

```

-----:
ORDIN DE PLATA NR.: 80                                TIP.DOC. 1 :
                                DATA EMITERII:miercuri, 7 iunie :
=====:
PLATITI: 13000-00                                LEI: Treisprezece Mii lei 00 bani :
:
:
=====:
PLATITOR: (R) S.C. "OXIVI                                CONTUL DE PLATI/CODUL IBAN :
T-MED" S.R.L.                                MD44ML000000002251729503 :
                                CODUL FISCAL :1007600044280 / :
:
:
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau                                :MOLDMD2X329:
=====:
BENEFICIAR (R) Centrul pen                                CONTUL DE PLATI/CODUL IBAN :
tru Achizi?ii Publice Central MD23TRPCCC518430B01859AA :
izate in Sanatate                                CODUL FISCAL :1016601000212 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
Ministerul Finantelor - Trezoreria de Stat                                :TREZMD2X :
=====:
DESTINATIA PLATII:/Pl02/13000,00 Pentru : TIPUL TRANSFERULUI :
garantia pentru oferta la procedura de a:                                NORMAL/URGENT :N:
chizi?ie publica nr. ocds-b3wdpl-MD-1684:                                :
832476582 din 08.06.2023 :                                :
:                                :
:                                :
:                                L.S. :
=====:
                                CODUL TRANZACTIEI:101: :
                                DATA PRIMIRII:07/06/2023 : SEMNATURILE :
                                DATA EXECUTARII: : EMITENTULUI :
-----:
CONducator:Web Kojevnikov Dmitrii
MIIGdAYJKoZIhvcNAQcCoIIGZTCCBmECAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBH0wggR5MIIDYaADAgECAhNHAADml2rTzDkidh/bAAAAAOaXMA0GCSqG:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIzMDMxNjE1MjYyMloXDTI2MDMxNjE1MzYyMlowgbAxCzAJBgNVBAYTAklEMRAw:
YDVQqIEwdNb2xkb3ZhmREwDwYDVQqHEwhDaGlzaW5hdTETMBEGA1UEChMKT3hp :
:
(semnatura electronica) :
CONTABIL-SEF:Web Kojevnikov Dmitrii :
MIIGdAYJKoZIhvcNAQcCoIIGZTCCBmECAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBH0wggR5MIIDYaADAgECAhNHAADml2rTzDkidh/bAAAAAOaXMA0GCSqG:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIzMDMxNjE1MjYyMloXDTI2MDMxNjE1MzYyMlowgbAxCzAJBgNVBAYTAklEMRAw:
YDVQqIEwdNb2xkb3ZhmREwDwYDVQqHEwhDaGlzaW5hdTETMBEGA1UEChMKT3hp :
:
L.S. (semnatura electronica) :
CONducator: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMnatura PRESTATORUL L.S. :
:
MOTIVUL REFUZULUI : L.S. :
-----:

```

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Din
От

1

DATE DESPRE CONTRIBUABIL/ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal/Numărul de identificare

Фискальный код/Идентификационный номер

Denumirea

Наименование

2

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT/ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ НЕДОИМКИ СОГЛАСНО ДАННЫХ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie/На дату выдачи данной справки, недоимка перед национальным публичным бюджетом составляет

 lei/лей

3

VALABIL PÂNĂ LA/ДЕЙСТВИТЕЛЕН ДО



Prezentul certificat este eliberat în temeiul Art. 131, alin. (5³) din Codul fiscal nr. 1163/1997, în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Antreprenorului/Сертификат выдан в соответствии со ст. 131, п. (5³) Налогового кодекса №1163/1997, на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Предпринимателя

Generat și semnat de Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) la

Prezentul certificat este semnat electronic în conformitate cu Legea nr. 124 din 19.05.2022 /

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022

Certificatul este descărcat de pe Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) și este semnat electronic de către posesorul acestui portal și are aceeași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală.
Verificarea autenticității semnăturii electronice poate fi realizată la adresa: <https://msign.gov.md>.

Сертификат выгружен с Правительственного Портала Предпринимателя (<https://mcabinet.gov.md>) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы, выдаваемые на бумаге органами налоговой администрации.
Проверку подлинности электронной подписи можно осуществить по адресу: <https://msign.gov.md>.

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2021 - 31.12.2021

Entitatea: S.C. OXIVIT-MED S.R.L.

Cod CUIŢO: 40424951

Cod IDNO: 1007600044280

Sediul:

MD:

Raionul(municipiul): 103, DDF BOTANICA

Cod CUATM: 0110, SEC.BOTANICA

Strada: Decebal bd. nr.82 of.90

Activitatea principală: G4774, Comert cu amanuntul al articolelor medicale si ortopedice, in magazine specializate

Forma de proprietate: 15, Proprietatea privată

Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:

Telefon: +37322808002

WEB:

E-mail: oxivit.medical@gmail.com

Numele și coordonatele al contabilului-șef: DI (dna) Kojevnikov Dmitrii Tel. 069200308

Numărul mediu al salariaților în perioada de gestiune: 5 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Kojevnikov Dmitrii

Unitatea de măsură: leu

BILANȚUL

la 31.12.2021

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020	1137	487
	din care:			
	2.1. concesiuni, licențe și mărci	021	1137	487
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024		
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	1137	487
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	9980	45953
	din care:			
	3.1. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	9235	45953
	3.4. mijloace de transport	084		

A.

3.5. inventar și mobilier	085		
3.6. alte mijloace fixe	086	745	
4. Resurse minerale	090		
5. Active biologice imobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru imobilizări corporale	120		
Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	9980	45953
III. Investiții financiare pe termen lung			
1. Investiții financiare pe termen lung în părți neafiliate	140		
2. Investiții financiare pe termen lung în părți afiliate, total	150		
din care:			
2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
2.2 împrumuturi acordate părților afiliate	152		
2.3 împrumuturi acordate aferente intereselor de participare	153		
2.4 alte investiții financiare	154		
Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
IV. Creanțe pe termen lung și alte active imobilizate			
1. Creanțe comerciale pe termen lung	170		
2. Creanțe ale părților afiliate pe termen lung	180		
inclusiv: creanțe aferente intereselor de participare	181		
3. Alte creanțe pe termen lung	190		
4. Cheltuieli anticipate pe termen lung	200		
5. Alte active imobilizate	210		
Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	11117	46440

B.

ACTIVE CIRCULANTE			
I. Stocuri			
1. Materiale și obiecte de mică valoare și scurtă durată	240	617	752
2. Active biologice circulante	250		
3. Producția în curs de execuție	260		
4. Produse și mărfuri	270	6895348	8612039
5. Avansuri acordate pentru stocuri	280		
Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	6895965	8612791
II. Creanțe curente și alte active circulante			
1. Creanțe comerciale curente	300	17423930	9151659
2. Creanțe ale părților afiliate curente	310		
inclusiv: creanțe aferente intereselor de participare	311		
3. Creanțe ale bugetului	320	1593996	685035
4. Creanțele ale personalului	330	1452	
5. Alte creanțe curente	340		
6. Cheltuieli anticipate curente	350	6076	4940
7. Alte active circulante	360	3786977	5022901
Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	22812431	14864535
III. Investiții financiare curente			
1. Investiții financiare curente în părți neafiliate	380		
2. Investiții financiare curente în părți afiliate, total	390		
din care:			
2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
2.2. împrumuturi acordate părților afiliate	392		
2.3. împrumuturi acordate aferente intereselor de participare	393		

	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	11586107	10982450
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	41294503	34459776
	TOTAL ACTIVE (rd.230 + rd.420)	430	41305620	34506216
	P A S I V			
	CAPITAL PROPRIU			
	I. Capital social și neînregistrat			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	()	()
	3. Capital neînregistrat	460		
	4. Capital retras	470	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	-178779
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	24939574	17439574
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	11125729
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	24939574	28386524
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	24944974	28391924
	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640	76630	
	din care:			
	2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643	76630	
	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700	76630	
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

	din care:			
	2.1. împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	15784405	4868225
E.	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	349631	938523
	6. Datorii față de personal	760	116957	107832
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780		199712
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	33023	
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	16284016	6114292
	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
F.	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	41305620	34506216

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2021 până la 31.12.2021

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	61054881	63146813
din care:			
venituri din vânzarea produselor și mărfurilor	011	61054881	63146813
venituri din prestarea serviciilor și executarea lucrărilor	012		
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016		
Costul vânzărilor, total	020	50207602	48882405
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	50207602	48882405
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	10847279	14264408
Alte venituri din activitatea operațională	040	1967064	9915
Cheltuieli de distribuire	050	68333	60149
Cheltuieli administrative	060	995848	968411
Alte cheltuieli din activitatea operațională	070	34858	239797
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	11715304	13005966

Venituri financiare, total	090	1752762	1026285
din care:	091		
venituri din interese de participare			
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093		1440
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	1752762	1024845
Cheltuieli financiare, total	100	1580853	1210147
din care:	101		
cheltuieli privind dobânzile			
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	1580853	1210147
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	171909	-183862
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		174839
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		-174839
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	171909	-358701
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	11887213	12647265
Cheltuieli privind impozitul pe venit	170	1431875	1521536
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	10455338	11125729

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la pînă la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
III.	Rezerve					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130			
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X		
	4. Profit utilizat al perioadei de gestiune	150	X	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160			
V.	Rezerve din reevaluare	170			
VI.	Alte elemente de capital propriu	180			
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190			

SITUAȚIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobînzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

[Versiune de imprimare](#)
[Salvare](#)

Recipisa

Respondent

Codul fiscal: 1007600044280, denumire: S.C. OXIVIT-MED S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscală: A/2021

Data prezentării: 30.05.2022

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 30.05.2022 16:42:42

[Versiune de imprimare](#)
Salvare

Recipisa 2

Respondent

Codul fiscal: 1007600044280, denumire: S.C. OXIVIT-MED S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2021

Data prezentarii: 30.05.2022

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 30.05.2022 22:47:31

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

Nr. 12101-504

18.03.2016

**CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE**

Prin prezentul, BC „Mobiasbancă – 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 "Mobiasbancă-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”



Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur”
Bd. Ștefan cel Mare și Sfânt 196
MD-2004, Chișinău, Moldova
Cod MOBBMD22
Cont de corespondență 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale” SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
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





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 8871 din 05.05.2021

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: **1007600044280.**

Data înregistrării de stat: **30.07.2007.**

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

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 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,

Asociați:

1. KOJEVNIKOV DMITRII , IDNP 0972305012362

cota 5400.00 lei, ce constituie 100 %.

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: 05.05.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EEI 0354094

OXIVIT MED

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chişinău, Republica Moldova

telefon: + 373 22 808002; fax: + 373 22 808003

web: www.oxivit-med.com; e-mail: info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

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



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 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



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.
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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Manufacturer:	implantcast GmbH Lüneburger Schanze 26 21614 Buxtehude Germany
Medical Device(s):	Bone Screw
Intended Use:	Bone Screws are intended for screwing into the bone for primary and/or permanent stable anchorage of an implant in case of inadequate primary stability.
REF Number(s):	REF-Numbers see Attachment I - IV
Classification:	Class IIb <i>(Council Directive 93/42/EEC, Annex IX, rule 8, in conjunction with commission directive 2005/50/EC)</i>
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 46646	Orthopaedic bone screw, non-bioabsorbable, sterile

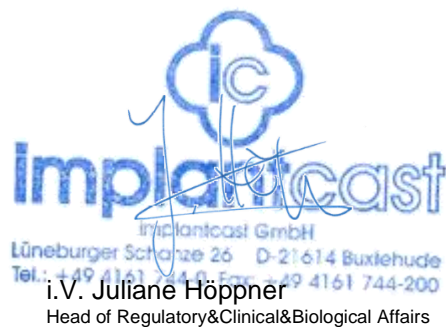
We declare under our sole responsibility that the medical device specified above are in conformity with the essential requirements listed in Annex I of Council Directive 93/42/EEC and has been gone through the conformity assessment procedure according to Annex II of Council Directive 93/42/EEC.

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

Identification:

CE 0482



implantcast
implantcast GmbH
Lüneburger Schanze 26 D-21614 Buxtehude
Tel.: +49 4161 744-200 Fax: +49 4161 744-200
i.V. Juliane Höppner
Head of Regulatory&Clinical&Biological Affairs

Buxtehude, 21.05.2021
Place, date

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN
57934026	cancellous screw	Ø 4,0 x 26mm	P 46646	04048844051051
57934028	cancellous screw	Ø 4,0 x 28mm	P 46646	04048844051068
57934030	cancellous screw	Ø 4,0 x 30mm	P 46646	04048844051075
57934032	cancellous screw	Ø 4,0 x 32mm	P 46646	04048844051082
57934034	cancellous screw	Ø 4,0 x 34mm	P 46646	04048844051099
57924525	cortical screw	Ø 4,5 x 25 mm	P 46646	04048844101961
57924530	cortical screw	Ø 4,5 x 30 mm	P 46646	04048844050955
57924535	cortical screw	Ø 4,5 x 35 mm	P 46646	04048844101978
57924540	cortical screw	Ø 4,5 x 40 mm	P 46646	04048844050962
57924545	cortical screw	Ø 4,5 x 45 mm	P 46646	04048844101985
57924550	cortical screw	Ø 4,5 x 50 mm	P 46646	04048844050986
57924555	cortical screw	Ø 4,5 x 55 mm	P 46646	04048844101992
57924560	cortical screw	Ø 4,5 x 60 mm	P 46646	04048844102005
57923510	Titanium cortical screw	Ø 3,5 x 10 mm	P 46646	04048844305703
57923512	Titanium cortical screw	Ø 3,5 x 12 mm	P 46646	04048844305710
57923514	Titanium cortical screw	Ø 3,5 x 14 mm	P 46646	04048844305727
57923516	Titanium cortical screw	Ø 3,5 x 16 mm	P 46646	04048844305734
57923518	Titanium cortical screw	Ø 3,5 x 18 mm	P 46646	04048844305741
57923520	Titanium cortical screw	Ø 3,5 x 20 mm	P 46646	04048844305758
57923522	Titanium cortical screw	Ø 3,5 x 22 mm	P 46646	04048844305765
57923524	Titanium cortical screw	Ø 3,5 x 24 mm	P 46646	04048844050900
57923526	Titanium cortical screw	Ø 3,5 x 26 mm	P 46646	04048844305772
57923528	Titanium cortical screw	Ø 3,5 x 28 mm	P 46646	04048844305789
57923530	Titanium cortical screw	Ø 3,5 x 30 mm	P 46646	04048844050924
57923532	Titanium cortical screw	Ø 3,5 x 32 mm	P 46646	04048844305796
57923534	Titanium cortical screw	Ø 3,5 x 34 mm	P 46646	04048844305802

EU Declaration of Conformity

Attachment II

Reference number	item description	size	GMDN	GTIN
57923536	Titanium cortical screw	Ø 3,5 x 36 mm	P 46646	04048844305819
57923538	Titanium cortical screw	Ø 3,5 x 38 mm	P 46646	04048844306281
57923545	Titanium cortical screw	Ø 3,5 x 45 mm	P 46646	04048844306304
57923555	Titanium cortical screw	Ø 3,5 x 55 mm	P 46646	04048844306311
57923560	Titanium cortical screw	Ø 3,5 x 60 mm	P 46646	04048844306328
57923565	Titanium cortical screw	Ø 3,5 x 65 mm	P 46646	04048844306335
57923570	Titanium cortical screw	Ø 3,5 x 70 mm	P 46646	04048844306342
57923575	Titanium cortical screw	Ø 3,5 x 75 mm	P 46646	04048844306359
57923580	Titanium cortical screw	Ø 3,5 x 80 mm	P 46646	04048844306366
57923585	Titanium cortical screw	Ø 3,5 x 85 mm	P 46646	04048844306373
57923590	Titanium cortical screw	Ø 3,5 x 90 mm	P 46646	04048844306380
57923595	Titanium cortical screw	Ø 3,5 x 95 mm	P 46646	04048844306397
579235100	Titanium cortical screw	Ø 3,5 x 100 mm	P 46646	04048844306403
579235105	Titanium cortical screw	Ø 3,5 x 105 mm	P 46646	04048844306410
579235110	Titanium cortical screw	Ø 3,5 x 110 mm	P 46646	04048844306427
579235115	Titanium cortical screw	Ø 3,5 x 115 mm	P 46646	04048844306434
579235120	Titanium cortical screw	Ø 3,5 x 120 mm	P 46646	04048844306441
02801015	spongiosa screw flat head	Ø 6,5 x 15 mm	P 46646	04048844006358
02801020	spongiosa screw flat head	Ø 6,5 x 20 mm	P 46646	04048844006365
02801025	spongiosa screw flat head	Ø 6,5 x 25 mm	P 46646	04048844006372
02801030	spongiosa screw flat head	Ø 6,5 x 30 mm	P 46646	04048844006389
02801035	spongiosa screw flat head	Ø 6,5 x 35 mm	P 46646	04048844006396
02801040	spongiosa screw flat head	Ø 6,5 x 40 mm	P 46646	04048844006402
02801045	spongiosa screw flat head	Ø 6,5 x 45 mm	P 46646	04048844006419
02801050	spongiosa screw flat head	Ø 6,5 x 50 mm	P 46646	04048844006426
02801055	spongiosa screw flat head	Ø 6,5 x 55 mm	P 46646	04048844006433
02801060	spongiosa screw flat head	Ø 6,5 x 60 mm	P 46646	04048844276430

EU Declaration of Conformity

Attachment III

Reference number	item description	size	GMDN	GTIN
02801065	spongiosa screw flat head	Ø 6,5 x 65 mm	P 46646	04048844248116
02801070	spongiosa screw flat head	Ø 6,5 x 70 mm	P 46646	04048844276751
02801075	spongiosa screw flat head	Ø 6,5 x 75 mm	P 46646	04048844248130
02801080	spongiosa screw flat head	Ø 6,5 x 80 mm	P 46646	04048844248147
57936525	cancellous screw	Ø 6,5 x 25 mm	P 46646	04048844051105
57936530	cancellous screw	Ø 6,5 x 30 mm	P 46646	04048844051112
57936535	cancellous screw	Ø 6,5 x 35 mm	P 46646	04048844051129
57936540	cancellous screw	Ø 6,5 x 40 mm	P 46646	04048844051136
57936545	cancellous screw	Ø 6,5 x 45 mm	P 46646	04048844051143
57936550	cancellous screw	Ø 6,5 x 50 mm	P 46646	04048844051150
57936555	cancellous screw	Ø 6,5 x 55 mm	P 46646	04048844051167
57936560	cancellous screw	Ø 6,5 x 60 mm	P 46646	04048844051174
57944210	cancellous screw angle stable	Ø 4,2 x 10mm	P 46646	04048844104900
57944212	cancellous screw angle stable	Ø 4,2 x 12mm	P 46646	04048844104917
57944214	cancellous screw angle stable	Ø 4,2 x 14mm	P 46646	04048844104924
57944216	cancellous screw angle stable	Ø 4,2 x 16mm	P 46646	04048844104931
57944218	cancellous screw angle stable	Ø 4,2 x 18mm	P 46646	04048844104948
57944220	cancellous screw angle stable	Ø 4,2 x 20mm	P 46646	04048844104955
57944222	cancellous screw angle stable	Ø 4,2 x 22mm	P 46646	04048844104962
57944224	cancellous screw angle stable	Ø 4,2 x 24mm	P 46646	04048844104979
57944226	cancellous screw angle stable	Ø 4,2 x 26mm	P 46646	04048844104986
57944228	cancellous screw angle stable	Ø 4,2 x 28mm	P 46646	04048844104993
57944230	cancellous screw angle stable	Ø 4,2 x 30mm	P 46646	04048844105006
57944232	cancellous screw angle stable	Ø 4,2 x 32mm	P 46646	04048844105013
57944234	cancellous screw angle stable	Ø 4,2 x 34mm	P 46646	04048844105020
57944236	cancellous screw angle stable	Ø 4,2 x 36mm	P 46646	04048844105037

EU Declaration of Conformity

Attachment IV

Reference number	item description	size	GMDN	GTIN
57944238	cancellous screw angle stable	Ø 4,2 x 38mm	P 46646	04048844105044
57944240	cancellous screw angle stable	Ø 4,2 x 40mm	P 46646	04048844105051
02870070	cancellous screw	Ø 8 x 70mm	P 46646	04048844009182
02870080	cancellous screw	Ø 8 x 80mm	P 46646	04048844009199
02870090	cancellous screw	Ø 8 x 90mm	P 46646	04048844009205
02870100	cancellous screw	Ø 8 x 100mm	P 46646	04048844009212

End of schedule. No additional information past this point.

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
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

EU Declaration of Conformity

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

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

EU Declaration of Conformity

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

EU Declaration of Conformity

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

EU Declaration of Conformity

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

EU Declaration of Conformity

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

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.

Manufacturer: implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s): **EcoFit® Hip Stem**

Intended Use:

The EcoFit® hip stems are femoral stems for total hip arthroplasty or hemi hip arthroplasty. They are intended either for a press-fit cementless meta-diaphyseal (Total HA), metaphyseal (proximal cpTi or cpTi + HA coating) or a cemented fixation.

The EcoFit® short stems are femoral stems for total hip arthroplasty or hemi hip arthroplasty. These bone conserving prostheses are intended for a press-fit cementless metaphyseal fixation and to better address minimally invasive techniques.

REF Number(s): REF-Numbers see Attachment I - XI

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 38155	Press-fit femoral stem prosthesis
P 33989	Uncoated femoral stem prosthesis, one-piece

We declare under our sole responsibility that the medical device specified above are in conformity with the essential requirements listed in Annex I of Council Directive 93/42/EEC and has been gone through 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.: 13188GB411190409
Validity: 09/04/2019 – 04/02/2024

Identification:

CE 0482



implantcast
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
30383062	EcoFit® hip stem cementless standard HA	6,25mm	P 38155	4048844023737
30383075	EcoFit® hip stem cementless standard HA	7,5mm	P 38155	4048844023744
30383087	EcoFit® hip stem cementless standard HA	8,75mm	P 38155	4048844023751
30383100	EcoFit® hip stem cementless standard HA	10mm	P 38155	4048844023768
30383112	EcoFit® hip stem cementless standard HA	11,25mm	P 38155	4048844023775
30383125	EcoFit® hip stem cementless standard HA	12,5mm	P 38155	4048844023782
30383137	EcoFit® hip stem cementless standard HA	13,75mm	P 38155	4048844023799
30383150	EcoFit® hip stem cementless standard HA	15mm	P 38155	4048844023805
30383162	EcoFit® hip stem cementless standard HA	16,25mm	P 38155	4048844413958
30383175	EcoFit® hip stem cementless standard HA	17,5mm	P 38155	4048844023812
30383187	EcoFit® hip stem cementless standard HA	18,75mm	P 38155	4048844413965
30383200	EcoFit® hip stem cementless standard HA	20mm	P 38155	4048844023829
30384062	EcoFit® hip stem cementless lateralized HA	6,25mm	P 38155	4048844023836
30384075	EcoFit® hip stem cementless lateralized HA	7,5mm	P 38155	4048844023843
30384087	EcoFit® hip stem cementless lateralized HA	8,75mm	P 38155	4048844023850
30384100	EcoFit® hip stem cementless lateralized HA	10mm	P 38155	4048844023867
30384112	EcoFit® hip stem cementless lateralized HA	11,25mm	P 38155	4048844023874
30384125	EcoFit® hip stem cementless lateralized HA	12,5mm	P 38155	4048844023881
30384137	EcoFit® hip stem cementless lateralized HA	13,75mm	P 38155	4048844023898
30384150	EcoFit® hip stem cementless lateralized HA	15mm	P 38155	4048844023904
30384162	EcoFit® hip stem cementless lateralized HA	16,25mm	P 38155	4048844413972
30384175	EcoFit® hip stem cementless lateralized HA	17,5mm	P 38155	4048844023911
30384187	EcoFit® hip stem cementless lateralized HA	18,75mm	P 38155	4048844413989
30384200	EcoFit® hip stem cementless lateralized HA	20mm	P 38155	4048844023928
30386062	EcoFit® hip stem cementless standard T-HA	6,25mm	P 38155	4048844023935
30386075	EcoFit® hip stem cementless standard T-HA	7,5mm	P 38155	4048844023942

EU Declaration of Conformity

Attachment II

Reference number	item description	size	GMDN	GTIN
30386087	EcoFit® hip stem cementless standard T-HA	8,75mm	P 38155	4048844023959
30386100	EcoFit® hip stem cementless standard T-HA	10mm	P 38155	4048844023966
30386112	EcoFit® hip stem cementless standard T-HA	11,25mm	P 38155	4048844023973
30386125	EcoFit® hip stem cementless standard T-HA	12,5mm	P 38155	4048844023980
30386137	EcoFit® hip stem cementless standard T-HA	13,75mm	P 38155	4048844023997
30386150	EcoFit® hip stem cementless standard T-HA	15mm	P 38155	4048844024000
30386175	EcoFit® hip stem cementless standard T-HA	17,5mm	P 38155	4048844024017
30386200	EcoFit® hip stem cementless standard T-HA	20mm	P 38155	4048844024024
30387062	EcoFit® hip stem cementless lateralized T-HA	6,25mm	P 38155	4048844024031
30387075	EcoFit® hip stem cementless lateralized T-HA	7,5mm	P 38155	4048844024048
30387087	EcoFit® hip stem cementless lateralized T-HA	8,75mm	P 38155	4048844024055
30387100	EcoFit® hip stem cementless lateralized T-HA	10mm	P 38155	4048844024062
30387112	EcoFit® hip stem cementless lateralized T-HA	11,25mm	P 38155	4048844024079
30387125	EcoFit® hip stem cementless lateralized T-HA	12,5mm	P 38155	4048844024086
30387137	EcoFit® hip stem cementless lateralized T-HA	13,75mm	P 38155	4048844024093
30387150	EcoFit® hip stem cementless lateralized T-HA	15mm	P 38155	4048844024109
30387175	EcoFit® hip stem cementless lateralized T-HA	17,5mm	P 38155	4048844024116
30387200	EcoFit® hip stem cementless lateralized T-HA	20mm	P 38155	4048844024123
30393062	EcoFit® hip stem cementless standard cpTi	6,25mm	P 38155	4048844024765
30393075	EcoFit® hip stem cementless standard cpTi	7,5mm	P 38155	4048844024772
30393087	EcoFit® hip stem cementless standard cpTi	8,75mm	P 38155	4048844024789
30393100	EcoFit® hip stem cementless standard cpTi	10mm	P 38155	4048844024796
30393112	EcoFit® hip stem cementless standard cpTi	11,25mm	P 38155	4048844024802
30393125	EcoFit® hip stem cementless standard cpTi	12,5mm	P 38155	4048844024819
30393137	EcoFit® hip stem cementless standard cpTi	13,75mm	P 38155	4048844024826
30393150	EcoFit® hip stem cementless standard cpTi	15mm	P 38155	4048844024833

EU Declaration of Conformity

Attachment III

Reference number	item description	size	GMDN	GTIN
30393162	EcoFit® hip stem cementless standard cpTi	16,25mm	P 38155	4048844413910
30393175	EcoFit® hip stem cementless standard cpTi	17,5mm	P 38155	4048844024840
30393187	EcoFit® hip stem cementless standard cpTi	18,75mm	P 38155	4048844413927
30393200	EcoFit® hip stem cementless standard cpTi	20mm	P 38155	4048844024857
30394062	EcoFit® hip stem cementless lateralized cpTi	6,25mm	P 38155	4048844024864
30394075	EcoFit® hip stem cementless lateralized cpTi	7,5mm	P 38155	4048844024871
30394087	EcoFit® hip stem cementless lateralized cpTi	8,75mm	P 38155	4048844024888
30394100	EcoFit® hip stem cementless lateralized cpTi	10mm	P 38155	4048844024895
30394112	EcoFit® hip stem cementless lateralized cpTi	11,25mm	P 38155	4048844024901
30394125	EcoFit® hip stem cementless lateralized cpTi	12,5mm	P 38155	4048844024918
30394137	EcoFit® hip stem cementless lateralized cpTi	13,75mm	P 38155	4048844024925
30394150	EcoFit® hip stem cementless lateralized cpTi	15mm	P 38155	4048844024932
30394162	EcoFit® hip stem cementless lateralized cpTi	16,25mm	P 38155	4048844413934
30394175	EcoFit® hip stem cementless lateralized cpTi	17,5mm	P 38155	4048844024949
30394187	EcoFit® hip stem cementless lateralized cpTi	18,75mm	P 38155	4048844413941
30394200	EcoFit® hip stem cementless lateralized cpTi	20mm	P 38155	4048844024956
30395062	EcoFit® hip stem cemented Titanium standard	6,25mm	P 33989	4048844024970
30395075	EcoFit® hip stem cemented Titanium standard	7,5mm	P 33989	4048844024987
30395087	EcoFit® hip stem cemented Titanium standard	8,75mm	P 33989	4048844024994
30395100	EcoFit® hip stem cemented Titanium standard	10mm	P 33989	4048844025007
30395112	EcoFit® hip stem cemented Titanium standard	11,25mm	P 33989	4048844025014
30395125	EcoFit® hip stem cemented Titanium standard	12,5mm	P 33989	4048844025021
30395137	EcoFit® hip stem cemented Titanium standard	13,75mm	P 33989	4048844025038
30395150	EcoFit® hip stem cemented Titanium standard	15mm	P 33989	4048844025045
30395175	EcoFit® hip stem cemented Titanium standard	17,5mm	P 33989	4048844025052

EU Declaration of Conformity

Attachment IV

Reference number	item description	size	GMDN	GTIN
30396062	EcoFit® hip stem cemented standard	6,25mm	P 33989	4048844025069
30396075	EcoFit® hip stem cemented standard	7,5mm	P 33989	4048844025076
30396100	EcoFit® hip stem cemented standard	10mm	P 33989	4048844025083
30396125	EcoFit® hip stem cemented standard	12,5mm	P 33989	4048844025090
30396150	EcoFit® hip stem cemented standard	15mm	P 33989	4048844025106
30396175	EcoFit® hip stem cemented standard	17,5mm	P 33989	4048844126070
30396062N	EcoFit® hip stem cemented standard TiN	6,25mm	P 33989	4048844081621
30396075N	EcoFit® hip stem cemented standard TiN	7,5mm	P 33989	4048844081645
30396100N	EcoFit® hip stem cemented standard TiN	10mm	P 33989	4048844081669
30396125N	EcoFit® hip stem cemented standard TiN	12,5mm	P 33989	4048844081683
30396150N	EcoFit® hip stem cemented standard TiN	15mm	P 33989	4048844081706
30396175N	EcoFit® hip stem cemented standard TiN	17,5mm	P 33989	4048844126117
30398062	EcoFit® hip stem cemented lateralized	6,25mm	P 33989	4048844025168
30398075	EcoFit® hip stem cemented lateralized	7,5mm	P 33989	4048844025175
30398100	EcoFit® hip stem cemented lateralized	10mm	P 33989	4048844025182
30398125	EcoFit® hip stem cemented lateralized	12,5mm	P 33989	4048844025199
30398150	EcoFit® hip stem cemented lateralized	15mm	P 33989	4048844025205
30398175	EcoFit® hip stem cemented lateralized	17,5mm	P 33989	4048844126087
30398062N	EcoFit® hip stem cemented lateralized TiN	6,25mm	P 33989	4048844081720
30398075N	EcoFit® hip stem cemented lateralized TiN	7,5mm	P 33989	4048844081744
30398100N	EcoFit® hip stem cemented lateralized TiN	10mm	P 33989	4048844081768
30398125N	EcoFit® hip stem cemented lateralized TiN	12,5mm	P 33989	4048844081782
30398150N	EcoFit® hip stem cemented lateralized TiN	15mm	P 33989	4048844081805
30398175N	EcoFit® hip stem cemented lateralized TiN	17,5mm	P 33989	4048844126124

EU Declaration of Conformity

Attachment V

Reference number	item description	size	GMDN	GTIN
30380062	EcoFit® hip stem cemented highly polished standard	6,25mm	P 33989	4048844023607
30380075	EcoFit® hip stem cemented highly polished standard	7,5mm	P 33989	4048844023614
30380100	EcoFit® hip stem cemented highly polished standard	10mm	P 33989	4048844023621
30380125	EcoFit® hip stem cemented highly polished standard	12,5mm	P 33989	4048844023638
30380150	EcoFit® hip stem cemented highly polished standard	15mm	P 33989	4048844023645
30380175	EcoFit® hip stem cemented highly polished standard	17,5mm	P 33989	4048844126094
30381062	EcoFit® hip stem cemented highly polished lateralized	6,25mm	P 33989	4048844023652
30381075	EcoFit® hip stem cemented highly polished lateralized	7,5mm	P 33989	4048844023669
30381100	EcoFit® hip stem cemented highly polished lateralized	10mm	P 33989	4048844023676
30381125	EcoFit® hip stem cemented highly polished lateralized	12,5mm	P 33989	4048844023683
30381150	EcoFit® hip stem cemented highly polished lateralized	15mm	P 33989	4048844023690
30381175	EcoFit® hip stem cemented highly polished lateralized	17,5mm	P 33989	4048844126100
30388062	EcoFit® hip stem coxa vara cementless standard cpTi	6,25mm	P 38155	4048844260637
30388075	EcoFit® hip stem coxa vara cementless standard cpTi	7,5mm	P 38155	4048844260644
30388087	EcoFit® hip stem coxa vara cementless standard cpTi	8,75mm	P 38155	4048844259389
30388100	EcoFit® hip stem coxa vara cementless standard cpTi	10mm	P 38155	4048844303761
30388112	EcoFit® hip stem coxa vara cementless standard cpTi	11,25mm	P 38155	4048844259402
30388125	EcoFit® hip stem coxa vara cementless standard cpTi	12,5mm	P 38155	4048844260668
30388137	EcoFit® hip stem coxa vara cementless standard cpTi	13,75mm	P 38155	4048844260675
30388150	EcoFit® hip stem coxa vara cementless standard cpTi	15mm	P 38155	4048844260682
30388175	EcoFit® hip stem coxa vara cementless standard cpTi	17,5mm	P 38155	4048844260699
30388200	EcoFit® hip stem coxa vara cementless standard cpTi	20mm	P 38155	4048844260705
30382062	EcoFit® hip stem coxa vara cementless standard HA	6,25mm	P 38155	4048844261115
30382075	EcoFit® hip stem coxa vara cementless standard HA	7,5mm	P 38155	4048844324452
30382087	EcoFit® hip stem coxa vara cementless standard HA	8,75mm	P 38155	4048844261122

EU Declaration of Conformity

Attachment VI

Reference number	item description	size	GMDN	GTIN
30382100	EcoFit® hip stem coxa vara cementless standard HA	10mm	P 38155	4048844261139
30382112	EcoFit® hip stem coxa vara cementless standard HA	11,25mm	P 38155	4048844261146
30382125	EcoFit® hip stem coxa vara cementless standard HA	12,5mm	P 38155	4048844261153
30382137	EcoFit® hip stem coxa vara cementless standard HA	13,75mm	P 38155	4048844261160
30382150	EcoFit® hip stem coxa vara cementless standard HA	15mm	P 38155	4048844261177
30382175	EcoFit® hip stem coxa vara cementless standard HA	17,5mm	P 38155	4048844261184
30382200	EcoFit® hip stem coxa vara cementless standard HA	20mm	P 38155	4048844261191
30399062	EcoFit® hip stem coxa vara cemented standard	6,25mm	P 33989	4048844261306
30399075	EcoFit® hip stem coxa vara cemented standard	7,5mm	P 33989	4048844261313
30399100	EcoFit® hip stem coxa vara cemented standard	10mm	P 33989	4048844261320
30399125	EcoFit® hip stem coxa vara cemented standard	12,5mm	P 33989	4048844261337
30399150	EcoFit® hip stem coxa vara cemented standard	15mm	P 33989	4048844261344
30399175	EcoFit® hip stem coxa vara cemented standard	17,5mm	P 33989	4048844261351
30385062	EcoFit® hip stem coxa vara cementless standard T-HA	6,25mm	P 38155	4048844274788
30385075	EcoFit® hip stem coxa vara cementless standard T-HA	7,5mm	P 38155	4048844274795
30385087	EcoFit® hip stem coxa vara cementless standard T-HA	8,75mm	P 38155	4048844274801
30385100	EcoFit® hip stem coxa vara cementless standard T-HA	10mm	P 38155	4048844303778
30385112	EcoFit® hip stem coxa vara cementless standard T-HA	11,25mm	P 38155	4048844274818
30385125	EcoFit® hip stem coxa vara cementless standard T-HA	12,5mm	P 38155	4048844324469
30385137	EcoFit® hip stem coxa vara cementless standard T-HA	13,75mm	P 38155	4048844274825
30385150	EcoFit® hip stem coxa vara cementless standard T-HA	15mm	P 38155	4048844274832
30385175	EcoFit® hip stem coxa vara cementless standard T-HA	17,5mm	P 38155	4048844274849
30385200	EcoFit® hip stem coxa vara cementless standard T-HA	20mm	P 38155	4048844274856
30389062	EcoFit® hip stem coxa vara cemented highly polished standard	6,25mm	P 38155	4048844274863
30389075	EcoFit® hip stem coxa vara cemented highly polished standard	7,5mm	P 38155	4048844274870

EU Declaration of Conformity

Attachment VII

Reference number	item description	size	GMDN	GTIN
30389100	EcoFit® hip stem coxa vara cemented highly polished standard	10mm	P 38155	4048844274887
30389125	EcoFit® hip stem coxa vara cemented highly polished standard	12,5mm	P 38155	4048844274894
30389150	EcoFit® hip stem coxa vara cemented highly polished standard	15mm	P 38155	4048844274900
30389175	EcoFit® hip stem coxa vara cemented highly polished standard	17,5mm	P 38155	4048844274917
30373062	EcoFit® hip stem 133° cementless standard cpTi	6,25mm	P 38155	4048844256241
30373075	EcoFit® hip stem 133° cementless standard cpTi	7,5mm	P 38155	4048844256258
30373087	EcoFit® hip stem 133° cementless standard cpTi	8,75mm	P 38155	4048844256265
30373100	EcoFit® hip stem 133° cementless standard cpTi	10mm	P 38155	4048844256272
30373112	EcoFit® hip stem 133° cementless standard cpTi	11,25mm	P 38155	4048844256289
30373125	EcoFit® hip stem 133° cementless standard cpTi	12,5mm	P 38155	4048844256296
30373137	EcoFit® hip stem 133° cementless standard cpTi	13,75mm	P 38155	4048844256302
30373150	EcoFit® hip stem 133° cementless standard cpTi	15mm	P 38155	4048844256326
30373162	EcoFit® hip stem 133° cementless standard cpTi	16,25mm	P 38155	4048844407100
30373175	EcoFit® hip stem 133° cementless standard cpTi	17,5mm	P 38155	4048844256333
30373187	EcoFit® hip stem 133° cementless standard cpTi	18,75mm	P 38155	4048844407117
30373200	EcoFit® hip stem 133° cementless standard cpTi	20mm	P 38155	4048844256340
30374062	EcoFit® hip stem 133° cementless lateralized cpTi	6,25mm	P 38155	4048844256357
30374075	EcoFit® hip stem 133° cementless lateralized cpTi	7,5mm	P 38155	4048844256364
30374087	EcoFit® hip stem 133° cementless lateralized cpTi	8,75mm	P 38155	4048844256371
30374100	EcoFit® hip stem 133° cementless lateralized cpTi	10mm	P 38155	4048844256388
30374112	EcoFit® hip stem 133° cementless lateralized cpTi	11,25mm	P 38155	4048844256395
30374125	EcoFit® hip stem 133° cementless lateralized cpTi	12,5mm	P 38155	4048844256401
30374137	EcoFit® hip stem 133° cementless lateralized cpTi	13,75mm	P 38155	4048844256418
30374150	EcoFit® hip stem 133° cementless lateralized cpTi	15mm	P 38155	4048844256425
30374162	EcoFit® hip stem 133° cementless lateralized cpTi	16,25mm	P 38155	4048844407124
30374175	EcoFit® hip stem 133° cementless lateralized cpTi	17,5mm	P 38155	4048844256432

EU Declaration of Conformity

Attachment VIII

Reference number	item description	size	GMDN	GTIN
30374187	EcoFit® hip stem 133° cementless lateralized cpTi	18,75mm	P 38155	4048844407131
30374200	EcoFit® hip stem 133° cementless lateralized cpTi	20mm	P 38155	4048844256449
30363062	EcoFit® hip stem 133° cementless standard HA	6,25mm	P 38155	4048844256456
30363075	EcoFit® hip stem 133° cementless standard HA	7,5mm	P 38155	4048844256463
30363087	EcoFit® hip stem 133° cementless standard HA	8,75mm	P 38155	4048844256470
30363100	EcoFit® hip stem 133° cementless standard HA	10mm	P 38155	4048844256487
30363112	EcoFit® hip stem 133° cementless standard HA	11,25mm	P 38155	4048844256494
30363125	EcoFit® hip stem 133° cementless standard HA	12,5mm	P 38155	4048844256500
30363137	EcoFit® hip stem 133° cementless standard HA	13,75mm	P 38155	4048844256517
30363150	EcoFit® hip stem 133° cementless standard HA	15mm	P 38155	4048844256524
30363162	EcoFit® hip stem 133° cementless standard HA	16,25mm	P 38155	4048844407148
30363175	EcoFit® hip stem 133° cementless standard HA	17,5mm	P 38155	4048844256531
30363187	EcoFit® hip stem 133° cementless standard HA	18,75mm	P 38155	4048844407155
30363200	EcoFit® hip stem 133° cementless standard HA	20mm	P 38155	4048844256548
30364062	EcoFit® hip stem 133° cementless lateralized HA	6,25mm	P 38155	4048844282554
30364075	EcoFit® hip stem 133° cementless lateralized HA	7,5mm	P 38155	4048844256555
30364087	EcoFit® hip stem 133° cementless lateralized HA	8,75mm	P 38155	4048844256562
30364100	EcoFit® hip stem 133° cementless lateralized HA	10mm	P 38155	4048844256579
30364112	EcoFit® hip stem 133° cementless lateralized HA	11,25mm	P 38155	4048844256586
30364125	EcoFit® hip stem 133° cementless lateralized HA	12,5mm	P 38155	4048844256593
30364137	EcoFit® hip stem 133° cementless lateralized HA	13,75mm	P 38155	4048844256609
30364150	EcoFit® hip stem 133° cementless lateralized HA	15mm	P 38155	4048844256616
30364162	EcoFit® hip stem 133° cementless lateralized HA	16,25mm	P 38155	4048844407162
30364175	EcoFit® hip stem 133° cementless lateralized HA	17,5mm	P 38155	4048844256623
30364187	EcoFit® hip stem 133° cementless lateralized HA	18,75mm	P 38155	4048844407179
30364200	EcoFit® hip stem 133° cementless lateralized HA	20mm	P 38155	4048844256630

EU Declaration of Conformity

Attachment IX

Reference number	item description	size	GMDN	GTIN
30346062	EcoFit® hip stem 133° cemented standard	6,25mm	P 33989	4048844256647
30346075	EcoFit® hip stem 133° cemented standard	7,5mm	P 33989	4048844256654
30346100	EcoFit® hip stem 133° cemented standard	10mm	P 33989	4048844256661
30346125	EcoFit® hip stem 133° cemented standard	12,5mm	P 33989	4048844256678
30346150	EcoFit® hip stem 133° cemented standard	15mm	P 33989	4048844256685
30346175	EcoFit® hip stem 133° cemented standard	17,5mm	P 33989	4048844256692
30348062	EcoFit® hip stem 133° cemented lateralized	6,25mm	P 33989	4048844256708
30348075	EcoFit® hip stem 133° cemented lateralized	7,5mm	P 33989	4048844256715
30348100	EcoFit® hip stem 133° cemented lateralized	10mm	P 33989	4048844256722
30348125	EcoFit® hip stem 133° cemented lateralized	12,5mm	P 33989	4048844256760
30348150	EcoFit® hip stem 133° cemented lateralized	15mm	P 33989	4048844256746
30348175	EcoFit® hip stem 133° cemented lateralized	17,5mm	P 33989	4048844256753
30330062	EcoFit® hip stem 133° cemented highly polished standard	6,25mm	P 33989	4048844256777
30330075	EcoFit® hip stem 133° cemented highly polished standard	7,5mm	P 33989	4048844256784
30330100	EcoFit® hip stem 133° cemented highly polished standard	10mm	P 33989	4048844256791
30330125	EcoFit® hip stem 133° cemented highly polished standard	12,5mm	P 33989	4048844256807
30330150	EcoFit® hip stem 133° cemented highly polished standard	15mm	P 33989	4048844256814
30330175	EcoFit® hip stem 133° cemented highly polished standard	17,5mm	P 33989	4048844256821
30331062	EcoFit® hip stem 133° cemented highly polished lateralized	6,25mm	P 33989	4048844256838
30331075	EcoFit® hip stem 133° cemented highly polished lateralized	7,5mm	P 33989	4048844256845
30331100	EcoFit® hip stem 133° cemented highly polished lateralized	10mm	P 33989	4048844256852
30331125	EcoFit® hip stem 133° cemented highly polished lateralized	12,5mm	P 33989	4048844256869
30331150	EcoFit® hip stem 133° cemented highly polished lateralized	15mm	P 33989	4048844256876
30331175	EcoFit® hip stem 133° cemented highly polished lateralized	17,5mm	P 33989	4048844256883

EU Declaration of Conformity

Attachment X

Reference number	item description	size	GMDN	GTIN
30320625	EcoFit® short stem standard cementless cpTi	6,25mm	P 38155	4048844321918
30320075	EcoFit® short stem standard cementless cpTi	7,5mm	P 38155	4048844321925
30320875	EcoFit® short stem standard cementless cpTi	8,75mm	P 38155	4048844321932
30320100	EcoFit® short stem standard cementless cpTi	10mm	P 38155	4048844321949
30321125	EcoFit® short stem standard cementless cpTi	11,25 mm	P 38155	4048844321956
30320125	EcoFit® short stem standard cementless cpTi	12,5mm	P 38155	4048844321963
30321375	EcoFit® short stem standard cementless cpTi	13,75mm	P 38155	4048844321970
30321500	EcoFit® short stem standard cementless cpTi	15mm	P 38155	4048844321987
30320175	EcoFit® short stem standard cementless cpTi	17,5mm	P 38155	4048844321994
30320200	EcoFit® short stem standard cementless cpTi	20mm	P 38155	4048844322007
30420625	EcoFit® short stem lateralized cementless cpTi	6,25mm	P 38155	4048844322014
30420075	EcoFit® short stem lateralized cementless cpTi	7,5mm	P 38155	4048844322021
30420875	EcoFit® short stem lateralized cementless cpTi	8,75mm	P 38155	4048844322038
30420100	EcoFit® short stem lateralized cementless cpTi	10mm	P 38155	4048844322045
30421125	EcoFit® short stem lateralized cementless cpTi	11,25 mm	P 38155	4048844322052
30420125	EcoFit® short stem lateralized cementless cpTi	12,5mm	P 38155	4048844322069
30421375	EcoFit® short stem lateralized cementless cpTi	13,75mm	P 38155	4048844322076
30421500	EcoFit® short stem lateralized cementless cpTi	15mm	P 38155	4048844322083
30420175	EcoFit® short stem lateralized cementless cpTi	17,5mm	P 38155	4048844322090
30420200	EcoFit® short stem lateralized cementless cpTi	20mm	P 38155	4048844322106
30430625	EcoFit® short stem standard cementless cpTi + HA	6,25mm	P 38155	4048844329075
30430075	EcoFit® short stem standard cementless cpTi + HA	7,5mm	P 38155	4048844329082
30430875	EcoFit® short stem standard cementless cpTi + HA	8,75mm	P 38155	4048844329099
30430100	EcoFit® short stem standard cementless cpTi + HA	10mm	P 38155	4048844329105
30431125	EcoFit® short stem standard cementless cpTi + HA	11,25 mm	P 38155	4048844329112

EU Declaration of Conformity

Attachment XI

Reference number	item description	size	GMDN	GTIN
30430125	EcoFit® short stem standard cementless cpTi + HA	12,5mm	P 38155	4048844329129
30431375	EcoFit® short stem standard cementless cpTi + HA	13,75mm	P 38155	4048844329136
30431500	EcoFit® short stem standard cementless cpTi + HA	15mm	P 38155	4048844329143
30430175	EcoFit® short stem standard cementless cpTi + HA	17,5mm	P 38155	4048844329150
30430200	EcoFit® short stem standard cementless cpTi + HA	20mm	P 38155	4048844329167
30440625	EcoFit® short stem lateralized cementless cpTi + HA	6,25mm	P 38155	4048844329174
30440075	EcoFit® short stem lateralized cementless cpTi + HA	7,5mm	P 38155	4048844329181
30440875	EcoFit® short stem lateralized cementless cpTi + HA	8,75mm	P 38155	4048844329198
30440100	EcoFit® short stem lateralized cementless cpTi + HA	10mm	P 38155	4048844329204
30441125	EcoFit® short stem lateralized cementless cpTi + HA	11,25 mm	P 38155	4048844329211
30440125	EcoFit® short stem lateralized cementless cpTi + HA	12,5mm	P 38155	4048844329228
30441375	EcoFit® short stem lateralized cementless cpTi + HA	13,75mm	P 38155	4048844329235
30441500	EcoFit® short stem lateralized cementless cpTi + HA	15mm	P 38155	4048844329242
30440175	EcoFit® short stem lateralized cementless cpTi + HA	17,5mm	P 38155	4048844329259
30440200	EcoFit® short stem lateralized cementless cpTi + HA	20mm	P 38155	4048844329266

End of schedule. No additional information past this point.

Manufacturer:	implantcast GmbH Lüneburger Schanze 26 21614 Buxtehude Germany
Medical Device(s):	ic-Heads
Intended Use:	<p>The ic-Heads are femoral heads intended for articulation with acetabular cup inserts as part of a total hip arthroplasty or with bipolar components as part of a hemi hip arthroplasty. They are connected modularly with hip stems.</p> <p>The ic-Bipolar Head and ic-Unipolar Head are femoral heads for the hemi hip arthroplasty.</p> <p>The ic-Bipolar Head is intended to articulate freely with the natural acetabulum on its outer surface, and interface with an ic-head on its inner surface where it allows free rotation of the ic-head.</p> <p>The ic-Unipolar Head is connected to a hip stem and intended to articulate freely with the natural acetabulum.</p>
REF Number(s):	REF-Numbers see Attachment I - IV
Classification:	<p>Class III</p> <p><i>(Council Directive 93/42/EEC, Annex IX, rule 8, in conjunction with commission directive 2005/50/EC)</i></p>
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 33175	Metallic femoral head prosthesis
P 33695	Femoral head bipolar component
P 61786	Hip hemiarthroplasty femur prosthesis (en)

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.: 13190GB411210112A
Validity: 12/01/2021 – 27/05/2024

Identification:

CE 0482



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

Buxtehude, 14.01.2021
Place, date

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

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN
23122200	ic-head CoCrMo taper 12/14mm	Ø 22mm S	P 33175	4048844016616
23122205	ic-head CoCrMo taper 12/14mm	Ø 22mm M	P 33175	4048844016623
23122210	ic-head CoCrMo taper 12/14mm	Ø 22mm L	P 33175	4048844016630
23872800	ic-head CoCrMo taper 12/14mm	Ø 28mm S	P 33175	4048844017040
23872805	ic-head CoCrMo taper 12/14mm	Ø 28mm M	P 33175	4048844017057
23872810	ic-head CoCrMo taper 12/14mm	Ø 28mm L	P 33175	4048844017064
23872815	ic-head CoCrMo taper 12/14mm	Ø 28mm XL	P 33175	4048844017071
23872820	ic-head CoCrMo taper 12/14mm	Ø 28mm, XXL	P 33175	4048844017088
23872825	ic-head CoCrMo taper 12/14mm	Ø 28mm, XXXL	P 33175	4048844017095
23873200	ic-head CoCrMo taper 12/14mm	Ø 32mm S	P 33175	4048844017101
23873205	ic-head CoCrMo taper 12/14mm	Ø 32mm M	P 33175	4048844017118
23873210	ic-head CoCrMo taper 12/14mm	Ø 32mm L	P 33175	4048844017125
23873215	ic-head CoCrMo taper 12/14mm	Ø 32mm XL	P 33175	4048844017132
23873220	ic-head CoCrMo taper 12/14mm	Ø 32mm, XXL	P 33175	4048844017149
23873225	ic-head CoCrMo taper 12/14mm	Ø 32mm, XXXL	P 33175	4048844017156
23873600	ic-head CoCrMo taper 12/14mm	Ø 36mm S	P 33175	4048844255589
23873605	ic-head CoCrMo taper 12/14mm	Ø 36mm M	P 33175	4048844245276
23873610	ic-head CoCrMo taper 12/14mm	Ø 36mm L	P 33175	4048844255596
23873615	ic-head CoCrMo taper 12/14mm	Ø 36mm XL	P 33175	4048844245290
23873620	ic-head CoCrMo taper 12/14mm	Ø 36mm, XXL	P 33175	4048844255602
23873625	ic-head CoCrMo taper 12/14mm	Ø 36mm, XXXL	P 33175	4048844245313
23222200	ic-head CoCroMo TiN taper 12/14mm	Ø 22mm, S	P 33175	4048844278182
23222205	ic-head CoCroMo TiN taper 12/14mm	Ø 22mm, M	P 33175	4048844282585
23222210	ic-head CoCroMo TiN taper 12/14mm	Ø 22mm, L	P 33175	4048844278366
27872800	ic-head titanium taper 12/14mm	Ø 28mm S	P 33175	4048844018092
27872805	ic-head titanium taper 12/14mm	Ø 28mm M	P 33175	4048844018108

EU Declaration of Conformity

Attachment II

Reference number	item description	size	GMDN	GTIN
27872810	ic-head titanium taper 12/14mm	Ø 28mm L	P 33175	4048844018115
27872815	ic-head titanium taper 12/14mm	Ø 28mm XL	P 33175	4048844018122
27872820	ic-head titanium taper 12/14mm	Ø 28mm, XXL	P 33175	4048844018139
27872825	ic-head titanium taper 12/14mm	Ø 28mm, XXXL	P 33175	4048844018146
27873200	ic-head titanium taper 12/14mm	Ø 32mm S	P 33175	4048844018153
27873205	ic-head titanium taper 12/14mm	Ø 32mm M	P 33175	4048844018160
27873210	ic-head titanium taper 12/14mm	Ø 32mm L	P 33175	4048844018177
27873215	ic-head titanium taper 12/14mm	Ø 32mm XL	P 33175	4048844018184
27873220	ic-head titanium taper 12/14mm	Ø 32mm, XXL	P 33175	4048844018191
27873225	ic-head titanium taper 12/14mm	Ø 32mm, XXXL	P 33175	4048844018207
27873600	ic-head titanium taper 12/14mm	Ø 36mm S	P 33175	4048844018214
27873605	ic-head titanium taper 12/14mm	Ø 36mm M	P 33175	4048844018221
27873610	ic-head titanium taper 12/14mm	Ø 36mm L	P 33175	4048844018238
27873615	ic-head titanium taper 12/14mm	Ø 36mm XL	P 33175	4048844018245
27873620	ic-head titanium taper 12/14mm	Ø 36mm, XXL	P 33175	4048844018252
27873625	ic-head titanium taper 12/14mm	Ø 36mm, XXXL	P 33175	4048844018269
27122800*	ic-head titanium taper 14/16mm	Ø 28mm, S	P 33175	4048844017934
27122805*	ic-head titanium taper 14/16mm	Ø 28mm, M	P 33175	4048844017941
27122810*	ic-head titanium taper 14/16mm	Ø 28mm, L	P 33175	4048844017958
27122815*	ic-head titanium taper 14/16mm	Ø 28mm, XL	P 33175	4048844017965
27122820*	ic-head titanium taper 14/16mm	Ø 28mm, XXL	P 33175	4048844017972
27122825*	ic-head titanium taper 14/16mm	Ø 28mm, XXXL	P 33175	4048844017989
27123200*	ic-head titanium taper 14/16mm	Ø 32mm, S	P 33175	4048844017996
27123205*	ic-head titanium taper 14/16mm	Ø 32mm, M	P 33175	4048844018009
27123210*	ic-head titanium taper 14/16mm	Ø 32mm, L	P 33175	4048844018016
27123215*	ic-head titanium taper 14/16mm	Ø 32mm, XL	P 33175	4048844018023
27123220*	ic-head titanium taper 14/16mm	Ø 32mm, XXL	P 33175	4048844018030
27123225*	ic-head titanium taper 14/16mm	Ø 32mm, XXXL	P 33175	4048844018047

EU Declaration of Conformity

Attachment III

Reference number	item description	size	GMDN	GTIN
27123600*	ic-head titanium taper 14/16mm	Ø 36mm, S	P 33175	4048844018054
27123605*	ic-head titanium taper 14/16mm	Ø 36mm, M	P 33175	4048844108137
27123610*	ic-head titanium taper 14/16mm	Ø 36mm, L	P 33175	4048844018078
27123615*	ic-head titanium taper 14/16mm	Ø 36mm, XL	P 33175	4048844018085
26874000	ic-Unipolar head taper 12/14mm	Ø 40mm	P 61786	4048844107796
26874200	ic-Unipolar head taper 12/14mm	Ø 42mm	P 61786	4048844017811
26874400	ic-Unipolar head taper 12/14mm	Ø 44mm	P 61786	4048844017828
26874600	ic-Unipolar head taper 12/14mm	Ø 46mm	P 61786	4048844017835
26874700	ic-Unipolar head taper 12/14mm	Ø 47mm	P 61786	4048844017842
26874800	ic-Unipolar head taper 12/14mm	Ø 48mm	P 61786	4048844017859
26874900	ic-Unipolar head taper 12/14mm	Ø 49mm	P 61786	4048844017866
26875000	ic-Unipolar head taper 12/14mm	Ø 50mm	P 61786	4048844017873
26875100	ic-Unipolar head taper 12/14mm	Ø 51mm	P 61786	4048844017880
26875200	ic-Unipolar head taper 12/14mm	Ø 52mm	P 61786	4048844017897
26875400	ic-Unipolar head taper 12/14mm	Ø 54mm	P 61786	4048844017903
26875600	ic-Unipolar head taper 12/14mm	Ø 56mm	P 61786	4048844017910
26875800	ic-Unipolar head taper 12/14mm	Ø 58mm	P 61786	4048844017927
21512238	ic-bipolar head CoCrMo	Ø 22/38mm	P 33695	4048844015855
21512239	ic-bipolar head CoCrMo	Ø 22/39mm	P 33695	4048844112127
21512240	ic-bipolar head CoCrMo	Ø 22/40mm	P 33695	4048844015879
21512241	ic-bipolar head CoCrMo	Ø 22/41mm	P 33695	4048844112134
21510042	ic-bipolar head CoCrMo	Ø 28/42mm	P 33695	4048844015657
21510043	ic-bipolar head CoCrMo	Ø 28/43mm	P 33695	4048844015664
21510044	ic-bipolar head CoCrMo	Ø 28/44mm	P 33695	4048844015671
21510045	ic-bipolar head CoCrMo	Ø 28/45mm	P 33695	4048844015688
21510046	ic-bipolar head CoCrMo	Ø 28/46mm	P 33695	4048844015695
21510047	ic-bipolar head CoCrMo	Ø 28/47mm	P 33695	4048844015701

EU Declaration of Conformity

Attachment IV

Reference number	item description	size	GMDN	GTIN
21510048	ic-bipolar head CoCrMo	Ø 28/48mm	P 33695	4048844105211
21510049	ic-bipolar head CoCrMo	Ø 28/49mm	P 33695	4048844015725
21510050	ic-bipolar head CoCrMo	Ø 28/50mm	P 33695	4048844015732
21510051	ic-bipolar head CoCrMo	Ø 28/51mm	P 33695	4048844015749
21510052	ic-bipolar head CoCrMo	Ø 28/52mm	P 33695	4048844015756
21510053	ic-bipolar head CoCrMo	Ø 28/53mm	P 33695	4048844015763
21510054	ic-bipolar head CoCrMo	Ø 28/54mm	P 33695	4048844015770
21510055	ic-bipolar head CoCrMo	Ø 28/55mm	P 33695	4048844015787
21510056	ic-bipolar head CoCrMo	Ø 28/56mm	P 33695	4048844015794
21510057	ic-bipolar head CoCrMo	Ø 28/57mm	P 33695	4048844105204
21510058	ic-bipolar head CoCrMo	Ø 28/58mm	P 33695	4048844015817
21510059	ic-bipolar head CoCrMo	Ø 28/59mm	P 33695	4048844015824
21510060	ic-bipolar head CoCrMo	Ø 28/60mm	P 33695	4048844015831
21510062	ic-bipolar head CoCrMo	Ø 28/62mm	P 33695	4048844015848

End of schedule. No additional information past this point.



Certificate

No. Q6 095446 0004 Rev. 01

Holder of Certificate: **Wuhu Ruijin Medical Instrument & Device Co., Ltd.**

No.33, Wanchun Road
Economic and Technological Development Zone
241000 Wuhu City, Anhui Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Wuhu Ruijin Medical Instrument & Device Co., Ltd.
No.33, Wanchun Road, Economic and Technological
Development Zone, 241000 Wuhu City, Anhui Province,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:



Scope of Certificate:

**Production and Distribution of
Medical Electric Saw Drill,
Medical Electric Drill, Medical Electric Saw,
Saw Blade, Drill Bit, Autoclavable Box, Flexible Reamer**

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6_095446_0004_Rev.01

Report No.: SH22104901

Valid from: 2022-11-08

Valid until: 2025-11-07

Date, 2022-10-24

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT • CERTIFICATE • 認證證書 • CERTIFICADO • CERTIFICAT

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

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 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.
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 is a management systems certification body
accredited by DAkkS.