

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 13 din 19.10.2023

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 și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Proteze pentru articulații de umar, model AGILON®

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de imputernicire

Data 19/10/2023

Semnătura _____

Tabelul de recepționare a notificării

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

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

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

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

- Proteze pentru articulații de umăr, model AGILON®
Sunt autentice și corespund realității.

Numele, prenumele și funcția

Semnătura _____

Kojevnikov Dmitrii, director

Data 19/10/2023

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

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

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

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


Vadim Lioubitski
Export Manager
C.I.S. countries

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

Manufacturer:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s):

AGILON® Shoulder System

Intended Use:

The modular AGILON® Shoulder System is intended for hemi or total shoulder replacement. The system consists of different functional components designed to reconstruct the glenohumeral joint. Depending on indication, the humeral component may be used in conjunction with a glenoid component for conventional total shoulder replacement or to articulate directly with the natural glenoid in a hemi-shoulder application. The AGILON® Shoulder System is also intended for reverse shoulder replacement.

AGILON® MI is a stemless version of the AGILON® shoulder system. The metaphyseal implant is intended for cementless fixation to replace a shoulder joint in case of hemi or total anatomic shoulder replacement.

The AGILON® Cap and AGILON® CTA Cap are caps intended to replace the humeral head by articulation with the glenoid component or the natural glenoid. The AGILON® CTA Cap has an enlarged articulation surface which allows articulation with the acromion in case of a rotator cuff deficiency.

The AGILON® Cap Inverse and AGILON® Retentive Cap Inverse are caps intended to replace the humeral head by articulation with a glenosphere for a reverse shoulder replacement.

The AGILON® Glenoid Cementless Round and AGILON® Glenoid Baseplate Round are glenoid components intended for cementless fixation to replace the natural glenoid by combination with a glenosphere for a reverse shoulder replacement.

The AGILON® Glenoid Cementless Anatomical and AGILON® Glenoid Baseplate Cementless Anatomical are glenoid components intended for cementless fixation to replace the natural glenoid by combination with a glenoid PE-insert or a glenosphere for total shoulder replacement (anatomical or reverse).

The AGILON® Glenoid PE-Insert is intended to replace the surface of the natural glenoid in total anatomic shoulder replacement.

The AGILON® PE-Glenosphere and Glenosphere are components intended to replace the natural glenoid by combination with the AGILON® Glenoid Cementless Round or AGILON® Glenoid Baseplate Round for a reverse total shoulder replacement.

The AGILON® PE-Glenoid Cemented and Glenoid Cemented are glenoid components intended for cemented fixation to replace the glenoid surface in case of an anatomical total shoulder replacement.

The AGILON® Extension Piece is intended for length adjustment in the case of a shoulder replacement.

The AGILON® Metaphyseal Component Trauma is a component intended to replace the metaphyseal part of the humerus in case of a traumatic destroyed shoulder joint.

The AGILON® Metaphyseal Component Omarthrosis is a component intended to replace the metaphyseal part of the humerus

The AGILON® Stem is a stem for cemented or cementless fixation intended for diaphyseal anchorage of the shoulder joint replacement in the humerus.

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 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 33711	Reverse shoulder prosthesis
P 34197	Uncoated shoulder humeral stem
P 35670	Total shoulder prosthesis
P 36259	Shoulder glenoid fossa prosthesis
P 48088	Humeral head prosthesis
P 48091	Reverse shoulder prosthesis baseplate
P 48093	Reverse shoulder prosthesis head
P 48094	Shoulder prosthesis screw
P 58951	Metaphyseal anchor-fixed humeral head prosthesis
P 60512	Shoulder humeral body prosthesis
P 61006	Humeral stem extension prosthesis
P 63998	Implantable orthopaedic fixation device connection screw

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.: 13261GB411200529
Validity: 29/05/2020 - 29/08/2022

Identification:

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
38200001	AGILON® metaphyseal component trauma incl. safety screw	/	P 60512	4048844203993
38200002	AGILON® metaphyseal component primary incl. safety screw	40mm	P 60512	4048844204075
38200003	AGILON® metaphyseal component primary incl. safety screw	30mm	P 60512	4048844204082
38210001	AGILON® metaphyseal component trauma incl. safety screw	135°	P 60512	4048844330613
38210011	AGILON® metaphyseal component trauma incl. safety screw	155°	P 60512	4048844330675
38210002	AGILON® metaphyseal component omarthrosis incl. safety screw	40mm 135°	P 60512	4048844330620
38210003	AGILON® metaphyseal component omarthrosis incl. safety screw	30mm 135°	P 60512	4048844330668
38210012	AGILON® metaphyseal component omarthrosis incl. safety screw	40mm 155°	P 60512	4048844330682
38210013	AGILON® metaphyseal component omarthrosis incl. safety screw	30mm 155°	P 60512	4048844330699
38004114	AGILON® cap	Ø 41/14mm	P 48088	4048844325688
38004117	AGILON® cap	Ø 41/17mm	P 48088	4048844325695
38004120	AGILON® cap	Ø 41/20mm	P 48088	4048844325701
38004414	AGILON® cap	Ø 44/14mm	P 48088	4048844028398
38004417	AGILON® cap	Ø 44/17mm	P 48088	4048844028404
38004420	AGILON® cap	Ø 44/20mm	P 48088	4048844028411
38004714	AGILON® cap	Ø 47/14mm	P 48088	4048844028428
38004717	AGILON® cap	Ø 47/17mm	P 48088	4048844028435
38004720	AGILON® cap	Ø 47/20mm	P 48088	4048844028442
38005014	AGILON® cap	Ø 50/14mm	P 48088	4048844028459
38005017	AGILON® cap	Ø 50/17mm	P 48088	4048844028466
38005020	AGILON® cap	Ø 50/20mm	P 48088	4048844028473
38005314	AGILON® cap	Ø 53/14mm	P 48088	4048844028480
38005317	AGILON® cap	Ø 53/17mm	P 48088	4048844028497
38005320	AGILON® cap	Ø 53/20mm	P 48088	4048844028503

EU Declaration of Conformity

Attachment II

Reference number	item description	size	GMDN	GTIN
38224414	AGILON® CTA cap	Ø44/14mm	P 48088	4048844230326
38224417	AGILON® CTA cap	Ø44/17mm	P 48088	4048844230333
38224420	AGILON® CTA cap	Ø44/20mm	P 48088	4048844230340
38224714	AGILON® CTA cap	Ø47/14mm	P 48088	4048844230357
38224717	AGILON® CTA cap	Ø47/17mm	P 48088	4048844230364
38224720	AGILON® CTA cap	Ø47/20mm	P 48088	4048844230371
38225014	AGILON® CTA cap	Ø50/14mm	P 48088	4048844230388
38225017	AGILON® CTA cap	Ø50/17mm	P 48088	4048844230395
38225020	AGILON® CTA cap	Ø50/20mm	P 48088	4048844230401
38225314	AGILON® CTA cap	Ø53/14mm	P 48088	4048844229610
38225317	AGILON® CTA cap	Ø53/17mm	P 48088	4048844249250
38225320	AGILON® CTA cap	Ø53/20mm	P 48088	4048844229634
38013200	AGILON® cap inverse	Ø 32mm S	P 33711	4048844325657
38013205	AGILON® cap inverse	Ø 32mm M	P 33711	4048844325664
38013210	AGILON® cap inverse	Ø 32mm L	P 33711	4048844325671
38013600	AGILON® cap inverse	Ø 36mm S	P 33711	4048844028596
38013605	AGILON® cap inverse	Ø 36mm M	P 33711	4048844028602
38013610	AGILON® cap inverse	Ø 36mm L	P 33711	4048844028619
38014000	AGILON® cap inverse	Ø 40 mm S	P 33711	4048844028626
38014005	AGILON® cap inverse	Ø 40 mm M	P 33711	4048844028633
38014010	AGILON® cap inverse	Ø 40 mm L	P 33711	4048844028640
38014400	AGILON® cap inverse	Ø 44 mm S	P 33711	4048844028657
38014405	AGILON® cap inverse	Ø 44 mm M	P 33711	4048844028664
38014410	AGILON® cap inverse	Ø 44 mm L	P 33711	4048844028671
38015200	AGILON® retentive cap inverse	Ø 32mm S	P 33711	4048844324476

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Attachment III

Reference number	item description	size	GMDN	GTIN
38015205	AGILON® retentive cap inverse	Ø 32mm M	P 33711	4048844324483
38015210	AGILON® retentive cap inverse	Ø 32mm L	P 33711	4048844324490
38015600	AGILON® retentive cap inverse	Ø 36mm S	P 33711	4048844276348
38015605	AGILON® retentive cap inverse	Ø 36mm M	P 33711	4048844276355
38015610	AGILON® retentive cap inverse	Ø 36mm L	P 33711	4048844276362
38016000	AGILON® retentive cap inverse	Ø 40 mm S	P 33711	4048844276379
38016005	AGILON® retentive cap inverse	Ø 40 mm M	P 33711	4048844276386
38016010	AGILON® retentive cap inverse	Ø 40 mm L	P 33711	4048844276393
38016400	AGILON® retentive cap inverse	Ø 44 mm S	P 33711	4048844276409
38016405	AGILON® retentive cap inverse	Ø 44 mm M	P 33711	4048844276416
38016410	AGILON® retentive cap inverse	Ø 44 mm L	P 33711	4048844276423
38004005	Glenoid cemented	small	P 36259	4048844126292
38004006	Glenoid cemented	standard	P 36259	4048844126308
38030032	AGILON® PE-glenoid cemented	2	P 36259	4048844325824
38030036	AGILON® PE-glenoid cemented	3	P 36259	4048844325831
38030040	AGILON® PE-glenoid cemented	4	P 36259	4048844325848
38020032	AGILON® glenoid implacross® E cemented	2	P 36259	4048844325626
38020036	AGILON® glenoid implacross® E cemented	3	P 36259	4048844325633
38020040	AGILON® glenoid implacross® E cemented	4	P 36259	4048844325640
38004060	Glenoid PE-inlay anatomical	small	P 35670	4048844229641
38004061	Glenoid PE-inlay anatomical	standard	P 35670	4048844229658
38031028	AGILON® glenoid PE-insert	2	P 35670	4048844325718
38031032	AGILON® glenoid PE-insert	3	P 35670	4048844326500

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Attachment IV

Reference number	item description	size	GMDN	GTIN
38031036	AGILON® glenoid PE-insert	4	P 35670	4048844325725
38021028	AGILON® glenoid PE-insert implacross® E	2	P 35670	4048844325503
38021032	AGILON® glenoid PE-insert implacross® E	3	P 35670	4048844325510
38021036	AGILON® glenoid PE-insert implacross® E	4	P 35670	4048844325527
38004025	AGILON® glenoid cementless round	1	P 48091	4048844324704
38004001	glenoid cementless round	3	P 48091	4048844028336
38004070	AGILON® glenoid baseplate round	1	P 48091	4048844347482
38004075	AGILON® glenoid baseplate round	3	P 48091	4048844347536
38004028	AGILON® glenoid cementless anatomical	2 short	P 48091	4048844324711
38004029	AGILON® glenoid cementless anatomical	2 long	P 48091	4048844324728
38004009	AGILON® glenoid cementless anatomical	3 short	P 48091	4048844230319
38004010	AGILON® glenoid cementless anatomical	3 long	P 48091	4048844276126
38004071	AGILON® glenoid baseplate cementless anatomical	2	P 48091	4048844347499
38004072	AGILON® glenoid baseplate cementless anatomical	long 2	P 48091	4048844347567
38004073	AGILON® glenoid baseplate cementless anatomical	3	P 48091	4048844347512
38004074	AGILON® glenoid baseplate cementless anatomical	long 3	P 48091	4048844347529
38004036	glenosphere	Ø36mm neutral	P 33711	4048844028367
38004040	glenosphere	Ø40mm eccentric	P 33711	4048844028374
38004044	glenosphere	Ø44mm eccentric	P 33711	4048844028381
38004236	PE-glenosphere	36mm neutral	P 48093	4048844244583
38004240	PE-glenosphere	40mm eccentric	P 48093	4048844244590

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Attachment V

Reference number	item description	size	GMDN	GTIN
38004244	PE-glenosphere	44mm eccentrical	P 48093	4048844244606
38032532	AGILON® PE-glenosphere	1 Ø32mm neutral	P 48093	4048844325732
38032536	AGILON® PE-glenosphere	1 Ø36mm eccentrical	P 48093	4048844325749
38032832	AGILON® PE-glenosphere	2 Ø32mm neutral	P 48093	4048844325756
38032836	AGILON® PE-glenosphere	2 Ø36mm eccentrical	P 48093	4048844325763
38032840	AGILON® PE-glenosphere	2 Ø40mm eccentrical	P 48093	4048844325770
38032844	AGILON® PE-glenosphere	2 Ø44mm eccentrical	P 48093	4048844325787
38033236	AGILON® PE-glenosphere	3 Ø36mm neutral	P 48093	4048844325794
38033240	AGILON® PE-glenosphere	3 Ø40mm eccentrical	P 48093	4048844325800
38033244	AGILON® PE-glenosphere	3 Ø44mm eccentrical	P 48093	4048844325817
38022532	AGILON® glenosphere implacross® E	1 Ø32mm neutral	P 48093	4048844325534
38022536	AGILON® glenosphere implacross® E	1 Ø36mm eccentrical	P 48093	4048844325541
38022832	AGILON® glenosphere implacross® E	2 Ø32mm neutral	P 48093	4048844325558
38022836	AGILON® glenosphere implacross® E	2 Ø36mm eccentrical	P 48093	4048844325565
38022840	AGILON® glenosphere implacross® E	2 Ø40mm eccentrical	P 48093	4048844325572
38022844	AGILON® glenosphere implacross® E	2 Ø44mm eccentrical	P 48093	4048844325589
38023236	AGILON® glenosphere implacross® E	3 Ø36mm neutral	P 48093	4048844325596
38023240	AGILON® glenosphere implacross® E	3 Ø40mm eccentrical	P 48093	4048844325602
38023244	AGILON® glenosphere implacross® E	3 Ø44mm eccentrical	P 48093	4048844325619
38200050	AGILON® extension piece	5mm	P 61006	4048844204006
38200075	AGILON® extension piece	7.5mm	P 61006	4048844204013
38200100	AGILON® extension piece	10mm	P 61006	4048844204020
38210075	AGILON® extension piece	7.5mm	P 61006	4048844330705
38210100	AGILON® extension piece	10mm	P 61006	4048844334840

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Attachment VI

Reference number	item description	size	GMDN	GTIN
38210125	AGILON® extension piece	12.5mm	P 61006	4048844330712
38210150	AGILON® extension piece	15mm	P 61006	4048844330729
38210175	AGILON® extension piece	17.5mm	P 61006	4048844330736
38200025	AGILON® screw	M6/25mm	P 48094	4048844204037
38200030	AGILON® screw	M6/30mm	P 48094	4048844204044
38200035	AGILON® screw	M6/35mm	P 48094	4048844204051
38200040	AGILON® screw	M6/40mm	P 48094	4048844204068
38210022	AGILON® screw	M6/22.5mm	P 48094	4048844330743
38210030	AGILON® screw	M6/30mm	P 48094	4048844330750
38210032	AGILON® screw	M6/32.5mm	P 48094	4048844330767
38210035	AGILON® screw	M6/35mm	P 48094	4048844330774
38210037	AGILON® screw	M6/37.5mm	P 48094	4048844330781
38210040	AGILON® screw	M6/40mm	P 48094	4048844330798
38206006	AGILON® stem cemented	Ø6/60mm	P 34197	4048844307677
38206008	AGILON® stem cemented	Ø8/60mm	P 34197	4048844307684
38206010	AGILON® stem cemented	Ø10/60mm	P 34197	4048844307691
38206012	AGILON® stem cemented	Ø12/60mm	P 34197	4048844307707
38209006	AGILON® stem cemented	Ø6/90mm	P 34197	4048844204174
38209008	AGILON® stem cemented	Ø8/90mm	P 34197	4048844204181
38209010	AGILON® stem cemented	Ø10/90mm	P 34197	4048844204198
38209012	AGILON® stem cemented	Ø12/90mm	P 34197	4048844204204
38212006	AGILON® stem cemented	Ø6/120mm	P 34197	4048844204211
38212008	AGILON® stem cemented	Ø8/120mm	P 34197	4048844204228
38212010	AGILON® stem cemented	Ø10/120mm	P 34197	4048844204235
38212012	AGILON® stem cemented	Ø12/120mm	P 34197	4048844204242

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Attachment VII

Reference number	item description	size	GMDN	GTIN
38406006	AGILON® stem cemented	Ø6/60mm	P 34197	4048844344436
38406008	AGILON® stem cemented	Ø8/60mm	P 34197	4048844330804
38406010	AGILON® stem cemented	Ø10/60mm	P 34197	4048844330811
38406012	AGILON® stem cemented	Ø12/60mm	P 34197	4048844330828
38409006	AGILON® stem cemented	Ø6/90mm	P 34197	4048844330835
38409008	AGILON® stem cemented	Ø8/90mm	P 34197	4048844330842
38409010	AGILON® stem cemented	Ø10/90mm	P 34197	4048844330859
38409012	AGILON® stem cemented	Ø12/90mm	P 34197	4048844330866
38412006	AGILON® stem cemented	Ø6/120mm	P 34197	4048844330873
38412008	AGILON® stem cemented	Ø8/120mm	P 34197	4048844330941
38412010	AGILON® stem cemented	Ø10/120mm	P 34197	4048844330958
38412012	AGILON® stem cemented	Ø12/120mm	P 34197	4048844330965
38206006N	AGILON® stem cemented TiN	Ø6/60mm	P 34197	4048844323714
38206008N	AGILON® stem cemented TiN	Ø8/60mm	P 34197	4048844323721
38206010N	AGILON® stem cemented TiN	Ø10/60mm	P 34197	4048844323738
38206012N	AGILON® stem cemented TiN	Ø12/60mm	P 34197	4048844323745
38209006N	AGILON® stem cemented TiN	Ø6/90mm	P 34197	4048844203917
38209008N	AGILON® stem cemented TiN	Ø8/90mm	P 34197	4048844203924
38209010N	AGILON® stem cemented TiN	Ø10/90mm	P 34197	4048844203931
38209012N	AGILON® stem cemented TiN	Ø12/90mm	P 34197	4048844203948
38212006N	AGILON® stem cemented TiN	Ø6/120mm	P 34197	4048844203955
38212008N	AGILON® stem cemented TiN	Ø8/120mm	P 34197	4048844203962
38212010N	AGILON® stem cemented TiN	Ø10/120mm	P 34197	4048844203979
38212012N	AGILON® stem cemented TiN	Ø12/120mm	P 34197	4048844203986
38406006N	AGILON® stem cemented TiN	Ø6/60mm	P 34197	4048844330972

EU Declaration of Conformity

Attachment VIII

Reference number	item description	size	GMDN	GTIN
38406008N	AGILON® stem cemented TiN	Ø8/60mm	P 34197	4048844330989
38406010N	AGILON® stem cemented TiN	Ø10/60mm	P 34197	4048844330996
38406012N	AGILON® stem cemented TiN	Ø12/60mm	P 34197	4048844331009
38409006N	AGILON® stem cemented TiN	Ø6/90mm	P 34197	4048844331016
38409008N	AGILON® stem cemented TiN	Ø8/90mm	P 34197	4048844331023
38409010N	AGILON® stem cemented TiN	Ø10/90mm	P 34197	4048844331030
38409012N	AGILON® stem cemented TiN	Ø12/90mm	P 34197	4048844331047
38412006N	AGILON® stem cemented TiN	Ø6/120mm	P 34197	4048844331054
38412008N	AGILON® stem cemented TiN	Ø8/120mm	P 34197	4048844331061
38412010N	AGILON® stem cemented TiN	Ø10/120mm	P 34197	4048844331078
38412012N	AGILON® stem cemented TiN	Ø12/120mm	P 34197	4048844331085
38303010	AGILON® stem cementless	Ø10/30mm	P 34197	4048844307592
38303011	AGILON® stem cementless	Ø11/30mm	P 34197	4048844307608
38303012	AGILON® stem cementless	Ø12/30mm	P 34197	4048844307615
38303013	AGILON® stem cementless	Ø13/30mm	P 34197	4048844307622
38303014	AGILON® stem cementless	Ø14/30mm	P 34197	4048844319762
38303015	AGILON® stem cementless	Ø15/30mm	P 34197	4048844307639
38303016	AGILON® stem cementless	Ø16/30mm	P 34197	4048844307646
38303017	AGILON® stem cementless	Ø17/30mm	P 34197	4048844307653
38303018	AGILON® stem cementless	Ø18/30mm	P 34197	4048844307660
38306010	AGILON® stem cementless	Ø10/60mm	P 34197	4048844203825
38306011	AGILON® stem cementless	Ø11/60mm	P 34197	4048844203832
38306012	AGILON® stem cementless	Ø12/60mm	P 34197	4048844203849
38306013	AGILON® stem cementless	Ø13/60mm	P 34197	4048844203856
38306014	AGILON® stem cementless	Ø14/60mm	P 34197	4048844203863
38306015	AGILON® stem cementless	Ø15/60mm	P 34197	4048844203870
38306016	AGILON® stem cementless	Ø16/60mm	P 34197	4048844203887

EU Declaration of Conformity

Attachment IX

Reference number	item description	size	GMDN	GTIN
38306017	AGILON® stem cementless	Ø17/60mm	P 34197	4048844203894
38306018	AGILON® stem cementless	Ø18/60mm	P 34197	4048844203900
38312010	AGILON® stem cementless	Ø10/120mm	P 34197	4048844204105
38312011	AGILON® stem cementless	Ø11/120mm	P 34197	4048844204112
38312012	AGILON® stem cementless	Ø12/120mm	P 34197	4048844204129
38312013	AGILON® stem cementless	Ø13/120mm	P 34197	4048844204136
38312014	AGILON® stem cementless	Ø14/120mm	P 34197	4048844204143
38312015	AGILON® stem cementless	Ø15/120mm	P 34197	4048844204150
38312016	AGILON® stem cementless	Ø16/120mm	P 34197	4048844204167
38318009	AGILON® stem cementless	Ø9/180mm	P 34197	4048844203733
38318010	AGILON® stem cementless	Ø10/180mm	P 34197	4048844203665
38318011	AGILON® stem cementless	Ø11/180mm	P 34197	4048844203672
38318012	AGILON® stem cementless	Ø12/180mm	P 34197	4048844203689
38318013	AGILON® stem cementless	Ø13/180mm	P 34197	4048844203696
38318014	AGILON® stem cementless	Ø14/180mm	P 34197	4048844203702
38318015	AGILON® stem cementless	Ø15/180mm	P 34197	4048844203719
38318016	AGILON® stem cementless	Ø16/180mm	P 34197	4048844203726
38324009	AGILON® stem cementless	Ø9/240mm	P 34197	4048844203818
38324010	AGILON® stem cementless	Ø10/240mm	P 34197	4048844203740
38324011	AGILON® stem cementless	Ø11/240mm	P 34197	4048844203757
38324012	AGILON® stem cementless	Ø12/240mm	P 34197	4048844203764
38324013	AGILON® stem cementless	Ø13/240mm	P 34197	4048844203771
38324014	AGILON® stem cementless	Ø14/240mm	P 34197	4048844203788
38324015	AGILON® stem cementless	Ø15/240mm	P 34197	4048844203795
38324016	AGILON® stem cementless	Ø16/240mm	P 34197	4048844203801
38503010	AGILON® stem cementless	Ø10/30mm	P 34197	4048844331092
38503011	AGILON® stem cementless	Ø11/30mm	P 34197	4048844331108

EU Declaration of Conformity

Attachment X

Reference number	item description	size	GMDN	GTIN
38503012	AGILON® stem cementless	Ø12/30mm	P 34197	4048844331115
38503013	AGILON® stem cementless	Ø13/30mm	P 34197	4048844331122
38503014	AGILON® stem cementless	Ø14/30mm	P 34197	4048844331139
38503015	AGILON® stem cementless	Ø15/30mm	P 34197	4048844331146
38503016	AGILON® stem cementless	Ø16/30mm	P 34197	4048844331153
38503017	AGILON® stem cementless	Ø17/30mm	P 34197	4048844331160
38503018	AGILON® stem cementless	Ø18/30mm	P 34197	4048844331177
38506009	AGILON® stem cementless	Ø9/60mm	P 34197	4048844331207
38506010	AGILON® stem cementless	Ø10/60mm	P 34197	4048844331214
38506011	AGILON® stem cementless	Ø11/60mm	P 34197	4048844331221
38506012	AGILON® stem cementless	Ø12/60mm	P 34197	4048844331238
38506013	AGILON® stem cementless	Ø13/60mm	P 34197	4048844331245
38506014	AGILON® stem cementless	Ø14/60mm	P 34197	4048844331252
38506015	AGILON® stem cementless	Ø15/60mm	P 34197	4048844331269
38506016	AGILON® stem cementless	Ø16/60mm	P 34197	4048844331276
38506017	AGILON® stem cementless	Ø17/60mm	P 34197	4048844331283
38506018	AGILON® stem cementless	Ø18/60mm	P 34197	4048844331290
38512009	AGILON® stem cementless	Ø9/120mm	P 34197	4048844331320
38512010	AGILON® stem cementless	Ø10/120mm	P 34197	4048844331337
38512011	AGILON® stem cementless	Ø11/120mm	P 34197	4048844331344
38512012	AGILON® stem cementless	Ø12/120mm	P 34197	4048844331351
38512013	AGILON® stem cementless	Ø13/120mm	P 34197	4048844331368
38512014	AGILON® stem cementless	Ø14/120mm	P 34197	4048844331375
38512015	AGILON® stem cementless	Ø15/120mm	P 34197	4048844331382
38512016	AGILON® stem cementless	Ø16/120mm	P 34197	4048844331399
38518009	AGILON® stem cementless	Ø9/180mm	P 34197	4048844331429
38518010	AGILON® stem cementless	Ø10/180mm	P 34197	4048844331436
38518011	AGILON® stem cementless	Ø11/180mm	P 34197	4048844331443

EU Declaration of Conformity

Attachment XI

Reference number	item description	size	GMDN	GTIN
38518012	AGILON® stem cementless	Ø12/180mm	P 34197	4048844331450
38518013	AGILON® stem cementless	Ø13/180mm	P 34197	4048844331467
38518014	AGILON® stem cementless	Ø14/180mm	P 34197	4048844331474
38518015	AGILON® stem cementless	Ø15/180mm	P 34197	4048844331481
38518016	AGILON® stem cementless	Ø16/180mm	P 34197	4048844331498
38524009	AGILON® stem cementless	Ø9/240mm	P 34197	4048844331528
38524010	AGILON® stem cementless	Ø10/240mm	P 34197	4048844331535
38524011	AGILON® stem cementless	Ø11/240mm	P 34197	4048844331542
38524012	AGILON® stem cementless	Ø12/240mm	P 34197	4048844331559
38524013	AGILON® stem cementless	Ø13/240mm	P 34197	4048844331566
38524014	AGILON® stem cementless	Ø14/240mm	P 34197	4048844331573
38524015	AGILON® stem cementless	Ø15/240mm	P 34197	4048844331580
38524016	AGILON® stem cementless	Ø16/240mm	P 34197	4048844331597
38200101	safety screw	M10/1 SW5	P 63998	4048844204099
38206001	AGILON® MI cementless	1	P 58951	4048844243319
38206002	AGILON® MI cementless	2	P 58951	4048844243326
38206003	AGILON® MI cementless	3	P 58951	4048844243333
38206004	AGILON® MI cementless	4	P 58951	4048844243340
38206005	AGILON® MI cementless	5	P 58951	4048844243357

End of schedule. No additional information past this point.

EC Certificate of Conformity

The Notified Body

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

herewith certifies that the company:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

with locations listed in the appendix

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

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

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

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

Effective date: 2020-12-01

Expiry date: 2024-05-27

Report No.: 7092FS12F

Process No.: QS – 7092

Certificate No.: 7092GB410201201A

Hamburg, 2020-12-01



MEDCERT Certification Body
(Lorenz Runge)

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Appendix of EC Certificate of Conformity

Process No.: QS – 7092

Certificate No.: 7092GB410201201A

List of locations included in the scope of certificate

**Alter Postweg 10b
21614 Buxtehude
Germany**

– End of list –

This appendix is integral part of the above-referenced certificate.
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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 –

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EC Design Examination Certificate

The Notified Body

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

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

Shoulder Implants
AGILON®

with specifications listed in the appendix

of the manufacturer:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

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

Annex II, section 4

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

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

Effective date: 2020-05-29

Expiry date: 2022-08-29

Report No.: 13261PS11F

Process No.: PP – 13261

Certificate No.: 13261GB411200529

Hamburg, 2020-05-29


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MEDCERT Identification Number: 0482



Appendix of EC Design Examination Certificate

Process No.: PP – 13261

Certificate No.: 13261GB411200529

Specifications

AGILON® metaphyseal component trauma incl. safety screw						
38200001	38210001	38210011	—	—	—	—

AGILON® metaphyseal component primary incl. safety screw						
38200002	38200003	—	—	—	—	—

AGILON® metaphyseal component omarthrosis incl. safety screw						
38210002	38210003	38210012	38210013	—	—	—

AGILON® MI cementless						
38206001	38206002	38206003	38206004	38206005	—	—

AGILON® cap						
38004114	38004117	38004120	38004414	38004417	38004420	38004714
38004717	38004720	38005014	38005017	38005020	38005314	38005317
38005320	—	—	—	—	—	—

AGILON® retentive cap inverse						
38015200	38015205	38015210	38015600	38015605	38015610	38016000
38016005	38016010	38016400	38016405	38016410	—	—

AGILON® CTA cap						
38224414	38224417	38224420	38224714	38224717	38224720	38225014
38225017	38225020	38225314	38225317	38225320	—	—

Glenoid cemented						
38004005	38004006	—	—	—	—	—

AGILON® PE-glenoid cemented						
38030032	38030036	38030040	—	—	—	—

AGILON® PE-glenoid implacross® E cemented						
38020032	38020036	38020040	—	—	—	—

AGILON® cap inverse						
38013200	38013205	38013210	38013600	38013605	38013610	38014000
38014005	38014010	38014400	38014405	38014410	—	—

AGILON® glenoid cementless round						
38004025	—	—	—	—	—	—

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Appendix of EC Design Examination Certificate

Process No.: PP – 13261

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glenoid cementless round						
38004001	—	—	—	—	—	—

AGILON® glenoid baseplate round						
38004070	38004075	—	—	—	—	—

AGILON® glenoid cementless anatomical						
38004028	38004029	38004009	38004010	—	—	—

AGILON® glenoid baseplate cementless anatomical						
38004071	38004072	38004073	38004074	—	—	—

Glenoid PE-inlay anatomical						
38004060	38004061	—	—	—	—	—

AGILON® glenoid PE-insert						
38031028	38031032	38031036	—	—	—	—

AGILON® glenoid PE-insert implacross® E						
38021028	38021032	38021036	—	—	—	—

glenosphere						
38004036	38004040	38004044	—	—	—	—

AGILON® PE-glenosphere						
38032532	38032536	38032832	38032836	38032840	38032844	38033236
38033240	38033244	—	—	—	—	—

AGILON® PE-glenosphere implacross® E						
38022532	38022536	38022832	38022836	38022840	38022844	38023236
38023240	38023244	—	—	—	—	—

PE-glenosphere						
38004236	38004240	38004244	—	—	—	—

AGILON® extension piece						
38200050	38200075	38200100	38210075	38210100	38210125	38210150
38210175	—	—	—	—	—	—

AGILON® screw						
38200025	38200030	38200035	38200040	38210022	38210030	38210032
38210035	38210037	38210040	—	—	—	—

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Appendix of EC Design Examination Certificate

Process No.: PP – 13261

Certificate No.: 13261GB411200529

safety screw						
38200101	—	—	—	—	—	—

AGILON® stem cemented						
38206006	38206008	38206010	38206012	38209006	38209008	38209010
38209012	38212006	38212008	38212010	38212012	38406006	38406008
38406010	38406012	38409006	38409008	38409010	38409012	38412006
38412008	38412010	38412012	—	—	—	—

AGILON® stem cemented TiN					
38206006N	38206008N	38206010N	38206012N	38209006N	38209008N
38209010N	38209012N	38212006N	38212008N	38212010N	38212012N
38406006N	38406008N	38406010N	38406012N	38409006N	38409008N
38409010N	38409012N	38412006N	38412008N	38412010N	38412012N

AGILON® stem cementless						
38503010	38503011	38503012	38503013	38503014	38503015	38503016
38503017	38503018	38506009	38506010	38506011	38506012	38506013
38506014	38506015	38506016	38506017	38506018	38512009	38512010
38512011	38512012	38512013	38512014	38512015	38512016	38518009
38518010	38518011	38518012	38518013	38518014	38518015	38518016
38524009	38524010	38524011	38524012	38524013	38524014	38524015
38524016	38303010	38303011	38303012	38303013	38303014	38303015
38303016	38303017	38303018	38306010	38306011	38306012	38306013
38306014	38306015	38306016	38306017	38306018	38318009	38318010
38318011	38318012	38318013	38318014	38318015	38318016	38312010
38312011	38312012	38312013	38312014	38312015	38312016	38324009
38324010	38324011	38324012	38324013	38324014	38324015	38324016

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