® cup ROM cementless incl. central hole cover	Ø 52mm	P 43167	4048844099107
20610054	Ceraco® cup ROM cementless incl. central hole cover	Ø 54mm	P 43167	4048844099114
20610056	Ceraco® cup ROM cementless incl. central hole cover	Ø 56mm	P 43167	4048844099121
20610058	Ceraco® cup ROM cementless incl. central hole cover	Ø 58mm	P 43167	4048844099138
20610060	Ceraco® cup ROM cementless incl. central hole cover	Ø 60mm	P 43167	4048844099145
20610062	Ceraco® cup ROM cementless incl. central hole cover	Ø 62mm	P 43167	4048844099152
20610064	Ceraco® cup ROM cementless incl. central hole cover	Ø 64mm	P 43167	4048844099169
20610066	Ceraco® cup ROM cementless incl. central hole cover	Ø 66mm	P 43167	4048844099176
20610068	Ceraco® cup ROM cementless incl. central hole cover	Ø 68mm	P 43167	4048844099183
02803100	central hole cover threaded M10x1	/	P 56710	4048844006808
02200001	plug	/	P 56710	4048844108533
02200246	EcoFit® SC screw cup cementless	Ø 46mm	P 43167	4048844108755
02200248	EcoFit® SC screw cup cementless	Ø 48mm	P 43167	4048844108762
02200250	EcoFit® SC screw cup cementless	Ø 50mm	P 43167	4048844108779
02200252	EcoFit® SC screw cup cementless	Ø 52mm	P 43167	4048844108786
02200254	EcoFit® SC screw cup cementless	Ø 54mm	P 43167	4048844108793
02200256	EcoFit® SC screw cup cementless	Ø 56mm	P 43167	4048844108809
02200258	EcoFit® SC screw cup cementless	Ø 58mm	P 43167	4048844108823
02200260	EcoFit® SC screw cup cementless	Ø 60mm	P 43167	4048844108830
02200262	EcoFit® SC screw cup cementless	Ø 62mm	P 43167	4048844108847
02200264	EcoFit® SC screw cup cementless	Ø 64mm	P 43167	4048844108854
02200266	EcoFit® SC screw cup cementless	Ø 66mm	P 43167	4048844108861
02200268	EcoFit® SC screw cup cementless	Ø 68mm	P 43167	4048844108878

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Attachment VII

Reference number	item description	size	GMDN	GTIN
02200216	central plug M16x1	/	P 56710	4048844108885
02200742	EcoFit® cup EPORE® cementless	Ø 42mm	P 43167	4048844260569
02200744	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 44mm	P 43167	4048844260880
02200746	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 46mm	P 43167	4048844260897
02200748	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 48mm	P 43167	4048844260903
02200750	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 50mm	P 43167	4048844260910
02200752	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 52mm	P 43167	4048844260927
02200754	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 54mm	P 43167	4048844260934
02200756	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 56mm	P 43167	4048844260941
02200758	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 58mm	P 43167	4048844260958
02200760	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 60mm	P 43167	4048844260965
02200762	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 62mm	P 43167	4048844260972
02200764	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 64mm	P 43167	4048844260989
02200766	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 66mm	P 43167	4048844260996
02200768	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 68mm	P 43167	4048844261009
02200770	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 70mm	P 43167	4048844306120
02200772	EcoFit® cup EPORE® cementless incl. central hole cover	Ø 72mm	P 43167	4048844306137
02200942	EcoFit® cup EPORE® NH cementless	Ø 42mm	P 43167	4048844291037
02200944	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 44mm	P 43167	4048844298869
02200946	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 46mm	P 43167	4048844291051
02200948	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 48mm	P 43167	4048844298876
02200950	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 50mm	P 43167	4048844298883
02200952	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 52mm	P 43167	4048844291082
02200954	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 54mm	P 43167	4048844298890
02200956	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 56mm	P 43167	4048844291105
02200958	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 58mm	P 43167	4048844291112

EU Declaration of Conformity

Attachment VIII

Reference number	item description	size	GMDN	GTIN
02200960	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 60mm	P 43167	4048844291129
02200962	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 62mm	P 43167	4048844298906
02200964	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 64mm	P 43167	4048844298913
02200966	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 66mm	P 43167	4048844298920
02200968	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 68mm	P 43167	4048844298937
02200970	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 70mm	P 43167	4048844306144
02200972	EcoFit® cup EPORE® NH cementless incl. central hole cover	Ø 72mm	P 43167	4048844306151
02200642	EcoFit® cup EPORE® multi-hole cementless	Ø 42mm	P 43167	4048844255831
02200644	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 44mm	P 43167	4048844255848
02200646	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 46mm	P 43167	4048844255855
02200648	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 48mm	P 43167	4048844255862
02200650	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 50mm	P 43167	4048844255879
02200652	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 52mm	P 43167	4048844255886
02200654	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 54mm	P 43167	4048844255893
02200656	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 56mm	P 43167	4048844255909
02200658	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 58mm	P 43167	4048844255916
02200660	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 60mm	P 43167	4048844255923
02200662	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 62mm	P 43167	4048844255930
02200664	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 64mm	P 43167	4048844255947
02200666	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 66mm	P 43167	4048844255954
02200668	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 68mm	P 43167	4048844255961
02200670	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 70mm	P 43167	4048844306168
02200672	EcoFit® cup EPORE® multi-hole cementless incl. central hole cover	Ø 72mm	P 43167	4048844306175
02202042	EcoFit® cup EPORE® / TCP cementless	Ø 42mm	P 43167	4048844309534
02202044	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 44mm	P 43167	4048844309978
02202046	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 46mm	P 43167	4048844309985
02202048	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 48mm	P 43167	4048844309992

EU Declaration of Conformity

Attachment IX

Reference number	item description	size	GMDN	GTIN
02202050	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 50mm	P 43167	4048844310004
02202052	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 52mm	P 43167	4048844310011
02202054	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 54mm	P 43167	4048844310028
02202056	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 56mm	P 43167	4048844310035
02202058	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 58mm	P 43167	4048844310042
02202060	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 60mm	P 43167	4048844310059
02202062	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 62mm	P 43167	4048844310066
02202064	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 64mm	P 43167	4048844310073
02202066	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 66mm	P 43167	4048844310080
02202068	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 68mm	P 43167	4048844310097
02202070	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 70mm	P 43167	4048844348908
02202072	EcoFit® cup EPORE® / TCP cementless incl. central hole cover	Ø 72mm	P 43167	4048844346386
02207042	EcoFit® cup EPORE® / TCP NH cementless	Ø 42mm	P 43167	4048844313876
02207044	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 44mm	P 43167	4048844313883
02207046	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 46mm	P 43167	4048844313890
02207048	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 48mm	P 43167	4048844313906
02207050	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 50mm	P 43167	4048844313913
02207052	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 52mm	P 43167	4048844313920
02207054	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 54mm	P 43167	4048844313937
02207056	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 56mm	P 43167	4048844313944
02207058	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 58mm	P 43167	4048844313951
02207060	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 60mm	P 43167	4048844313968
02207062	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 62mm	P 43167	4048844313975
02207064	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 64mm	P 43167	4048844313982
02207066	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 66mm	P 43167	4048844313999
02207068	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 68mm	P 43167	4048844314002
02207070	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 70mm	P 43167	4048844346416
02207072	EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover	Ø 72mm	P 43167	4048844346423

EU Declaration of Conformity

Attachment X

Reference number	item description	size	GMDN	GTIN
02206042	EcoFit® cup EPORE® / TCP multi-hole cementless	Ø 42mm	P 43167	4048844313739
02206044	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 44mm	P 43167	4048844313746
02206046	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 46mm	P 43167	4048844313753
02206048	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 48mm	P 43167	4048844313760
02206050	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 50mm	P 43167	4048844313777
02206052	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 52mm	P 43167	4048844313784
02206054	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 54mm	P 43167	4048844313791
02206056	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 56mm	P 43167	4048844313807
02206058	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 58mm	P 43167	4048844313814
02206060	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 60mm	P 43167	4048844313821
02206062	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 62mm	P 43167	4048844313838
02206064	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 64mm	P 43167	4048844313845
02206066	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 66mm	P 43167	4048844313852
02206068	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 68mm	P 43167	4048844313869
02206070	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 70mm	P 43167	4048844346393
02206072	EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover	Ø 72mm	P 43167	4048844346409
10212240	PE- cup Mueller II cemented	Ø 22/40mm	P 34076	4048844012939
10212242	PE- cup Mueller II cemented	Ø 22/42mm	P 34076	4048844012946
10212244	PE- cup Mueller II cemented	Ø 22/44mm	P 34076	4048844012953
10212246	PE- cup Mueller II cemented	Ø 22/46mm	P 34076	4048844012960
10212248	PE- cup Mueller II cemented	Ø 22/48mm	P 34076	4048844012977
10212844	PE- cup Mueller II cemented	Ø 28/44mm	P 34076	4048844012984
10212846	PE- cup Mueller II cemented	Ø 28/46mm	P 34076	4048844012991
10212848	PE- cup Mueller II cemented	Ø 28/48mm	P 34076	4048844013004
10212850	PE- cup Mueller II cemented	Ø 28/50mm	P 34076	4048844013011
10212852	PE- cup Mueller II cemented	Ø 28/52mm	P 34076	4048844013028
10212854	PE- cup Mueller II cemented	Ø 28/54mm	P 34076	4048844013035

EU Declaration of Conformity

Attachment XI

Reference number	item description	size	GMDN	GTIN
10212856	PE- cup Mueller II cemented	Ø 28/56mm	P 34076	4048844013042
10212858	PE- cup Mueller II cemented	Ø 28/58mm	P 34076	4048844013059
10212860	PE- cup Mueller II cemented	Ø 28/60mm	P 34076	4048844013066
10212862	PE- cup Mueller II cemented	Ø 28/62mm	P 34076	4048844013073
10212864	PE- cup Mueller II cemented	Ø 28/64mm	P 34076	4048844013080
10213244	PE- cup Mueller II cemented	Ø 32/44mm	P 34076	4048844013110
10213246	PE- cup Mueller II cemented	Ø 32/46mm	P 34076	4048844013127
10213248	PE- cup Mueller II cemented	Ø 32/48mm	P 34076	4048844013134
10213250	PE- cup Mueller II cemented	Ø 32/50mm	P 34076	4048844013141
10213252	PE- cup Mueller II cemented	Ø 32/52mm	P 34076	4048844013158
10213254	PE- cup Mueller II cemented	Ø 32/54mm	P 34076	4048844013165
10213256	PE- cup Mueller II cemented	Ø 32/56mm	P 34076	4048844013172
10213258	PE- cup Mueller II cemented	Ø 32/58mm	P 34076	4048844013189
10213260	PE- cup Mueller II cemented	Ø 32/60mm	P 34076	4048844013196
10213262	PE- cup Mueller II cemented	Ø 32/62mm	P 34076	4048844013202
10213264	PE- cup Mueller II cemented	Ø 32/64mm	P 34076	4048844013219
10103244	PE- cup Mueller II implacross® E cemented	Ø 32/44mm	P 34076	4048844207298
10103246	PE- cup Mueller II implacross® E cemented	Ø 32/46mm	P 34076	4048844207311
10103248	PE- cup Mueller II implacross® E cemented	Ø 32/48mm	P 34076	4048844207328
10103250	PE- cup Mueller II implacross® E cemented	Ø 32/50mm	P 34076	4048844207335
10103252	PE- cup Mueller II implacross® E cemented	Ø 32/52mm	P 34076	4048844207342
10103254	PE- cup Mueller II implacross® E cemented	Ø 32/54mm	P 34076	4048844207359
10103256	PE- cup Mueller II implacross® E cemented	Ø 32/56mm	P 34076	4048844207366
10103258	PE- cup Mueller II implacross® E cemented	Ø 32/58mm	P 34076	4048844207373
10103260	PE- cup Mueller II implacross® E cemented	Ø 32/60mm	P 34076	4048844207380
10103262	PE- cup Mueller II implacross® E cemented	Ø 32/62mm	P 34076	4048844207397
10103264	PE- cup Mueller II implacross® E cemented	Ø 32/64mm	P 34076	4048844217112
10103648	PE- cup Mueller II implacross® E cemented	Ø 36/48mm	P 34076	4048844207199

EU Declaration of Conformity

Attachment XII

Reference number	item description	size	GMDN	GTIN
10103650	PE- cup Mueller II implacross® E cemented	Ø 36/50mm	P 34076	4048844207205
10103652	PE- cup Mueller II implacross® E cemented	Ø 36/52mm	P 34076	4048844207212
10103654	PE- cup Mueller II implacross® E cemented	Ø 36/54mm	P 34076	4048844207229
10103656	PE- cup Mueller II implacross® E cemented	Ø 36/56mm	P 34076	4048844207236
10103658	PE- cup Mueller II implacross® E cemented	Ø 36/58mm	P 34076	4048844207250
10103660	PE- cup Mueller II implacross® E cemented	Ø 36/60mm	P 34076	4048844207274
10103662	PE- cup Mueller II implacross® E cemented	Ø 36/62mm	P 34076	4048844207281
10103664	PE- cup Mueller II implacross® E cemented	Ø 36/64mm	P 34076	4048844210410
10413244	PE- cup Mueller II snap cemented	Ø 32/44mm	P 34076	4048844013417
10413246	PE- cup Mueller II snap cemented	Ø 32/46mm	P 34076	4048844013424
10413248	PE- cup Mueller II snap cemented	Ø 32/48mm	P 34076	4048844013431
10413250	PE- cup Mueller II snap cemented	Ø 32/50mm	P 34076	4048844013448
10413252	PE- cup Mueller II snap cemented	Ø 32/52mm	P 34076	4048844013455
10413254	PE- cup Mueller II snap cemented	Ø 32/54mm	P 34076	4048844013462
10413256	PE- cup Mueller II snap cemented	Ø 32/56mm	P 34076	4048844013479
10413258	PE- cup Mueller II snap cemented	Ø 32/58mm	P 34076	4048844013486
10413260	PE- cup Mueller II snap cemented	Ø 32/60mm	P 34076	4048844013493
10413262	PE- cup Mueller II snap cemented	Ø 32/62mm	P 34076	4048844013509
10413264	PE- cup Mueller II snap cemented	Ø 32/64mm	P 34076	4048844013516
10712844	PE- cup Mueller II dysplasia 10° cemented	Ø 28/44mm	P 34076	4048844013899
10712846	PE- cup Mueller II dysplasia 10° cemented	Ø 28/46mm	P 34076	4048844013905
10712848	PE- cup Mueller II dysplasia 10° cemented	Ø 28/48mm	P 34076	4048844013912
10712850	PE- cup Mueller II dysplasia 10° cemented	Ø 28/50mm	P 34076	4048844013929
10712852	PE- cup Mueller II dysplasia 10° cemented	Ø 28/52mm	P 34076	4048844013936
10712854	PE- cup Mueller II dysplasia 10° cemented	Ø 28/54mm	P 34076	4048844013943
10712856	PE- cup Mueller II dysplasia 10° cemented	Ø 28/56mm	P 34076	4048844013950
10712858	PE- cup Mueller II dysplasia 10° cemented	Ø 28/58mm	P 34076	4048844013967

EU Declaration of Conformity

Attachment XIII

Reference number	item description	size	GMDN	GTIN
10712860	PE- cup Mueller II dysplasia 10° cemented	Ø 28/60mm	P 34076	4048844013974
10712862	PE- cup Mueller II dysplasia 10° cemented	Ø 28/62mm	P 34076	4048844013981
10713244	PE- cup Mueller II dysplasia 10° cemented	Ø 32/44mm	P 34076	4048844013998
10713246	PE- cup Mueller II dysplasia 10° cemented	Ø 32/46mm	P 34076	4048844014001
10713248	PE- cup Mueller II dysplasia 10° cemented	Ø 32/48mm	P 34076	4048844014018
10713250	PE- cup Mueller II dysplasia 10° cemented	Ø 32/50mm	P 34076	4048844014025
10713252	PE- cup Mueller II dysplasia 10° cemented	Ø 32/52mm	P 34076	4048844014032
10713254	PE- cup Mueller II dysplasia 10° cemented	Ø 32/54mm	P 34076	4048844014049
10713256	PE- cup Mueller II dysplasia 10° cemented	Ø 32/56mm	P 34076	4048844014056
10713258	PE- cup Mueller II dysplasia 10° cemented	Ø 32/58mm	P 34076	4048844014063
10713260	PE- cup Mueller II dysplasia 10° cemented	Ø 32/60mm	P 34076	4048844014070
10713262	PE- cup Mueller II dysplasia 10° cemented	Ø 32/62 mm	P 34076	4048844014087
10713264	PE- cup Mueller II dysplasia 10° cemented	Ø 32/64 mm	P 34076	4048844014094

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



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.
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MEDCERT Identification Number: 0482



Benannt durch/Designated by
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 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



EC Design Examination Certificate

The Notified Body

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

herewith certifies that the design of the medical device(s):

Hip Implants
Acetabular cups and cup inserts
with specifications listed in the appendix

of the manufacturer:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

fulfills the below mentioned requirements of the **Council Directive 93/42/EEC**:

Annex II, section 4

This certificate assumes that MEDCERT has to be informed about any changes of the approved design. Changes need further approval by MEDCERT.

For the placing on the market of medical devices covered by this certificate, a separate EC certificate of conformity according to Annex II without section 4 of Council Directive 93/42/EEC is required.

Effective date: 2021-01-18

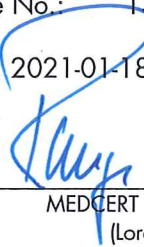
Expiry date: 2024-05-27

Report No.: 13191FS11F

Process No.: PP – 13191

Certificate No.: 13191GB411210118A

Hamburg, 2021-01-18



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(Lorenz Runge)

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MEDCERT Identification Number: 0482



Appendix of EC Design Examination Certificate

Process No.: PP – 13191

Certificate No.: 13191GB411210118A

Specifications

PE insert 0°						
02802037	02802039	02802041	02802044	02802048	02802052	02803441
02803444	02803448	02803452	02804448	02804452	—	—

PE insert 10°						
02802137	02802139	02802141	02802144	02802148	02802152	02803141
02803144	02803148	02803152	02804548	02804552	—	—

implacross® PE insert 0°						
02232837	02232839	02232841	02232844	02232848	02232852	02233239
02233241	02233244	02233248	02233252	02233644	02233648	02233652

implacross® PE insert 10°						
02242835	02242837	02242839	02242841	02242844	02242848	02242852
02243239	02243241	02243244	02243248	02243252	02243644	02243648
02243652	—	—	—	—	—	—

implacross® E PE insert 0°						
02333239	02333244	02333248	02333252	02333644	02333648	02333652

implacross® E PE insert 10°						
02262835	02343239	02343244	02343248	02343252	02343644	02343648
02343652	—	—	—	—	—	—

EcoFit® insert TiN						
02203844	02204248	02204652	—	—	—	—

EcoFit® insert						
02233844	02234248	02234652	—	—	—	—

insert for Ceraco® dysplasia- cup 10°						
02809140	02809144	—	—	—	—	—

insert for Ceraco® revision cup 10°						
02809148	02809152	02809156	02809160	02809164	02809168	—

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MEDCERT Identification Number: 0482



Appendix of EC Design Examination Certificate

Process No.: PP – 13191

Certificate No.: 13191GB411210118A

PE- cup Mueller II cemented

10212240	10212242	10212244	10212246	10212248	10212844	10212846
10212848	10212850	10212852	10212854	10212856	10212858	10212860
10212862	10212864	10213244	10213246	10213248	10213250	10213252
10213254	10213256	10213258	10213260	10213262	10213264	—

PE- cup Mueller II implacross® E cemented

10103244	10103246	10103248	10103250	10103252	10103254	10103256
10103258	10103260	10103262	10103264	10103648	10103650	10103652
10103654	10103656	10103658	10103660	10103662	10103664	—

PE- cup Mueller II snap cemented

10413244	10413246	10413248	10413250	10413252	10413254	10413256
10413258	10413260	10413262	10413264	—	—	—

PE- cup Mueller II dysplasia 10° cemented

10712844	10712846	10712848	10712850	10712852	10712854	10712856
10712858	10712860	10712862	10713244	10713246	10713248	10713250
10713252	10713254	10713256	10713258	10713260	10713262	10713264

EcoFit® cup cementless incl. central hole cover

02200046	02200048	02200050	02200052	02200054	02200056	02200058
02200060	02200062	02200064	02200066	02200068	—	—

EcoFit® cup HA cementless incl. central hole cover

02200346	02200348	02200350	02200352	02200354	02200356	02200358
02200360	02200362	02200364	02200366	02200368	—	—

EcoFit® NH cup cementless incl. central hole cover

02200146	02200148	02200150	02200152	02200154	02200156	02200158
02200160	02200162	02200164	02200166	02200168	—	—

EcoFit® NH cup HA cementless incl. central hole cover

02200446	02200448	02200450	02200452	02200454	02200456	02200458
02200460	02200462	02200464	02200466	02200468	—	—

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MEDCERT Identification Number: 0482

Appendix of EC Design Examination Certificate

Process No.: PP – 13191

Certificate No.: 13191GB411210118A

EcoFit® cup EPORE® cementless						
02200742	—	—	—	—	—	—

EcoFit® cup EPORE® cementless incl. central hole cover						
02200744	02200746	02200748	02200750	02200752	02200754	02200756
02200758	02200760	02200762	02200764	02200766	02200768	02200770
02200772	—	—	—	—	—	—

EcoFit® cup EPORE® NH cementless						
02200942	—	—	—	—	—	—

EcoFit® cup EPORE® NH cementless incl. central hole cover						
02200944	02200946	02200948	02200950	02200952	02200954	02200956
02200958	02200960	02200962	02200964	02200966	02200968	02200970
02200972	—	—	—	—	—	—

EcoFit® cup EPORE® multi-hole cementless						
02200642	—	—	—	—	—	—

EcoFit® cup EPORE® multi-hole cementless incl. central hole cover						
02200644	02200646	02200648	02200650	02200652	02200654	02200656
02200658	02200660	02200662	02200664	02200666	02200668	02200670
02200672	—	—	—	—	—	—

EcoFit® cup EPORE® / TCP cementless						
02202042	—	—	—	—	—	—

EcoFit® cup EPORE® / TCP cementless incl. central hole cover						
02202044	02202046	02202048	02202050	02202052	02202054	02202056
02202058	02202060	02202062	02202064	02202066	02202068	02202070
02202072	—	—	—	—	—	—

EcoFit® cup EPORE® / TCP NH cementless						
02207042	—	—	—	—	—	—

EcoFit® cup EPORE® / TCP NH cementless incl. central hole cover						
02207044	02207046	02207048	02207050	02207052	02207054	02207056
02207058	02207060	02207062	02207064	02207066	02207068	02207070
02207072	—	—	—	—	—	—

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MEDCERT Identification Number: 0482



Appendix of EC Design Examination Certificate

Process No.: PP – 13191

Certificate No.: 13191GB411210118A

EcoFit® cup EPORE® / TCP multi-hole cementless						
02206042	—	—	—	—	—	—

EcoFit® cup EPORE® / TCP multi-hole cementless incl. central hole cover						
02206044	02206046	02206048	02206050	02206052	02206054	02206056
02206058	02206060	02206062	02206064	02206066	02206068	02206070
02206072	—	—	—	—	—	—

EcoFit® SC screw cup cementless						
02200246	02200248	02200250	02200252	02200254	02200256	02200258
02200260	02200262	02200264	02200266	02200268	—	—

Ceraco® cup ROM cementless incl. central hole cover						
20610046	20610048	20610050	20610052	20610054	20610056	20610058
20610060	20610062	20610064	20610066	20610068	—	—

central plug M16x1						
02200216	—	—	—	—	—	—

plug						
02200001	—	—	—	—	—	—

central hole cover threaded M10x1						
02803100	—	—	—	—	—	—

– End of appendix –

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MEDCERT Identification Number: 0482

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	.02200346	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 46mm	P 43167
2	.02200348	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 48mm	P 43167
3	.02200350	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 50mm	P 43167
4	.02200352	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 52mm	P 43167
5	.02200354	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 54mm	P 43167
6	.02200356	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 56mm	P 43167
7	.02200358	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 58mm	P 43167
8	.02200360	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 60mm	P 43167
9	.02200362	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 62mm	P 43167
10	.02200364	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 64mm	P 43167
11	.02200366	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 66mm	P 43167
12	.02200368	Proteza pentru articulatii:cupa acetabulara necimentata HA	EcoFit®	Ø 68mm	P 43167