Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 1 din 04.12.2023

Solicitantul Oxivit Med SRL, cu sediul mun.Chisinau, MD-2020, Stradela Studentilor, 6b, tel./fax: +37368781333, e-mail oxivit.medical@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea şi punerea la dispoziţie pe piaţă a:

1 Proteze pentru articulaţii:
- AGILON® Shoulder System
- Acetabular Cups and Cup Inserts
- EcoFit® 2M
- MUTARS® Knee System
- MUTARS® Hip System

Se anexează următoarele acte:

Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Data 04/12/2023

Semnătura

Tabelul de recepţionare a notificării

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

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	Nr: 8196 din 04.12.2023
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	Corlat Marin Ştiinţ.
Semnătura persoanei responsabile	Corlat

Digitally signed by Kojevnikov Dmitrii
Date: 2023.12.08 17:20:40 EET
Reason: MoldSign Signature
Location: Moldova

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date:
2023-08-07

Our reference:
QS-7092, PP-13195, PP-13226,
PP-13261, PP-13211, PP-13185

Notified Body Confirmation Letter
Certification No: 7092GB454230807

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany
SRN[2]: DE-MF-000010002

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.
[2] Single registration number (SRN) according to Article 31 (2) of MDR.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa devices, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

For DNV MEDCERT GmbH

Lorenz Runge
Chief Certification

Appendix (see following pages):

- Table 1 and Table 2
- Revision history

Appendix

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
4048844MUT2MINS15TINSK 4048844MUTCOLOVALTCPPN 4048844MUTCOLROUNDTCP6P 4048844MUTCOLTIBIALTCP5G 4048844MUTCONPUNCQG 4048844MUTENDPUNCMP 4048844MUTEXTPUNCX9 4048844MUTFEMSSUNCH6 4048844MUTFEMSTHACDEE 4048844MUTFEMSTHACLEW 4048844MUTFEMSTTINCDRA 4048844MUTFEMSTUNCCDQZ 4048844MUTFEMSTUNCCLRH 4048844MUTICMGENUXMKUNCUH 4048844MUTICMGENUXUNCSQ 4048844MUTICMKRIUNCFR 4048844MUTLUMICCUPHATD 4048844MUTLUMICCUPUNC7X 4048844MUTLUMICFBOLTRN 4048844MUTLUMICSCREWUNCCG 4048844MUTLUMICSSUNCZW 4048844MUTLUMICSTHACL8R 4048844MUTLUMICSTUNCCDUJ 4048844MUTPRFEMREVUNC8W 4048844MUTPRFEMUNCM2 4048844MUTPTEXTPUNC28 4048844MUTPTFEMSTHACL9M 4048844MUTPTREDUNCQZ 4048844MUTPTSCREWUNC7F 4048844MUTREDUNC2N 4048844MUTRSCODEUNCNC 4048844MUTRSCUPFBOLT3G 4048844MUTRSCUPLUNCCLJQ 4048844MUTRSCUPRUNCCLM6 4048844MUTRSEXTPHAUX 4048844MUTRSEXTPUNC33 4048844MUTRSMCHA5X 4048844MUTRSMCUNCWV 4048844MUTRSPCUNCXW 4048844MUTRSSCCODEUNC9B 4048844MUTRSSCREWUNC8J 4048844MUTRSSSUNC4J 4048844MUTRSSTHACLUH 4048844MUTRSSTTINCD5A 4048844MUTRSSTUNCCD4Z 4048844MUTRSSTUNCCL5H 4048844MUTRSSTXSHACLHX 4048844MUTSCONPUNCN9 4048844MUTSCREWUNCMW 4048844MUTSTMCTINCDUE 4048844MUTSTMCUNCCDU5 4048844MUTSTMSTINCD2Z 4048844MUTSTMSUNCCD2Q 4048844MUTTPPRFEMREVUNCSX 4048844MUTXLPEINS15N05M 4048844MUTXLPEINS15O45Y 4048844MUTCONPSJQ 4048844MUTHMRSADFSJA 4048844MUTHMRSADMSJX 4048844MUTREDSAS	Class III	N/A	Certificate 13195DE411200427 NB 0482 Certificate 13195GB411200427 NB 0482

4048844MUTPRFEMS56 **4048844MUTPRFEMREVSP2** **4048844MUTEXTPSNB** **4048844MUTENDPSHM** **4048844MUTRSPCSPU** **4048844MUTICMKRISME** **4048844MUTICMGENUXSCP** **4048844MUTICMGENUXMKSS7** **4048844MUTRSCODESTK** **4048844MUTLUMICCUPSNH**			
4048844MUTCONPTIBUNCRH **4048844MUTCOTINBNPG** **4048844MUTCOUNCJM** **4048844MUTEPMETTIBH5** **4048844MUTEPMETTIBMKQC** **4048844MUTFEMDHDTIN7G** **4048844MUTFEMDHDUNC7E** **4048844MUTFEMDMOMTINFR** **4048844MUTFEMDMOMUNCFP** **4048844MUTFEMDTINK4** **4048844MUTFEMDUNCK2** **4048844MUTFEMGMKHDTINCDFT** **4048844MUTFEMGMKHDTINCLGB** **4048844MUTFEMGMKHDUNCCDFJ** **4048844MUTFEMGMKHDUNCCLG2** **4048844MUTFEMGMKMHUNCCDKT** **4048844MUTFEMGMKMUNCCD3H** **4048844MUTFEMGMKTINCDNY** **4048844MUTFEMGMKTINCLPG** **4048844MUTFEMGMKUNCCDNP** **4048844MUTFEMGMKUNCCLP7** **4048844MUTFEMGTINCDBS** **4048844MUTFEMGTINCLCA** **4048844MUTFEMGUNCCDBH** **4048844MUTFEMGUNCCLBZ** **4048844MUTFEMKRIHDTINQ4** **4048844MUTFEMKRIHDUNCQ2** **4048844MUTFEMKRIMOMTITU** **4048844MUTFEMKRIMOMUNU9** **4048844MUTFEMKRITINEU** **4048844MUTFEMKRIUNCES** **4048844MUTGENMKOFADUNC2P** **4048844MUTHDCOCOMTINCP** **4048844MUTHDCOCOMUNCCM** **4048844MUTHDCOMOMCPEGL6** **4048844MUTHDCOMOMTINBN4G** **4048844MUTHDCOMOMUNCGP** **4048844MUTPATPESTDCDUF** **4048844MUTPEEKOPLOCKPWQ** **4048844MUTPEFBSTDMT** **4048844MUTPEGENMKFBSTD5C** **4048844MUTPEGENMKFBXLE5F** **4048844MUTPEGENMKMBSTD7R** **4048844MUTPEGENMKMBXLE7U** **4048844MUTPEGTIBGMKTIN9T** **4048844MUTPEGTIBGMKUNC9R** **4048844MUTPEGTIBMOMTINDD** **4048844MUTPEGTIBMOMUNCDB** **4048844MUTPLUGTIB2MOM6A** **4048844MUTPLUGTIBMOM23** **4048844MUTSCRCOUNT2** **4048844MUTSCRCOUPT6** **4048844MUTSCRKRI4M** **4048844MUTSCRSPAFEMPU** **4048844MUTSCRSPAMKNG** **4048844MUTSCRSPATIBCXW** **4048844MUTSCRSPATIBRQ** **4048844MUTSCRTIBMODPJ** **4048844MUTSCRTIBMOMQ4** **4048844MUTSFEMUNCRK** **4048844MUTSLFEMUNCKM**	Class III	N/A	Certificate 13226GB411200831 NB 0482 Certificate 13226DE411200831 NB 0482

4048844MUTSMKFEMDUNCT7 **4048844MUTSMKFEMPUNCVT** **4048844MUTSMKTIBBIUNC7A** **4048844MUTSMKTIBUNCSU** **4048844MUTSTGENMKEXUNCTH** **4048844MUTSTGENMKHACL89** **4048844MUTSTGENMKTINCDTB** **4048844MUTSTGENMKUNCCDT2** **4048844MUTSTGENMKUNCCLTJ** **4048844MUTSTGENTINCD2H** **4048844MUTSTGENUNCCD28** **4048844MUTSTGENUNCCL2Q** **4048844MUTSTIBUNCW8** **4048844MUTSTTIBCPTICDEM** **4048844MUTSTTIBHACDS5** **4048844MUTSTTIBHACLSM** **4048844MUTSTTIBMTIBCDGK** **4048844MUTSTTIBMUNCCDJ6** **4048844MUTSTTIBMUNCCLJN** **4048844MUTSTTIBPTHACLHW** **4048844MUTSTTIBTINCD7G** **4048844MUTSTTIBUNCCD77** **4048844MUTSTTIBUNCCL7P** **4048844MUTTIBBMKUNCCLVH** **4048844MUTTIBBTINCLGU** **4048844MUTTIBGMKMUNCDYG** **4048844MUTTIBGMKTIBCDWD** **4048844MUTTIBGMKTIBCLWV** **4048844MUTTIBGMKUNCCDXY** **4048844MUTTIBGMKUNCCLYG** **4048844MUTTIBMKPRTINW7** **4048844MUTTIBMOMTINCD5S** **4048844MUTTIBMOMTINCL6A** **4048844MUTTIBMOMUNCCD5H** **4048844MUTTIBMOMUNCCL5Z** **4048844MUTTIBMPROUNCY7** **4048844MUTPEEKOPLOCKP7** **4048844MUTCONPTIBSILRA** **4048844MUTSFEMSILRC** **4048844MUTSLFEMSILKE** **4048844MUTSTIBSILVZ** **4048844MUTFEMDMOMSILFG** **4048844MUTFEMDMOMTSBU** **4048844MUTFEMDSILJT** **4048844MUTFEMKRIMOMTSUG** **4048844MUTSMKFEMDSILSY** **4048844MUTSMKFEMPSILVL** **4048844MUTSMKTIBBISIL73** **4048844MUTSMKTIBSILSM** **4048844MUTTIBMKPRSILVW** **4048844MUTTIBMOMSILCD55** **4048844MUTTIBMPROSILXY**			
4048844MUTHUAXLD2UNCNM **4048844MUTHUAXLDTINBN65** **4048844MUTHUAXLDUNCMG** **4048844MUTHUCAPITINFQ** **4048844MUTHUCAPTINFZ** **4048844MUTHUCOLFTCPJX** **4048844MUTHUCOLTCPKH** **4048844MUTHUCONPUNCN7** **4048844MUTHUDH230UNCXQ** **4048844MUTHUDH250UNCYE** **4048844MUTHUDH30UNC46** **4048844MUTHUDH50TINBNBA** **4048844MUTHUDH50UNC4U** **4048844MUTHUENDPUNCKE** **4048844MUTHUEXTPUNCUY** **4048844MUTHUGLENUNCKK** **4048844MUTHUGLRHACLK5** **4048844MUTHUGLUNCCDMA** **4048844MUTHUHEADUNCDP** **4048844MUTHUHSSUNCQT**	Class III	N/A	Certificate 13266DE411180608 NB 0482 Certificate 13266GB411180608 NB 0482

4048844MUTHUHSUNCU6 **4048844MUTHULSDUNCP6** **4048844MUTHUPEFCSTDKR** **4048844MUTHUPESCSTDQ8** **4048844MUTHUREDUNCLS** **4048844MUTHUSCONPUNCZ6** **4048844MUTHUSDSW5UNCYQ** **4048844MUTHUSSD30UNCMG** **4048844MUTHUSTAMTINCDDY** **4048844MUTHUSTAMUNCCDDP** **4048844MUTHUSTAMUNCCLE7** **4048844MUTHUSTHACDP5** **4048844MUTHUSTHACLPM** **4048844MUTHUSTOP2UNC4M** **4048844MUTHUSTOPUNCZ3** **4048844MUTHUSTTINCDX7** **4048844MUTHUSTUNCCDWW** **4048844MUTHUSTUNCCLXE** **4048844MUTHUUA2CPHACLME** **4048844MUTHUUACPHACLPR** **4048844MUTHUUATINBNCL9H** **4048844MUTHUUC2UNCCDM6** **4048844MUTHUUCIITINCD7X** **4048844MUTHUUCTINBNCDA7** **4048844MUTHUUCUNCCDR3** **4048844MUTHUULNA2TINTY** **4048844MUTHUULNA2UNCTW** **4048844MUTHUULNAUNCT9** **4048844MUTHUHEADSN2** **4048844MUTHUEXTPSV9** **4048844MUTHUCONPSRN** **4048844MUTHUENDPSQK** **4048844MUTHUREDS4Q** **4048844MUTHUDH50SHT** **4048844MUTHUULNASVS**			
4048844AGILOCAPITIN9J **4048844AGILOCAPTINEV** **4048844AGILOCTACAPTINAZ** **4048844AGILOEXTPRUNCU6** **4048844AGILOEXTPUNCNS** **4048844AGILOGLAHACL74** **4048844AGILOGLBAUNCCLBX** **4048844AGILOGLBRUNCCLJU** **4048844AGILOGLPEICLCU** **4048844AGILOGLPEIXLECLVX** **4048844AGILOMETOAWR** **4048844AGILOMETPRXW** **4048844AGILOMETTRRNA** **4048844AGILOMETTRYA** **4048844AGILOMICLCE** **4048844AGILONGLRHACLG5** **4048844AGILOPEGLENHX** **4048844AGILOPEGLENXLEKK** **4048844AGILOPEGLXLECDMS** **4048844AGILORCAPITINF4** **4048844AGILOSRTIN3Z** **4048844AGILOSSUNC46** **4048844AGILOSTING5** **4048844AGILOSTRTINCDWV** **4048844AGILOSTRUNCCDWL** **4048844AGILOSTRUNCCLX4** **4048844AGILOSTTINCDQZ** **4048844AGILOSTUNCCDQQ** **4048844AGILOSTUNCCLR8**	Class III	N/A	Certificate 13261GB411200529 NB 0482 Certificate 13261DE411200529 NB 0482
4048844ECO2MCUPCDTINWE **4048844ECO2MCUPCDUNCWC** **4048844ECO2MCUPCLCPHAY2** **4048844ECO2MCUPCLSPCPHAQN** **4048844ECO2MHEADPEZ6** **4048844ECO2MHEADXLESU**	Class III	N/A	Certificate 13211DE411180302 NB 0482 Certificate 13211GB411180302 NB 0482

4048844BICANRSTUNCCDHD **4048844BICANSTUNCCDDV**	Class III	N/A	Certificate 13185DE411180528 NB 0482 Certificate 13185GB411180528 NB 0482

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
None	None	None	None

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2023-06-29	N/A	Initial issue
2023-07-13	N/A	Correction Basic UDI-DI
2023-07-17	N/A	Correction Basic UDI-DI
2023-08-07	7092GB454230807	Insert of Certificate Number

implantcast GmbH · Lüneburger Schanze 26 · 21614 Buxtehude

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Tel.: +49 4161 744-0
Fax: +49 4161 744-200
E-Mail: info@implantcast.de
Internet: www.implantcast.de

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

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

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

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

Vadim Lioubitski
Export Manager
C.I.S. countries

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

EU Declaration of Conformity

Manufacturer:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s):

EcoFit® 2M System

Intended Use:

The EcoFit® 2M system is a tripolar acetabular cup system (dual mobility) for total hip arthroplasty that consists of a metallic acetabular shell (EcoFit® 2M Cup) and a head made of polyethylene (EcoFit® 2M head / 2M implacross® E head) which serves as an internal bearing. The head made of polyethylene is intended for connection with a metallic or ceramic femoral head. The EcoFit® 2M Cup is intended either for a cementless or a cemented fixation.

The heads (EcoFit® 2M Head / 2M implacross® E Head) can additionally be used with a metallic insert (EcoFit® Insert / EcoFit® Insert TiN/ 2M insert 15° for MUTARS® RS cup and LUMiC® TiN) in combination with press-fit acetabular cups and revision / tumor acetabular cups respectively in a modular dual mobility hip replacement.

REF Number(s):

REF-Numbers see Attachment I - III

Classification:

Class III

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

Standard(s) applied:

EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 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 – 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 43167	Acetabular shell
P 43168	Non-constrained polyethylene acetabular liner

EU Declaration of Conformity

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.: 13211GB411180302 Validity: 02/03/2018 - 28/10/2022
Identification:	CE 0482

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

Buxtehude, 03.12.2020
Place, date

i.V. Juliane Höppner
Head of Regulatory Affairs

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN
02201042	EcoFit® 2M cup cementless	38/42	P 43167	4048844206598
02201044	EcoFit® 2M cup cementless	40/44	P 43167	4048844206604
02201046	EcoFit® 2M cup cementless	42/46	P 43167	4048844206611
02201048	EcoFit® 2M cup cementless	44/48	P 43167	4048844219925
02201050	EcoFit® 2M cup cementless	46/50	P 43167	4048844206628
02201052	EcoFit® 2M cup cementless	48/52	P 43167	4048844219932
02201054	EcoFit® 2M cup cementless	50/54	P 43167	4048844206642
02201056	EcoFit® 2M cup cementless	52/56	P 43167	4048844206659
02201058	EcoFit® 2M cup cementless	54/58	P 43167	4048844206666
02201060	EcoFit® 2M cup cementless	56/60	P 43167	4048844206673
02201062	EcoFit® 2M cup cementless	58/62	P 43167	4048844206574
02201064	EcoFit® 2M cup cementless	58/64	P 43167	4048844206581
02201144	EcoFit® 2M cup cemented	38/44	P 43167	4048844206475
02201146	EcoFit® 2M cup cemented	40/46	P 43167	4048844206482
02201148	EcoFit® 2M cup cemented	42/48	P 43167	4048844206499
02201150	EcoFit® 2M cup cemented	44/50	P 43167	4048844206505
02201152	EcoFit® 2M cup cemented	46/52	P 43167	4048844206512
02201154	EcoFit® 2M cup cemented	48/54	P 43167	4048844206543
02201156	EcoFit® 2M cup cemented	50/56	P 43167	4048844206550
02201158	EcoFit® 2M cup cemented	52/58	P 43167	4048844206567
02201160	EcoFit® 2M cup cemented	54/60	P 43167	4048844206338
02201162	EcoFit® 2M cup cemented	56/62	P 43167	4048844206345
02201164	EcoFit® 2M cup cemented	58/64	P 43167	4048844206352
02201144N	EcoFit® 2M cup cemented TiN	38/44	P 43167	4048844206369
02201146N	EcoFit® 2M cup cemented TiN	40/46	P 43167	4048844206376
02201148N	EcoFit® 2M cup cemented TiN	42/48	P 43167	4048844206383

EU Declaration of Conformity

Attachment II

Reference number	item description	size	GMDN	GTIN
02201150N	EcoFit® 2M cup cemented TiN	44/50	P 43167	4048844206390
02201152N	EcoFit® 2M cup cemented TiN	46/52	P 43167	4048844206406
02201154N	EcoFit® 2M cup cemented TiN	48/54	P 43167	4048844206413
02201156N	EcoFit® 2M cup cemented TiN	50/56	P 43167	4048844206420
02201158N	EcoFit® 2M cup cemented TiN	52/58	P 43167	4048844206437
02201160N	EcoFit® 2M cup cemented TiN	54/60	P 43167	4048844206444
02201162N	EcoFit® 2M cup cemented TiN	56/62	P 43167	4048844206451
02201164N	EcoFit® 2M cup cemented TiN	58/64	P 43167	4048844206468
29052238	2M implacross® E head	22/38	P 43168	4048844206994
29052240	2M implacross® E head	22/40	P 43168	4048844207007
29052842	2M implacross® E head	28/42	P 43168	4048844207014
29052844	2M implacross® E head	28/44	P 43168	4048844207021
29052846	2M implacross® E head	28/46	P 43168	4048844207038
29052848	2M implacross® E head	28/48	P 43168	4048844207045
29052850	2M implacross® E head	28/50	P 43168	4048844207052
29052852	2M implacross® E head	28/52	P 43168	4048844207069
29052854	2M implacross® E head	28/54	P 43168	4048844207076
29052856	2M implacross® E head	28/56	P 43168	4048844207083
29052858	2M implacross® E head	28/58	P 43168	4048844206291
29053248	2M implacross® E head	32/48	P 43168	4048844218157
29053250	2M implacross® E head	32/50	P 43168	4048844217525
29053252	2M implacross® E head	32/52	P 43168	4048844218164
29053254	2M implacross® E head	32/54	P 43168	4048844217549
29053256	2M implacross® E head	32/56	P 43168	4048844218171
29053258	2M implacross® E head	32/58	P 43168	4048844217563
29062238	EcoFit® 2M head	22/38	P 43168	4048844240066
29062240	EcoFit® 2M head	22/40	P 43168	4048844240387

EU Declaration of Conformity

Attachment III

Reference number	item description	size	GMDN	GTIN
29062842	EcoFit® 2M head	28/42	P 43168	4048844240691
29062844	EcoFit® 2M head	28/44	P 43168	4048844240233
29062846	EcoFit® 2M head	28/46	P 43168	4048844240240
29062848	EcoFit® 2M head	28/48	P 43168	4048844240257
29062850	EcoFit® 2M head	28/50	P 43168	4048844240271
29062852	EcoFit® 2M head	28/52	P 43168	4048844240288
29062854	EcoFit® 2M head	28/54	P 43168	4048844240295
29062856	EcoFit® 2M head	28/56	P 43168	4048844240301
29062858	EcoFit® 2M head	28/58	P 43168	4048844240318
29063248	EcoFit® 2M head	32/48	P 43168	4048844240707
29063250	EcoFit® 2M head	32/50	P 43168	4048844240714
29063252	EcoFit® 2M head	32/52	P 43168	4048844240721
29063254	EcoFit® 2M head	32/54	P 43168	4048844240356
29063256	EcoFit® 2M head	32/56	P 43168	4048844240738
29063258	EcoFit® 2M head	32/58	P 43168	4048844240370
02201242	EcoFit® 2M cup cementless SP	38/42	P 43167	4048844356637
02201244	EcoFit® 2M cup cementless SP	40/44	P 43167	4048844356644
02201246	EcoFit® 2M cup cementless SP	42/46	P 43167	4048844356651
02201248	EcoFit® 2M cup cementless SP	44/48	P 43167	4048844356668
02201250	EcoFit® 2M cup cementless SP	46/50	P 43167	4048844356675
02201252	EcoFit® 2M cup cementless SP	48/52	P 43167	4048844356682
02201254	EcoFit® 2M cup cementless SP	50/54	P 43167	4048844356699
02201256	EcoFit® 2M cup cementless SP	52/56	P 43167	4048844356705
02201258	EcoFit® 2M cup cementless SP	54/58	P 43167	4048844356712
02201260	EcoFit® 2M cup cementless SP	56/60	P 43167	4048844356729
02201262	EcoFit® 2M cup cementless SP	58/62	P 43167	4048844356736
02201264	EcoFit® 2M cup cementless SP	60/64	P 43167	4048844356743

End of schedule. No additional information past this point.

MED CERT®

Certification. Medical Only.

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.

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

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

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

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

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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

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

MED CERT®

Certification. Medical Only.

EC Design Examination Certificate

The Notified Body

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

herewith confirms that the design of the medical device (s)

Hip implants
EcoFit® 2M acetabular hip cups and heads
Model numbers as per attachment 1

of the manufacturer

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

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

Annex II, Section 4

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

This certificate is valid until: 28 October 2022

Report No.: 13211FS06F
Process No.: PP – 13211
Certificate No.: 13211GB411180302

Hamburg, 02 March 2018

MEDCERT Identification No.: 0482

MEDCERT Certification Body
(Dr. Andreas Schich)

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

MED CERT®

Certification. Medical Only.

Attachment 1
EC Design Examination Certificate
PP – 13211

This attachment is valid only in connection with certificate No: 13211GB411180302

EcoFit® 2M cup cementless						
02201042	02201044	02201046	02201048	02201050	02201052	02201054
02201056	02201058	02201060	02201062	02201064	–	–

EcoFit® 2M cup cemented						
02201144	02201146	02201148	02201150	02201152	02201154	02201156
02201158	02201160	02201162	02201164	–	–	–

EcoFit® 2M cup cemented TiN						
02201144N	02201146N	02201148N	02201150N	02201152N	02201154N	02201156N
02201158N	02201160N	02201162N	02201164N	–	–	–

2M implacross® E head						
29052238	29052240	29052842	29052844	29052846	29052848	29052850
29052852	29052854	29052856	29052858	29053248	29053250	29053252
29053254	29053256	29053258	–	–	–	–

EcoFit® 2M head						
29062238	29062240	29062842	29062844	29062846	29062848	29062850
29062852	29062854	29062856	29062858	29063248	29063250	29063252
29063254	29063256	29063258	–	–	–	–

EcoFit® 2M cup cementless SP						
02201242	02201244	02201246	02201248	02201250	02201252	02201254
02201256	02201258	02201260	02201262	02201264	–	–

Hamburg, 02 March 2018

MEDCERT Certification Body
(Dr. Andreas Schich)

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

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului), Modelul	Denumire comercială (brand)*	Cod GMDN*
1	02201144	EcoFit® 2M cup cemented Ø 38/44mm	EcoFit®	P 43167
2	02201146	EcoFit® 2M cup cemented Ø 40/46mm	EcoFit®	P 43167
3	02201148	EcoFit® 2M cup cemented Ø 42/48mm	EcoFit®	P 43167
4	02201150	EcoFit® 2M cup cemented Ø 44/50mm	EcoFit®	P 43167
5	02201152	EcoFit® 2M cup cemented Ø 46/52mm	EcoFit®	P 43167
6	02201154	EcoFit® 2M cup cemented Ø 48/54mm	EcoFit®	P 43167
7	02201156	EcoFit® 2M cup cemented Ø 50/56mm	EcoFit®	P 43167
8	02201158	EcoFit® 2M cup cemented Ø 52/58mm	EcoFit®	P 43167
9	02201160	EcoFit® 2M cup cemented Ø 54/60mm	EcoFit®	P 43167
10	02201162	EcoFit® 2M cup cemented Ø 56/62mm	EcoFit®	P 43167
11	02201164	EcoFit® 2M cup cemented Ø 58/64mm	EcoFit®	P 43167
12	02201044	EcoFit® 2M cup cementless 40/44	EcoFit®	P 43167
13	02201046	EcoFit® 2M cup cementless 42/46	EcoFit®	P 43167
14	02201048	EcoFit® 2M cup cementless 44/48	EcoFit®	P 43167
15	02201050	EcoFit® 2M cup cementless 46/50	EcoFit®	P 43167
16	02201052	EcoFit® 2M cup cementless 48/52	EcoFit®	P 43167
17	02201054	EcoFit® 2M cup cementless 50/54	EcoFit®	P 43167
18	02201056	EcoFit® 2M cup cementless 52/56	EcoFit®	P 43167
19	02201058	EcoFit® 2M cup cementless 54/58	EcoFit®	P 43167
20	02201060	EcoFit® 2M cup cementless 56/60	EcoFit®	P 43167
21	02201062	EcoFit® 2M cup cementless 58/62	EcoFit®	P 43167
22	02201064	EcoFit® 2M cup cementless 58/64	EcoFit®	P 43167
24	29052238	2M implacross® E head Ø 22/38mm	implacross®	P 43168
25	29052240	2M implacross® E head Ø 22/40mm	implacross®	P 43168
26	29052842	2M implacross® E head Ø 28/42mm	implacross®	P 43168
27	29052844	2M implacross® E head Ø 28/44mm	implacross®	P 43168
28	29052846	2M implacross® E head Ø 28/46mm	implacross®	P 43168
29	29052848	2M implacross® E head Ø 28/48mm	implacross®	P 43168
30	29052850	2M implacross® E head Ø 28/50mm	implacross®	P 43168
31	29052852	2M implacross® E head Ø 28/52mm	implacross®	P 43168
32	29052854	2M implacross® E head Ø 28/54mm	implacross®	P 43168
33	29052856	2M implacross® E head Ø 28/56mm	implacross®	P 43168
34	29052858	2M implacross® E head Ø 28/58mm	implacross®	P 43168
35	29053248	2M implacross® E head Ø 32/48	implacross®	P 43168
36	29053250	2M implacross® E head Ø 32/50mm	implacross®	P 43168
37	29053252	2M implacross® E head Ø 32/52mm	implacross®	P 43168
38	29053254	2M implacross® E head Ø 32/54mm	implacross®	P 43168
39	29053256	2M implacross® E head Ø 32/56mm	implacross®	P 43168
40	29053258	2M implacross® E head Ø 32/58mm	implacross®	P 43168
41	29062238	EcoFit® 2M head Ø 22/38mm	EcoFit®	P 43168
42	29062240	EcoFit® 2M head Ø 22/40mm	EcoFit®	P 43168
43	29062842	EcoFit® 2M head Ø 28/42mm	EcoFit®	P 43168
44	29062844	EcoFit® 2M head Ø 28/44mm	EcoFit®	P 43168
45	29062846	EcoFit® 2M head Ø 28/46mm	EcoFit®	P 43168
46	29062848	EcoFit® 2M head Ø 28/48mm	EcoFit®	P 43168
47	29062850	EcoFit® 2M head Ø 28/50mm	EcoFit®	P 43168
48	29062852	EcoFit® 2M head Ø 28/52mm	EcoFit®	P 43168
49	29062854	EcoFit® 2M head Ø 28/54mm	EcoFit®	P 43168
50	29062856	EcoFit® 2M head Ø 28/56mm	EcoFit®	P 43168
51	29062858	EcoFit® 2M head Ø 28/58mm	EcoFit®	P 43168
52	29063248	EcoFit® 2M head Ø 32/48mm	EcoFit®	P 43168
53	29063250	EcoFit® 2M head Ø 32/50mm	EcoFit®	P 43168
54	29063252	EcoFit® 2M head Ø 32/52mm	EcoFit®	P 43168
55	29063254	EcoFit® 2M head Ø 32/54mm	EcoFit®	P 43168
56	29063256	EcoFit® 2M head Ø 32/56mm	EcoFit®	P 43168
57	29063258	EcoFit® 2M head Ø 32/58mm	EcoFit®	P 43168
58				
59				
60				

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: _ Oxivit Med SRL _____, cu sediul _____ mun.Chisinau, MD-2020, Stradela Studentilor, 6b,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Proteze pentru articulații:
  - AGILON® Shoulder System
  - Acetabular Cups and Cup Inserts
  - EcoFit® 2M
  - MUTARS® Knee System
  - MUTARS® Hip System

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Kojevnikov Dmitrii, director

Data _04/12/2023__