

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 2 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,
solicită înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor
categorii și tipuri de dispozitive medicale pentru introducerea și punerea la
dispoziție pe piață a:

- 1 Proteze pentru articulații:
 - MUTARS® Humerus System

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de imputernicire

Data 04/12/2023

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	<i>Accept</i>
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	<i>Nr. 8197 din 04.12.2023</i>
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	<i>Carlat Marina Georg</i>
Semnătura persoanei responsabile	<i>Carlat</i>

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
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Facilities implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

implantcast GmbH
Alter Postweg 10b
21614 Buxtehude
Germany

SRN DE-MF-000010002

Medical Device(s): **MUTARS® Humerus System**

Intended Use: The MUTARS® Humerus System is the humerus portion of the overall MUTARS® System. It is a modular shoulder and elbow replacement system offering various components that can be combined to replace the shoulder or elbow joint and address major bone defects.

details see Attachment I – XXI

REF Number(s): see Attachment I – XXI

Classification: Class III
(Regulation (EU) 2017/745 on medical devices Annex VIII Chapter III rule 8)

Common Specification Not applicable

MDN code(s) and term(s):
MDN 1102 Non-active osteo- and orthopaedic implants

GMDN code(s) and term(s):

P 16082	Bone cap
P 33711	Reverse shoulder prosthesis
P 34197	Uncoated shoulder humeral stem
P 35670	Total shoulder prosthesis
P 36259	Shoulder glenoid fossa prosthesis
P 39702	Coated shoulder humeral stem prosthesis
P 40124	Hinged total elbow prosthesis
P 48088	Humeral head prosthesis
P 48090	Press-fit shoulder humeral stem prosthesis
P 48094	Shoulder prosthesis screw
P 60512	Shoulder humeral body prosthesis
P 61006	Humeral stem extension prosthesis
P 63998	Implantable orthopaedic fixation device connection screw

EMDN code(s) and term(s):

P09010301	Shoulder Prosthesis and Metaglene Metal Back
P09010303	Glenospheres
P09010304	Monoblock Glenoids
P090104	Shoulder Prostheses Humeral Components
P090104010101	Epiphysary Humeral Components for Anatomical Prostheses - Humeral Heads
P090104010202	Epiphysary Humeral Components for Reverse Prostheses - Humeral Cups
P09010402	Diaphysary Humeral Components
P0901040299	Diaphysary Humeral Components - Other
P090180	Shoulder Prostheses - Accessories
P09018001	Shoulder Prostheses Fixing Screws
P090203	Elbow Prostheses Humeral Components
P090205	Elbow Prostheses Ulnar Components
P090280	Elbow Prostheses - Accessories
P090299	Elbow Prostheses - Other

We declare under our sole responsibility that the medical devices listed in the attachment(s) are in conformity with the general safety and performance requirements of Annex I of Regulation (EU) 2017/745 on medical devices and have undergone the conformity assessment procedure according to Annex IX of Regulation (EU) 2017/745 on medical devices.

Notified Body:

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

**EU Quality Management
System Certificate**

Effective date
Expiry date

Regulation (EU) 2017/745 on medical devices Annex IX Chapter I
Certificate No.: 7092GB448221006
2022-10-06
2026-01-02

**EU Technical Documentation
Assessment Certificate**

Effective date
Expiry date

Regulation (EU) 2017/745 on medical devices Annex IX Chapter II
Certificate No.: 13266GB450221104
2022-11-04
2027-11-03

Identification:

CE 0482



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

Buxtehude, 2022-11-07
Place, date

i.V. Juliane Höppner
Head of Regulatory & Clinical & Biological Affairs

This attachment is integral part of the declaration.
The declaration is only valid when provided entirely with all of its pages.

Basis-UDI-DI 4048844MUTHUAXLD2UNCNM
Intended use Axle intended to serve as a connection between the ulnar component and the MUTARS® Distal Humerus.
GMDN P 40124
EMDN P090280

Reference number	item description	size	UDI-DI
52510001	MUTARS® axle for dist. Humerus HD	/	04048844516949

End of schedule

Basis-UDI-DI 4048844MUTHUAXLDTINBN65
Intended use Axle intended to serve as a connection between the ulnar component and the MUTARS® Distal Humerus.
GMDN P 40124
EMDN P090280

Reference number	item description	size	UDI-DI
52500001N	MUTARS® axle for dist. humerus TiNbN	/	04048844143176

End of schedule

Basis-UDI-DI 4048844MUTHUAXLDUNCMG
Intended use Axle intended to serve as a connection between the ulnar component and the MUTARS® Distal Humerus.
GMDN P 40124
EMDN P090280

Reference number	item description	size	UDI-DI
52500001	MUTARS® axle for dist. humerus	/	04048844044947

End of schedule

EU Declaration of Conformity

Attachment II

This attachment is integral part of the declaration.
The declaration is only valid when provided entirely with all of its pages.

Basis-UDI-DI 4048844MUTHUCAPITINFQ

Intended use Cap that is combined with the MUTARS® Humerus Head intended to replace the humeral head in case of a reverse shoulder prosthesis.

GMDN P 33711

EMDN P090104010202

Reference number	item description	size	UDI-DI
52101000	MUTARS® humerus cap invers TiN	/	04048844044503
52101005	MUTARS® humerus cap invers TiN	+5 mm	04048844148010
52101010	MUTARS® humerus cap invers TiN	+10 mm	04048844148027

End of schedule

Basis-UDI-DI 4048844MUTHUCAPTINFZ

Intended use Cap that is combined with the MUTARS® Humerus Head intended to replace the humeral head.

GMDN P 48088

EMDN P090104010101

Reference number	item description	size	UDI-DI
52100000	MUTARS® humerus cap TiN	small	04048844044473
52100005	MUTARS® humerus cap TiN	medium	04048844044480
52100010	MUTARS® humerus cap TiN	large	04048844044497

End of schedule

Basis-UDI-DI 4048844MUTHUCOLFTCPJX
Intended use Modular stem collar for the MUTARS® Humerus Stem Type A Modular intended to enable bone ingrowth.
GMDN P39702
EMDN P0901040299

Reference number	item description	size	UDI-DI
52420018	MUTARS® EPORE® HA collar humerus with flange	18mm	04048844518653
52420019	MUTARS® EPORE® HA collar humerus with flange	19mm	04048844518660
52420020	MUTARS® EPORE® HA collar humerus with flange	20mm	04048844518677
52420021	MUTARS® EPORE® HA collar humerus with flange	21mm	04048844518684
52420022	MUTARS® EPORE® HA collar humerus with flange	22mm	04048844518691
52420023	MUTARS® EPORE® HA collar humerus with flange	23mm	04048844518707
52420024	MUTARS® EPORE® HA collar humerus with flange	24mm	04048844518714

End of schedule

Basis-UDI-DI 4048844MUTHUCOLTCPKH
Intended use Modular stem collar for the MUTARS® Humerus Stem Type A Modular intended to enable bone ingrowth.
GMDN P 39702
EMDN P0901040299

Reference number	item description	size	UDI-DI
52410018	MUTARS® EPORE® HA collar humerus	18mm	04048844518592
52410019	MUTARS® EPORE® HA collar humerus	19mm	04048844597122
52410020	MUTARS® EPORE® HA collar humerus	20mm	04048844518608
52410021	MUTARS® EPORE® HA collar humerus	21mm	04048844518615
52410022	MUTARS® EPORE® HA collar humerus	22mm	04048844518622
52410023	MUTARS® EPORE® HA collar humerus	23mm	04048844518639
52410024	MUTARS® EPORE® HA collar humerus	24mm	04048844518646

End of schedule

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Basis-UDI-DI 4048844MUTHUCONPUNCN7
Intended use Humerus Connecting Part intended for extraosseous length adjustment in the area of the proximal and distal humerus for the bridging of bone defects in cases where a proximal or distal humerus replacement component is used. The MUTARS® Humerus Connection Part may also be used when a total humerus replacement, total elbow replacement or proximal ulna replacement is required.
GMDN P 61006
EMDN P090104

Reference number	item description	size	UDI-DI
5221008001	MUTARS® humerus connecting part distal	80 mm	04048844125301
5221008002	MUTARS® humerus connecting part prox.	80 mm	04048844125325

End of schedule

Basis-UDI-DI 4048844MUTHUDH230UNCXQ
Intended use Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement or proximal ulna replacement.
GMDN P 40124
EMDN P090203

Reference number	item description	size	UDI-DI
5251230001	MUTARS® dist. humerus HD	30mm	04048844516925

End of schedule

Basis-UDI-DI 4048844MUTHUDH250UNCYE
Intended use Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement, total elbow replacement or total humerus replacement.
GMDN P 40124
EMDN P090203

Reference number	item description	size	UDI-DI
5251000001	MUTARS® dist. humerus HD	50mm	04048844516895

End of schedule

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Basis-UDI-DI 4048844MUTHUDH30UNC46
Intended use Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement or proximal ulna replacement.
GMDN P 40124
EMDN P090203

Reference number	item description	size	UDI-DI
5250230001	MUTARS® dist. humerus part 1	M6 30mm	04048844409470

End of schedule

Basis-UDI-DI 4048844MUTHUDH50TINBNA
Intended use Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement, total elbow replacement or total humerus replacement.
GMDN P 40124
EMDN P090203

Reference number	item description	size	UDI-DI
5250000000N	MUTARS® dist. humerus TiNbN	50 mm	04048844606053

End of schedule

Basis-UDI-DI 4048844MUTHUDH50UNC4U
Intended use Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement, total elbow replacement or total humerus replacement.
GMDN P 40124
EMDN P090203

Reference number	item description	size	UDI-DI
5250000000	MUTARS® dist. humerus	50 mm	04048844606039

End of schedule

Basis-UDI-DI 4048844MUTHUENDPUNCKE
Intended use Humerus End Piece used in rare cases of bone tumors and bone metastases in which no full extremity preserving surgery can be carried out. The end piece can serve to prosthetically preserve a terminal humeral or ulnar stump in cases of a part or total humerus replacement, total elbow replacement or proximal ulna replacement.
GMDN P 16082
EMDN P090104

Reference number	item description	size	UDI-DI
52200001	MUTARS® humerus end piece	20 mm	04048844044541

End of schedule

Basis-UDI-DI 4048844MTHUEXTPUNCUY
Intended use Humerus Extension Piece intended for extraosseous length adjustment in the area of the proximal and distal humerus for the bridging of bone defects in cases where a proximal or distal humerus replacement component is used. The extension piece may also be used when a total humerus replacement, total elbow replacement or proximal ulna replacement component is required.
GMDN P 61006
EMDN P090104

Reference number	item description	size	UDI-DI
52200020	MUTARS® humerus extension piece	20 mm	04048844044558
52200040	MUTARS® humerus extension piece	40 mm	04048844044565
52200060	MUTARS® humerus extension piece	60 mm	04048844044572

End of schedule

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Basis-UDI-DI 4048844MUTHUGLENUNCKK
Intended use Glenosphere intended to replace the glenoid surface in case of a reverse total shoulder replacement.
GMDN P 33711
EMDN P09010303

Reference number	item description	size	UDI-DI
52101002	MUTARS® glenosphere	40mm symmetric	04048844044527

End of schedule

Basis-UDI-DI 4048844MUTHUGLRHACKL5
Intended use Glenoid component intended for cementless fixation to replace the natural glenoid by combination with the MUTARS® Glenosphere for a reverse MUTARS® Humerus replacement.
GMDN P 36259
EMDN P09010301

Reference number	item description	size	UDI-DI
38004001	glenoid cementless round	3	04048844028336

End of schedule

Basis-UDI-DI 4048844MUTHUGLUNCCDMA
Intended use Glenoid component for cemented fixation intended to replace the natural glenoid.
GMDN P 36259
EMDN P09010304

Reference number	item description	size	UDI-DI
38030032	AGILON® PE-glenoid cemented	2	04048844325824
38030036	AGILON® PE-glenoid cemented	3	04048844325831
38030040	AGILON® PE-glenoid cemented	4	04048844325848

End of schedule

Basis-UDI-DI 4048844MUTHUHEADUNCDP
Intended use Component that is combined with the MUTARS® Humerus Cap or MUTARS® Humerus Cap Inverse intended to replace the proximal part of the humerus or the total humerus.
GMDN P 60512
EMDN P090104

Reference number	item description	size	UDI-DI
5200000000	MUTARS® humerus head	50 mm	04048844605087

End of schedule

Basis-UDI-DI 4048844MUTHUHSSUNCQT
Intended use Screw intended to secure the MUTARS® Humerus Screw.
GMDN P 63998
EMDN P090180

Reference number	item description	size	UDI-DI
52000099	MUTARS® humerus safety screw	/	04048844044459

End of schedule

Basis-UDI-DI 4048844MUTHUHSUNCU6
Intended use Screw intended to join components of the MUTARS® Humerus System.
GMDN P 48094
EMDN P09018001

Reference number	item description	size	UDI-DI
52300015	MUTARS® humerus screw	M 8x15 mm	04048844044626
52300035	MUTARS® humerus screw	M 8x35 mm	04048844044633
52300055	MUTARS® humerus screw	M 8x55 mm	04048844044640
52300075	MUTARS® humerus screw	M 8x75 mm	04048844044657

End of schedule

Basis-UDI-DI 4048844MUTHULSDUNCP6
Intended use Screw intended to secure the MUTARS® Axle.
GMDN P 63998
EMDN P090280

Reference number	item description	size	UDI-DI
52500003	MUTARS® locking screw for dist. humerus	/	04048844044961

End of schedule

Basis-UDI-DI 4048844MUTHUPEFCSTDKR
Intended use PE Bearing intended to be used in combination with the MUTARS® Distal Humerus HD 30mm or 50mm to act as one of the bearing surfaces of the hinged elbow system besides the MUTARS® Ulnar Component HD or MUTARS® Proximal Ulna HD.
GMDN P 40124
EMDN P090299

Reference number	item description	size	UDI-DI
52510002	PE bearing FC	/	04048844516956

End of schedule

Basis-UDI-DI 4048844MUTHUPESCSTDQ8
Intended use PE Bearing intended to be used in combination with the MUTARS® Distal Humerus HD 30mm or 50mm to act as one of the bearing surfaces of the hinged elbow system besides the MUTARS® Ulnar Component HD or MUTARS® Proximal Ulna HD.
GMDN P 40124
EMDN P090299

Reference number	item description	size	UDI-DI
52510003	PE bearing SC	/	04048844516970

End of schedule

Basis-UDI-DI 4048844MUTHUREDUNCLS
Intended use Humerus Reducer intended for extraosseous length adjustment in cases of a total humerus replacement to enable a connection between the MUTARS® Humerus Head and the Distal Humerus.
GMDN P 61006
EMDN P090104

Reference number	item description	size	UDI-DI
52210000	MUTARS® humerus reducer	10 mm	04048844044589
52210100	MUTARS® humerus reducer	100 mm	04048844044619

End of schedule

Basis-UDI-DI 4048844MUTHUSCONPUNCZ6
Intended use Screw intended to connect the MUTARS® Humerus Connecting Part Proximal to the MUTARS® Humerus Connecting Part Distal.
GMDN P 48094
EMDN P09018001

Reference number	item description	size	UDI-DI
52210099	MUTARS® humerus screw for connecting part	/	04048844044602

End of schedule

Basis-UDI-DI 4048844MUTHUSDSW5UNCYQ
Intended use Screw intended to join components of the MUTARS® Distal Humerus.
GMDN P 63998
EMDN P090280

Reference number	item description	size	UDI-DI
52300125	MUTARS® screw for dist. Humerus	M6x12.5mm, SW5	04048844348687
52300200	MUTARS® screw for dist. Humerus	M6x20mm, SW5	04048844348694
52300225	MUTARS® screw for dist. Humerus	M6x22.5mm, SW5	04048844348700
52300250	MUTARS® screw for dist. Humerus	M6x25mm, SW5	04048844348717
52300275	MUTARS® screw for dist. Humerus	M6x27.5mm, SW5	04048844348724
52300300	MUTARS® screw for dist. Humerus	M6x30mm, SW5	04048844348731

End of schedule

Basis-UDI-DI 4048844MUTHUSSD30UNCMG
Intended use Screw intended to secure the MUTARS® Screw for Distal Humerus.
GMDN P 63998
EMDN P090280

Reference number	item description	size	UDI-DI
52000097	MUTARS® safety screw for distal humerus	30mm SW5	04048844348748

End of schedule

Basis-UDI-DI 4048844MUTHUSTAMTINCDDY
Intended use Stem for cemented fixation intended to be used in combination with the MUTARS® EPORE® HA Collar Humerus for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
GMDN P 39702
EMDN P09010402

Reference number	item description	size	UDI-DI
52440708N	MUTARS® humerus stem type A modular cemented TiN	8/75mm	04048844579593
52440709N	MUTARS® humerus stem type A modular cemented TiN	9/75mm	04048844579609
52440710N	MUTARS® humerus stem type A modular cemented TiN	10/75mm	04048844579616
52440711N	MUTARS® humerus stem type A modular cemented TiN	11/75mm	04048844579623
52440712N	MUTARS® humerus stem type A modular cemented TiN	12/75mm	04048844579630
52440713N	MUTARS® humerus stem type A modular cemented TiN	13/75mm	04048844579647
52440714N	MUTARS® humerus stem type A modular cemented TiN	14/75mm	04048844579654
52440715N	MUTARS® humerus stem type A modular cemented TiN	15/75mm	04048844579661
52440716N	MUTARS® humerus stem type A modular cemented TiN	16/75mm	04048844579678
52441008N	MUTARS® humerus stem type A modular cemented TiN	8/100mm	04048844579685
52441009N	MUTARS® humerus stem type A modular cemented TiN	9/100mm	04048844579692
52441010N	MUTARS® humerus stem type A modular cemented TiN	10/100mm	04048844579708
52441011N	MUTARS® humerus stem type A modular cemented TiN	11/100mm	04048844579715
52441012N	MUTARS® humerus stem type A modular cemented TiN	12/100mm	04048844579722
52441013N	MUTARS® humerus stem type A modular cemented TiN	13/100mm	04048844579739
52441014N	MUTARS® humerus stem type A modular cemented TiN	14/100mm	04048844579746
52441015N	MUTARS® humerus stem type A modular cemented TiN	15/100mm	04048844579753
52441016N	MUTARS® humerus stem type A modular cemented TiN	16/100mm	04048844579760
52441508N	MUTARS® humerus stem type A modular cemented TiN	8/150mm	04048844579777
52441509N	MUTARS® humerus stem type A modular cemented TiN	9/150mm	04048844579784
52441510N	MUTARS® humerus stem type A modular cemented TiN	10/150mm	04048844579791
52441511N	MUTARS® humerus stem type A modular cemented TiN	11/150mm	04048844579807
52441512N	MUTARS® humerus stem type A modular cemented TiN	12/150mm	04048844579814
52441513N	MUTARS® humerus stem type A modular cemented TiN	13/150mm	04048844579821
52441514N	MUTARS® humerus stem type A modular cemented TiN	14/150mm	04048844579838
52441515N	MUTARS® humerus stem type A modular cemented TiN	15/150mm	04048844579845
52441516N	MUTARS® humerus stem type A modular cemented TiN	16/150mm	04048844579852

End of schedule

Basis-UDI-DI 4048844MUTHUSTAMUNCCDDP
Intended use Stem for cemented fixation intended to be used in combination with the MUTARS® EPORE® HA Collar Humerus for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
GMDN P 34197
EMDN P09010402

Reference number	item description	size	UDI-DI
52440708	MUTARS® humerus stem type A modular cemented	8/75mm	04048844517205
52440709	MUTARS® humerus stem type A modular cemented	9/75mm	04048844517212
52440710	MUTARS® humerus stem type A modular cemented	10/75mm	04048844517229
52440711	MUTARS® humerus stem type A modular cemented	11/75mm	04048844517236
52440712	MUTARS® humerus stem type A modular cemented	12/75mm	04048844517243
52440713	MUTARS® humerus stem type A modular cemented	13/75mm	04048844578350
52440714	MUTARS® humerus stem type A modular cemented	14/75mm	04048844578374
52440715	MUTARS® humerus stem type A modular cemented	15/75mm	04048844578381
52440716	MUTARS® humerus stem type A modular cemented	16/75mm	04048844578398
52441008	MUTARS® humerus stem type A modular cemented	8/100mm	04048844517250
52441009	MUTARS® humerus stem type A modular cemented	9/100mm	04048844517267
52441010	MUTARS® humerus stem type A modular cemented	10/100mm	04048844517274
52441011	MUTARS® humerus stem type A modular cemented	11/100mm	04048844517281
52441012	MUTARS® humerus stem type A modular cemented	12/100mm	04048844517298
52441013	MUTARS® humerus stem type A modular cemented	13/100mm	04048844578442
52441014	MUTARS® humerus stem type A modular cemented	14/100mm	04048844578459
52441015	MUTARS® humerus stem type A modular cemented	15/100mm	04048844578466
52441016	MUTARS® humerus stem type A modular cemented	16/100mm	04048844578473
52441508	MUTARS® humerus stem type A modular cemented	8/150mm	04048844517304
52441509	MUTARS® humerus stem type A modular cemented	9/150mm	04048844517311
52441510	MUTARS® humerus stem type A modular cemented	10/150mm	04048844517328
52441511	MUTARS® humerus stem type A modular cemented	11/150mm	04048844517335
52441512	MUTARS® humerus stem type A modular cemented	12/150mm	04048844517342
52441513	MUTARS® humerus stem type A modular cemented	13/150mm	04048844578480
52441514	MUTARS® humerus stem type A modular cemented	14/150mm	04048844578497
52441515	MUTARS® humerus stem type A modular cemented	15/150mm	04048844578503
52441516	MUTARS® humerus stem type A modular cemented	16/150mm	04048844578510

End of schedule

Basis-UDI-DI 4048844MUTHUSTAMUNCCL7
Intended use Stem for cementless fixation intended to be used in combination with the MUTARS® EPORE® HA Collar Humerus for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
GMDN P 48090
EMDN P09010402

Reference number	item description	size	UDI-DI
52470707	MUTARS® humerus stem type A modular cementless	7/75mm	04048844517809
52470708	MUTARS® humerus stem type A modular cementless	8/75mm	04048844517816
52470709	MUTARS® humerus stem type A modular cementless	9/75mm	04048844517823
52470710	MUTARS® humerus stem type A modular cementless	10/75mm	04048844517830
52470711	MUTARS® humerus stem type A modular cementless	11/75mm	04048844517847
52470712	MUTARS® humerus stem type A modular cementless	12/75mm	04048844517854
52470713	MUTARS® humerus stem type A modular cementless	13/75mm	04048844517861
52470714	MUTARS® humerus stem type A modular cementless	14/75mm	04048844517878
52470715	MUTARS® humerus stem type A modular cementless	15/75mm	04048844517885
52470716	MUTARS® humerus stem type A modular cementless	16/75mm	04048844517892
52471007	MUTARS® humerus stem type A modular cementless	7/100mm	04048844517908
52471008	MUTARS® humerus stem type A modular cementless	8/100mm	04048844517915
52471009	MUTARS® humerus stem type A modular cementless	9/100mm	04048844517922
52471010	MUTARS® humerus stem type A modular cementless	10/100mm	04048844517939
52471011	MUTARS® humerus stem type A modular cementless	11/100mm	04048844517946
52471012	MUTARS® humerus stem type A modular cementless	12/100mm	04048844517953
52471013	MUTARS® humerus stem type A modular cementless	13/100mm	04048844517960
52471014	MUTARS® humerus stem type A modular cementless	14/100mm	04048844517977
52471015	MUTARS® humerus stem type A modular cementless	15/100mm	04048844517984
52471016	MUTARS® humerus stem type A modular cementless	16/100mm	04048844517991
52471507	MUTARS® humerus stem type A modular cementless	7/150mm	04048844518004
52471508	MUTARS® humerus stem type A modular cementless	8/150mm	04048844518011
52471509	MUTARS® humerus stem type A modular cementless	9/150mm	04048844518028
52471510	MUTARS® humerus stem type A modular cementless	10/150mm	04048844518035
52471511	MUTARS® humerus stem type A modular cementless	11/150mm	04048844518042
52471512	MUTARS® humerus stem type A modular cementless	12/150mm	04048844518059
52471513	MUTARS® humerus stem type A modular cementless	13/150mm	04048844518066
52471514	MUTARS® humerus stem type A modular cementless	14/150mm	04048844518073
52471515	MUTARS® humerus stem type A modular cementless	15/150mm	04048844518080
52471516	MUTARS® humerus stem type A modular cementless	16/150mm	04048844518097

End of schedule

Basis-UDI-DI 4048844MUTHUSTHACDP5
Intended use Stem for cemented fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
GMDN P 39702
EMDN P09010402

Reference number	item description	size	UDI-DI
52490408	MUTARS® humerus stem cemented with HA collar	8/75 mm	04048844194819
52490409	MUTARS® humerus stem cemented with HA collar	9/75 mm	04048844194826
52490410	MUTARS® humerus stem cemented with HA collar	10/75 mm	04048844194833
52490411	MUTARS® humerus stem cemented with HA collar	11/75 mm	04048844194840
52490412	MUTARS® humerus stem cemented with HA collar	12/75 mm	04048844194857

End of schedule

Basis-UDI-DI 4048844MUTHUSTHACLPM
Intended use Stem for cementless fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
GMDN P 48090
EMDN P09010402

Reference number	item description	size	UDI-DI
52400807	MUTARS® humerus stem cementless HA	7/75 mm	04048844104122
52400808	MUTARS® humerus stem cementless HA	8/75 mm	04048844104139
52400809	MUTARS® humerus stem cementless HA	9/75 mm	04048844044848
52400810	MUTARS® humerus stem cementless HA	10/75 mm	04048844044855
52400811	MUTARS® humerus stem cementless HA	11/75 mm	04048844044862
52400812	MUTARS® humerus stem cementless HA	12/75 mm	04048844044879
52400813	MUTARS® humerus stem cementless HA	13/75 mm	04048844044886
52400814	MUTARS® humerus stem cementless HA	14/75 mm	04048844044893
52400815	MUTARS® humerus stem cementless HA	15/75 mm	04048844044909
52400816	MUTARS® humerus stem cementless HA	16/75 mm	04048844044916
52400817	MUTARS® humerus stem cementless HA	17/75 mm	04048844044923

End of schedule

EU Declaration of Conformity

Attachment XV

This attachment is integral part of the declaration.
The declaration is only valid when provided entirely with all of its pages.

Basis-UDI-DI 4048844MUTHUSTOP2UNC4M
Intended use Ulna Stop HD intended to be used in combination with the MUTARS® Distal Humerus HD 30mm and 50mm in order to prevent hyperextension of the elbow joint.
GMDN P 40124
EMDN P090299

Reference number	item description	size	UDI-DI
52511100	MUTARS® ulna stop HD	/	04048844516932

End of schedule

Basis-UDI-DI 4048844MUTHUSTOPUNCZ3
Intended use Ulna Stop intended to be used in combination with the MUTARS® Distal Humerus 30mm and 50mm in order to prevent hyperextension of the elbow joint.
GMDN P 40124
EMDN P090299

Reference number	item description	size	UDI-DI
52501100	MUTARS® ulna stop	/	04048844045067

End of schedule

Basis-UDI-DI 4048844MUTHUSTTINCDX7
Intended use Stem for cemented fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
GMDN P 39702
EMDN P09010402

Reference number	item description	size	UDI-DI
52400408N	MUTARS® humerus stem cemented TiN	8/75 mm	04048844104078
52400409N	MUTARS® humerus stem cemented TiN	9/75 mm	04048844104085
52400410N	MUTARS® humerus stem cemented TiN	10/75 mm	04048844104092
52400411N	MUTARS® humerus stem cemented TiN	11/75 mm	04048844104108
52400412N	MUTARS® humerus stem cemented TiN	12/75 mm	04048844104115
52400413N	MUTARS® humerus stem cemented TiN	13/75mm	04048844579869
52400414N	MUTARS® humerus stem cemented TiN	14/75mm	04048844579876
52400415N	MUTARS® humerus stem cemented TiN	15/75mm	04048844579890
52400416N	MUTARS® humerus stem cemented TiN	16/75mm	04048844579906
52401008N	MUTARS® humerus stem cemented TiN	8/100mm	04048844579883
52401009N	MUTARS® humerus stem cemented TiN	9/100mm	04048844579913
52401010N	MUTARS® humerus stem cemented TiN	10/100mm	04048844579920
52401011N	MUTARS® humerus stem cemented TiN	11/100mm	04048844579937
52401012N	MUTARS® humerus stem cemented TiN	12/100mm	04048844579944
52401013N	MUTARS® humerus stem cemented TiN	13/100mm	04048844579951
52401014N	MUTARS® humerus stem cemented TiN	14/100mm	04048844579968
52401015N	MUTARS® humerus stem cemented TiN	15/100mm	04048844579975
52401016N	MUTARS® humerus stem cemented TiN	16/100mm	04048844579982
52401508N	MUTARS® humerus stem cemented TiN	8/150mm	04048844579999
52401509N	MUTARS® humerus stem cemented TiN	9/150mm	04048844580001
52401510N	MUTARS® humerus stem cemented TiN	10/150mm	04048844580018
52401511N	MUTARS® humerus stem cemented TiN	11/150mm	04048844580025
52401512N	MUTARS® humerus stem cemented TiN	12/150mm	04048844580032
52401513N	MUTARS® humerus stem cemented TiN	13/150mm	04048844580049
52401514N	MUTARS® humerus stem cemented TiN	14/150mm	04048844580056
52401515N	MUTARS® humerus stem cemented TiN	15/150mm	04048844580063
52401516N	MUTARS® humerus stem cemented TiN	16/150mm	04048844580070

End of schedule

Basis-UDI-DI 4048844MUTHUSTUNCCDWW
Intended use Stem for cemented fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
GMDN P 34197
EMDN P09010402

Reference number	item description	size	UDI-DI
52400408	MUTARS® humerus stem cemented	8/75 mm	04048844044688
52400409	MUTARS® humerus stem cemented	9/75 mm	04048844044695
52400410	MUTARS® humerus stem cemented	10/75 mm	04048844044701
52400411	MUTARS® humerus stem cemented	11/75 mm	04048844044718
52400412	MUTARS® humerus stem cemented	12/75 mm	04048844044725
52400413	MUTARS® humerus stem cemented	13/75mm	04048844578527
52400414	MUTARS® humerus stem cemented	14/75mm	04048844578534
52400415	MUTARS® humerus stem cemented	15/75mm	04048844578541
52400416	MUTARS® humerus stem cemented	16/75mm	04048844578558
52401008	MUTARS® humerus stem cemented	8/100mm	04048844518493
52401009	MUTARS® humerus stem cemented	9/100mm	04048844518509
52401010	MUTARS® humerus stem cemented	10/100mm	04048844518516
52401011	MUTARS® humerus stem cemented	11/100mm	04048844518523
52401012	MUTARS® humerus stem cemented	12/100mm	04048844518530
52401013	MUTARS® humerus stem cemented	13/100mm	04048844578565
52401014	MUTARS® humerus stem cemented	14/100mm	04048844578572
52401015	MUTARS® humerus stem cemented	15/100mm	04048844578596
52401016	MUTARS® humerus stem cemented	16/100mm	04048844578602
52401508	MUTARS® humerus stem cemented	8/150mm	04048844518547
52401509	MUTARS® humerus stem cemented	9/150mm	04048844518554
52401510	MUTARS® humerus stem cemented	10/150mm	04048844518561
52401511	MUTARS® humerus stem cemented	11/150mm	04048844518578
52401512	MUTARS® humerus stem cemented	12/150mm	04048844518585
52401513	MUTARS® humerus stem cemented	13/150mm	04048844578633
52401514	MUTARS® humerus stem cemented	14/150mm	04048844578640
52401515	MUTARS® humerus stem cemented	15/150mm	04048844578657
52401516	MUTARS® humerus stem cemented	16/150mm	04048844578688

End of schedule

Basis-UDI-DI 4048844MUTHUSTUNCCLXE
Intended use Stem for cementless fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
GMDN P 48090
EMDN P09010402

Reference number	item description	size	UDI-DI
52400707	MUTARS® humerus stem cementless	7/75 mm	04048844044732
52400708	MUTARS® humerus stem cementless	8/75 mm	04048844044749
52400709	MUTARS® humerus stem cementless	9/75 mm	04048844044756
52400710	MUTARS® humerus stem cementless	10/75 mm	04048844044763
52400711	MUTARS® humerus stem cementless	11/75 mm	04048844044770
52400712	MUTARS® humerus stem cementless	12/75 mm	04048844044787
52400713	MUTARS® humerus stem cementless	13/75 mm	04048844044794
52400714	MUTARS® humerus stem cementless	14/75 mm	04048844044800
52400715	MUTARS® humerus stem cementless	15/75 mm	04048844044817
52400716	MUTARS® humerus stem cementless	16/75 mm	04048844044824
52400717	MUTARS® humerus stem cementless	17/75 mm	04048844044831

End of schedule

Basis-UDI-DI 4048844MUTHUUA2CPHACLME
Intended use Hinged elbow joint component intended to serve as cementless osseous anchorage in the ulna in case of a distal or total humerus replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
52501040	MUTARS® ulnar component HD cementless	right	04048844561956
52501045	MUTARS® ulnar component HD cementless	left	04048844561963

End of schedule

Basis-UDI-DI 4048844MUTHUUAACPHACLPR
Intended use Hinged elbow joint component intended to serve as cementless osseous anchorage in the ulna in case of a distal or total humerus replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
52501015	MUTARS® ulna anchorage cementless cpTi / HA	left	04048844045029
52501020	MUTARS® ulna anchorage cementless cpTi / HA	right	04048844045036

End of schedule

Basis-UDI-DI 4048844MUTHUUATINBNCL9H
Intended use Hinged elbow joint component intended to serve as cementless osseous anchorage in the ulna in case of a distal or total humerus replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
52501015N	MUTARS® ulna anchorage cementless TiNbN	left	04048844129866
52501020N	MUTARS® ulna anchorage cementless TiNbN	right	04048844129873

End of schedule

Basis-UDI-DI 4048844MUTHUUC2UNCCDM6
Intended use Hinged elbow joint component intended to serve as cemented osseous anchorage in the ulna in case of a distal or total humerus replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
52510070	MUTARS® ulnar component HD cemented	70mm right	04048844517014
52510100	MUTARS® ulnar component HD cemented	100mm right	04048844517021
52510130	MUTARS® ulnar component HD cemented	130mm right	04048844517045
52515070	MUTARS® ulnar component HD cemented	70mm left	04048844517007
52515100	MUTARS® ulnar component HD cemented	100mm left	04048844538934
52515130	MUTARS® ulnar component HD cemented	130mm left	04048844517038

End of schedule

Basis-UDI-DI 4048844MUTHUUCIITINCD7X
Intended use Hinged elbow joint component intended to serve as cemented osseous anchorage in the ulna in case of a distal or total humerus replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
52510070N	MUTARS® ulnar component HD cemented TiN	70mm right	04048844580094
52510100N	MUTARS® ulnar component HD cemented TiN	100mm right	04048844580117
52510130N	MUTARS® ulnar component HD cemented TiN	130mm right	04048844580131
52515070N	MUTARS® ulnar component HD cemented TiN	70mm left	04048844580087
52515100N	MUTARS® ulnar component HD cemented TiN	100mm left	04048844580100
52515130N	MUTARS® ulnar component HD cemented TiN	130mm left	04048844580124

End of schedule

Basis-UDI-DI 4048844MUTHUUCTINBNCD7
Intended use Hinged elbow joint component intended to serve as cemented osseous anchorage in the ulna in case of a distal or total humerus replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
52505070N	MUTARS® ulnar component cemented TiNbN	70 mm left	04048844135140
52500070N	MUTARS® ulnar component cemented TiNbN	70 mm right	04048844135157
52505100N	MUTARS® ulnar component cemented TiNbN	100 mm left	04048844135164
52500100N	MUTARS® ulnar component cemented TiNbN	100 mm right	04048844135171

End of schedule

Basis-UDI-DI 4048844MUTHUUCUNCCDR3
Intended use Hinged elbow joint component intended to serve as cemented osseous anchorage in the ulna in case of a distal or total humerus replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
52505070	MUTARS® ulnar component cemented	70 mm left	04048844135102
52500070	MUTARS® ulnar component cemented	70 mm right	04048844135119
52505100	MUTARS® ulnar component cemented	100 mm left	04048844135126
52500100	MUTARS® ulnar component cemented	100 mm right	04048844135133

End of schedule

This attachment is integral part of the declaration.
The declaration is only valid when provided entirely with all of its pages.

Basis-UDI-DI 4048844MUTHUULNA2TINTY
Intended use Hinged elbow joint component intended to replace the part of the proximal ulna in a proximal ulna replacement or total elbow replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
5251003001N	MUTARS® prox. ulna HD TiN	/	04048844580391

End of schedule

Basis-UDI-DI 4048844MUTHUULNA2UNCTW
Intended use Hinged elbow joint component intended to replace the part of the proximal ulna in a proximal ulna replacement or total elbow replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
5251003001	MUTARS® prox. ulna HD	/	04048844519285

End of schedule

Basis-UDI-DI 4048844MUTHUULNAUNCT9
Intended use Hinged elbow joint component intended to replace the part of the proximal ulna in a proximal ulna replacement or total elbow replacement.
GMDN P 40124
EMDN P090205

Reference number	item description	size	UDI-DI
5250003000	MUTARS® prox. ulna	/	04048844606060

End of schedule. No additional information past this point.

EU Quality Management System Certificate

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

SRN DE-MF-000010002

with locations representative listed in the appendix

has introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

The compliance of this quality management system to the requirements of the
Regulation (EU) 2017/745 on medical devices was verified by assessment according to:

Annex IX Chapter I

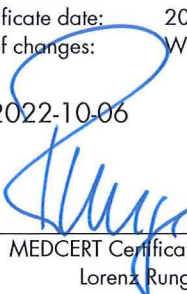
Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

Effective date: 2022-10-06
Expiry date: 2026-01-02

Report No.: 7092AU14F
Procedure No.: QS – 7092
Certificate No.: 7092GB448221006

Preceding certificate No.: 7092GB448220824
Preceding certificate date: 2022-08-24
Identification of changes: WO-009324, WO-010342

Hamburg, 2022-10-06


MEDCERT Certification Body
Lorenz Runge

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

MEDCERT Notified Body Identification Number: 0482



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www.zlg.de

BS-MDR-096

Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7092
Certificate No.: 7092GB448221006

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.
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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7092
Certificate No.: 7092GB448221006

Class I medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

Category	Medical devices/groups of medical devices	Class
MDN 1208	Sterile Systems and procedure packs	Is
	Non-active non-implantable instruments	Ir

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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7092
Certificate No.: 7092GB448221006

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1208	L091199	Orthopaedic prosthetics instruments, reusable - other
MDN 1208	Z121305	Motorised orthopaedic surgery system instruments
MDN 1208	L091001	Instruments for insertion and extraction of materials for osteosynthesis, reusable
MDN 1208	L030199	General surgery surgical cannulas and handpieces, reusable - other
MDN 1208	L091201	Orthopaedic surgery rasps, reusable
MDN 1208	Z121390	Various orthopaedic and traumatology instruments
MDN 1208	L091102	Orthopaedic prostheses reamers and burs, reusable

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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7092
Certificate No.: 7092GB448221006

Class III custom-made implantable medical devices

Category	Medical devices/groups of medical devices
MDN 1102	Non-active osteo- and orthopaedic implants

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MEDCERT Notified Body Identification Number: 0482



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Appendix of EU Quality Management System Certificate

Procedure No.: QS – 7092
Certificate No.: 7092GB448221006

Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional **EU Technical Documentation Assessment Certificate according to Annex IX Chapter II** of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	Medical devices/groups of medical devices
MDN 1102	Non-active osteo- and orthopaedic implants

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 Notified Body Identification Number: 0482



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BS-MDR-096

EU Technical Documentation Assessment Certificate

Certificate no.:
13266GB450221104

Final assessment report no.:
13266AU11F

Effective date:
2022-11-04

Expiry date:
2027-11-03

This is to certify that:
Medical devices listed on the following pages

Manufactured by:

implantcast GmbH

Lüneburger Schanze 26, 21614 Buxtehude, Germany

SRN: DE-MF-000010002

Have been assessed and found to comply with respect to:

**Technical Documentation Assessment as described in Annex IX
Chapter II of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certificate assumes that DNV MEDCERT has to be informed about any changes of the assessed device. Changes need further approval by DNV MEDCERT.

For conditions or for limitations to the validity refer to the relevant final assessment report. Examinations and tests performed, e. g. reference to relevant common specifications, harmonised standards, test reports and audit report(s), are recorded in the relevant reports. For placing on the market of the medical devices covered by this certificate, an additional EU Quality Management System Certificate according to Annex IX Chapter I of Regulation (EU) 2017/745 is required.

Place and date:
Hamburg, 2022-11-04



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For the issuing office:
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

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


Lorenz Runge
Director Certification Body

Products covered by this certificate

Class	III
Basic UDI-DI	4048844MUTHUAXLD2UNCNM
Intended purpose	Axle intended to serve as a connection between the ulnar component and the MUTARS® Distal Humerus.
Model (REF#)	Device name
52510001	MUTARS® axle for dist. humerus HD

Class	III
Basic UDI-DI	4048844MUTHUAXLDTINBN65
Intended purpose	Axle intended to serve as a connection between the ulnar component and the MUTARS® Distal Humerus.
Model (REF#)	Device name
52500001N	MUTARS® axle for dist. humerus TiNbN

Class	III
Basic UDI-DI	4048844MUTHUAXLDUNCMG
Intended purpose	Axle intended to serve as a connection between the ulnar component and the MUTARS® Distal Humerus.
Model (REF#)	Device name
52500001	MUTARS® axle for dist. humerus

Class	III
Basic UDI-DI	4048844MUTHUCAPITINFQ
Intended purpose	Cap that is combined with the MUTARS® Humerus Head intended to replace the humeral head in case of a reverse shoulder prosthesis.
Model (REF#)	Device name
52101000	MUTARS® humerus cap invers TiN
52101005	MUTARS® humerus cap invers +5 mm TiN
52101010	MUTARS® humerus cap invers +10 mm TiN

Class	III
Basic UDI-DI	4048844MUTHUCAPTINFZ
Intended purpose	Cap that is combined with the MUTARS® Humerus Head intended to replace the humeral head.
Model (REF#)	Device name
52100000	MUTARS® humerus cap small TiN
52100005	MUTARS® humerus cap medium TiN
52100010	MUTARS® humerus cap large TiN

Class	III
Basic UDI-DI	4048844MUTHUCOLFTCPJX
Intended purpose	Modular stem collar for the MUTARS® Humerus Stem Type A Modular intended to enable bone ingrowth.
Model (REF#)	Device name
52420018	MUTARS® EPORE® HA collar humerus with flange 18mm
52420019	MUTARS® EPORE® HA collar humerus with flange 19mm
52420020	MUTARS® EPORE® HA collar humerus with flange 20mm
52420021	MUTARS® EPORE® HA collar humerus with flange 21mm
52420022	MUTARS® EPORE® HA collar humerus with flange 22mm
52420023	MUTARS® EPORE® HA collar humerus with flange 23mm
52420024	MUTARS® EPORE® HA collar humerus with flange 24mm

Class	III
Basic UDI-DI	4048844MUTHUCOLTCPKH
Intended purpose	Modular stem collar for the MUTARS® Humerus Stem Type A Modular intended to enable bone ingrowth.
Model (REF#)	Device name
52410018	MUTARS® EPORE® HA collar humerus 18mm
52410019	MUTARS® EPORE® HA collar humerus 19mm
52410020	MUTARS® EPORE® HA collar humerus 20mm
52410021	MUTARS® EPORE® HA collar humerus 21mm
52410022	MUTARS® EPORE® HA collar humerus 22mm
52410023	MUTARS® EPORE® HA collar humerus 23mm
52410024	MUTARS® EPORE® HA collar humerus 24mm

Class	III
Basic UDI-DI	4048844MUTHUCONPUNCN7
Intended purpose	Humerus Connecting Part intended for extraosseous length adjustment in the area of the proximal and distal humerus for the bridging of bone defects in cases where a proximal or distal humerus replacement component is used. The MUTARS® Humerus Connection Part may also be used when a total humerus replacement, total elbow replacement or proximal ulna replacement is required.
Model (REF#)	Device name
5221008001	MUTARS® humerus connecting part distal 80mm
5221008002	MUTARS® humerus connecting part prox. 80mm

Class	III
Basic UDI-DI	4048844MUTHUDH230UNCXQ
Intended purpose	Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement or proximal ulna replacement.
Model (REF#)	Device name
5251230001	MUTARS® dist. humerus HD 30mm

Class	III
Basic UDI-DI	4048844MUTHUDH250UNCYE
Intended purpose	Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement, total elbow replacement or total humerus replacement.
Model (REF#)	Device name
5251000001	MUTARS® dist. humerus HD 50mm

Class	III
Basic UDI-DI	4048844MUTHUDH30UNC46
Intended purpose	Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement or proximal ulna replacement.
Model (REF#)	Device name
5250230001	MUTARS® dist. humerus M6 30mm part 1

Class	III
Basic UDI-DI	4048844MUTHUDH50TINBNBA
Intended purpose	Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement, total elbow replacement or total humerus replacement.
Model (REF#)	Device name
5250000000N	MUTARS® dist. humerus 50mm TiNbN

Class	III
Basic UDI-DI	4048844MUTHUDH50UNC4U
Intended purpose	Hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement, total elbow replacement or total humerus replacement.
Model (REF#)	Device name
5250000000	MUTARS® dist. humerus 50mm

Class	III
Basic UDI-DI	4048844MUTHUENDPUNCKE
Intended purpose	Humerus End Piece used in rare cases of bone tumors and bone metastases in which no full extremity preserving surgery can be carried out. The end piece can serve to prosthetically preserve a terminal humeral or ulnar stump in cases of a part or total humerus replacement, total elbow replacement or proximal ulna replacement.
Model (REF#)	Device name
52200001	MUTARS® humerus end piece 20mm

Class	III
Basic UDI-DI	4048844MUTHUEXTPUNCUY
Intended purpose	Humerus Extension Piece intended for extraosseous length adjustment in the area of the proximal and distal humerus for the bridging of bone defects in cases where a proximal or distal humerus replacement component is used. The extension piece may also be used when a total humerus replacement, total elbow replacement or proximal ulna replacement component is required.
Model (REF#)	Device name
52200020	MUTARS® humerus extension piece 20mm
52200040	MUTARS® humerus extension piece 40mm
52200060	MUTARS® humerus extension piece 60mm

Class	III
Basic UDI-DI	4048844MUTHUGLENUNCKK
Intended purpose	Glenosphere intended to replace the glenoid surface in case of a reverse total shoulder replacement.
Model (REF#)	Device name
52101002	MUTARS® glenosphere 40mm symmetric

Class	III
Basic UDI-DI	4048844MUTHUGLRHACKL5
Intended purpose	Glenoid component intended for cementless fixation to replace the natural glenoid by combination with the MUTARS® Glenosphere for a reverse MUTARS® Humerus replacement.
Model (REF#)	Device name
38004001	glenoid cementless sz. 3 round

Class	III
Basic UDI-DI	4048844MUTHUGLUNCCDMA
Intended purpose	Glenoid component for cemented fixation intended to replace the natural glenoid.
Model (REF#)	Device name
38030032	AGILON® PE-glenoid cemented sz. 2
38030036	AGILON® PE-glenoid cemented sz. 3
38030040	AGILON® PE-glenoid cemented sz. 4

Class	III
Basic UDI-DI	4048844MUTHUHEADUNCDP
Intended purpose	Component that is combined with the MUTARS® Humerus Cap or MUTARS® Humerus Cap Inverse intended to replace the proximal part of the humerus or the total humerus.
Model (REF#)	Device name
5200000000	MUTARS® humerus head 50 mm

Class	III
Basic UDI-DI	4048844MUTHUHSSUNCQT
Intended purpose	Screw intended to secure the MUTARS® Humerus Screw.
Model (REF#)	Device name
52000099	MUTARS® humerus safety screw

Class	III
Basic UDI-DI	4048844MUTHUHSUNCU6
Intended purpose	Screw intended to join components of the MUTARS® Humerus System.
Model (REF#)	Device name
52300015	MUTARS® humerus screw M8x15 mm
52300035	MUTARS® humerus screw M8x35 mm
52300055	MUTARS® humerus screw M8x55 mm
52300075	MUTARS® humerus screw M8x75 mm

Class	III
Basic UDI-DI	4048844MUTHULSDUNCP6
Intended purpose	Screw intended to secure the MUTARS® Axle.
Model (REF#)	Device name
52500003	MUTARS® locking screw for dist. humerus

Class	III
Basic UDI-DI	4048844MUTHUPEFCSTDKR
Intended purpose	PE Bearing intended to be used in combination with the MUTARS® Distal Humerus HD 30mm or 50mm to act as one of the bearing surfaces of the hinged elbow system besides the MUTARS® Ulnar Component HD or MUTARS® Proximal Ulna HD.
Model (REF#)	Device name
52510002	PE bearing FC

Class	III
Basic UDI-DI	4048844MUTHUPESCSTDQ8
Intended purpose	PE Bearing intended to be used in combination with the MUTARS® Distal Humerus HD 30mm or 50mm to act as one of the bearing surfaces of the hinged elbow system besides the MUTARS® Ulnar Component HD or MUTARS® Proximal Ulna HD.
Model (REF#)	Device name
52510003	PE bearing SC

Class	III
Basic UDI-DI	4048844MUTHUREDUNCLS
Intended purpose	Humerus Reducer intended for extraosseous length adjustment in cases of a total humerus replacement to enable a connection between the MUTARS® Humerus Head and the Distal Humerus.
Model (REF#)	Device name
52210000	MUTARS® humerus reducer 10mm
52210100	MUTARS® humerus reducer 100mm

Class	III
Basic UDI-DI	4048844MUTHUSCONPUNCZ6
Intended purpose	Screw intended to connect the MUTARS® Humerus Connecting Part Proximal to the MUTARS® Humerus Connecting Part Distal.
Model (REF#)	Device name
52210099	MUTARS® humerus screw for connecting part

Class	III
Basic UDI-DI	4048844MUTHUSDSW5UNCYQ
Intended purpose	Screw intended to join components of the MUTARS® Distal Humerus.
Model (REF#)	Device name
52300125	MUTARS® screw for dist. humerus M6x12.5mm SW5
52300200	MUTARS® screw for dist. humerus M6x20mm SW5
52300225	MUTARS® screw for dist. humerus M6x22.5mm SW5
52300250	MUTARS® screw for dist. humerus M6x25mm SW5
52300275	MUTARS® screw for dist. humerus M6x27.5mm SW5
52300300	MUTARS® screw for dist. humerus M6x30mm SW5

Class	III
Basic UDI-DI	4048844MUTHUSSD30UNCMG
Intended purpose	Screw intended to secure the MUTARS® Screw for Distal Humerus.
Model (REF#)	Device name
52000097	MUTARS® safety screw for distal humerus 30mm SW5

Class	III
Basic UDI-DI	4048844MUTHUSTAMTINCDDY
Intended purpose	Stem for cemented fixation intended to be used in combination with the MUTARS® EPORE® HA Collar Humerus for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
Model (REF#)	Device name
52440708N	MUTARS® humerus stem type A modular cemented 8/75mm TiN
52440709N	MUTARS® humerus stem type A modular cemented 9/75mm TiN
52440710N	MUTARS® humerus stem type A modular cemented 10/75mm TiN
52440711N	MUTARS® humerus stem type A modular cemented 11/75mm TiN
52440712N	MUTARS® humerus stem type A modular cemented 12/75mm TiN
52440713N	MUTARS® humerus stem type A modular cemented 13/75mm TiN
52440714N	MUTARS® humerus stem type A modular cemented 14/75mm TiN
52440715N	MUTARS® humerus stem type A modular cemented 15/75mm TiN
52440716N	MUTARS® humerus stem type A modular cemented 16/75mm TiN
52441008N	MUTARS® humerus stem type A modular cemented 8/100mm TiN
52441009N	MUTARS® humerus stem type A modular cemented 9/100mm TiN
52441010N	MUTARS® humerus stem type A modular cemented 10/100mm TiN
52441011N	MUTARS® humerus stem type A modular cemented 11/100mm TiN
52441012N	MUTARS® humerus stem type A modular cemented 12/100mm TiN
52441013N	MUTARS® humerus stem type A modular cemented 13/100mm TiN
52441014N	MUTARS® humerus stem type A modular cemented 14/100mm TiN
52441015N	MUTARS® humerus stem type A modular cemented 15/100mm TiN
52441016N	MUTARS® humerus stem type A modular cemented 16/100mm TiN
52441508N	MUTARS® humerus stem type A modular cemented 8/150mm TiN
52441509N	MUTARS® humerus stem type A modular cemented 9/150mm TiN
52441510N	MUTARS® humerus stem type A modular cemented 10/150mm TiN
52441511N	MUTARS® humerus stem type A modular cemented 11/150mm TiN
52441512N	MUTARS® humerus stem type A modular cemented 12/150mm TiN
52441513N	MUTARS® humerus stem type A modular cemented 13/150mm TiN
52441514N	MUTARS® humerus stem type A modular cemented 14/150mm TiN
52441515N	MUTARS® humerus stem type A modular cemented 15/150mm TiN
52441516N	MUTARS® humerus stem type A modular cemented 16/150mm TiN

Class	III
Basic UDI-DI	4048844MUTHUSTAMUNCCDDP
Intended purpose	Stem for cemented fixation intended to be used in combination with the MUTARS® EPORE® HA Collar Humerus for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
Model (REF#)	Device name
52440708	MUTARS® humerus stem type A modular cemented 8/75mm
52440709	MUTARS® humerus stem type A modular cemented 9/75mm
52440710	MUTARS® humerus stem type A modular cemented 10/75mm
52440711	MUTARS® humerus stem type A modular cemented 11/75mm
52440712	MUTARS® humerus stem type A modular cemented 12/75mm
52440713	MUTARS® humerus stem type A modular cemented 13/75mm
52440714	MUTARS® humerus stem type A modular cemented 14/75mm
52440715	MUTARS® humerus stem type A modular cemented 15/75mm
52440716	MUTARS® humerus stem type A modular cemented 16/75mm
52441008	MUTARS® humerus stem type A modular cemented 8/100mm
52441009	MUTARS® humerus stem type A modular cemented 9/100mm
52441010	MUTARS® humerus stem type A modular cemented 10/100mm
52441011	MUTARS® humerus stem type A modular cemented 11/100mm
52441012	MUTARS® humerus stem type A modular cemented 12/100mm
52441013	MUTARS® humerus stem type A modular cemented 13/100mm
52441014	MUTARS® humerus stem type A modular cemented 14/100mm
52441015	MUTARS® humerus stem type A modular cemented 15/100mm
52441016	MUTARS® humerus stem type A modular cemented 16/100mm
52441508	MUTARS® humerus stem type A modular cemented 8/150mm
52441509	MUTARS® humerus stem type A modular cemented 9/150mm
52441510	MUTARS® humerus stem type A modular cemented 10/150mm
52441511	MUTARS® humerus stem type A modular cemented 11/150mm
52441512	MUTARS® humerus stem type A modular cemented 12/150mm
52441513	MUTARS® humerus stem type A modular cemented 13/150mm
52441514	MUTARS® humerus stem type A modular cemented 14/150mm
52441515	MUTARS® humerus stem type A modular cemented 15/150mm
52441516	MUTARS® humerus stem type A modular cemented 16/150mm

Class	III
Basic UDI-DI	4048844MUTHUSTAMUNCCL7
Intended purpose	Stem for cementless fixation intended to be used in combination with the MUTARS® EPORE® HA Collar Humerus for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
Model (REF#)	Device name
52470707	MUTARS® humerus stem type A modular cementless 7/75mm
52470708	MUTARS® humerus stem type A modular cementless 8/75mm
52470709	MUTARS® humerus stem type A modular cementless 9/75mm
52470710	MUTARS® humerus stem type A modular cementless 10/75mm
52470711	MUTARS® humerus stem type A modular cementless 11/75mm
52470712	MUTARS® humerus stem type A modular cementless 12/75mm
52470713	MUTARS® humerus stem type A modular cementless 13/75mm
52470714	MUTARS® humerus stem type A modular cementless 14/75mm
52470715	MUTARS® humerus stem type A modular cementless 15/75mm
52470716	MUTARS® humerus stem type A modular cementless 16/75mm
52471007	MUTARS® humerus stem type A modular cementless 7/100mm
52471008	MUTARS® humerus stem type A modular cementless 8/100mm
52471009	MUTARS® humerus stem type A modular cementless 9/100mm
52471010	MUTARS® humerus stem type A modular cementless 10/100mm
52471011	MUTARS® humerus stem type A modular cementless 11/100mm
52471012	MUTARS® humerus stem type A modular cementless 12/100mm
52471013	MUTARS® humerus stem type A modular cementless 13/100mm
52471014	MUTARS® humerus stem type A modular cementless 14/100mm
52471015	MUTARS® humerus stem type A modular cementless 15/100mm
52471016	MUTARS® humerus stem type A modular cementless 16/100mm
52471507	MUTARS® humerus stem type A modular cementless 7/150mm
52471508	MUTARS® humerus stem type A modular cementless 8/150mm
52471509	MUTARS® humerus stem type A modular cementless 9/150mm
52471510	MUTARS® humerus stem type A modular cementless 10/150mm
52471511	MUTARS® humerus stem type A modular cementless 11/150mm
52471512	MUTARS® humerus stem type A modular cementless 12/150mm
52471513	MUTARS® humerus stem type A modular cementless 13/150mm
52471514	MUTARS® humerus stem type A modular cementless 14/150mm
52471515	MUTARS® humerus stem type A modular cementless 15/150mm
52471516	MUTARS® humerus stem type A modular cementless 16/150mm

Class	III
Basic UDI-DI	4048844MUTHUSTHACDP5
Intended purpose	Stem for cemented fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
Model (REF#)	Device name
52490408	MUTARS® humerus stem cemented with HA collar 8/75 mm
52490409	MUTARS® humerus stem cemented with HA collar 9/75 mm
52490410	MUTARS® humerus stem cemented with HA collar 10/75 mm
52490411	MUTARS® humerus stem cemented with HA collar 11/75 mm
52490412	MUTARS® humerus stem cemented with HA collar 12/75 mm

Class	III
Basic UDI-DI	4048844MUTHUSTHACLPM
Intended purpose	Stem for cementless fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
Model (REF#)	Device name
52400807	MUTARS® humerus stem cementless 7/75mm HA
52400808	MUTARS® humerus stem cementless 8/75mm HA
52400809	MUTARS® humerus stem cementless 9/75mm HA
52400810	MUTARS® humerus stem cementless 10/75mm HA
52400811	MUTARS® humerus stem cementless 11/75mm HA
52400812	MUTARS® humerus stem cementless 12/75mm HA
52400813	MUTARS® humerus stem cementless 13/75mm HA
52400814	MUTARS® humerus stem cementless 14/75mm HA
52400815	MUTARS® humerus stem cementless 15/75mm HA
52400816	MUTARS® humerus stem cementless 16/75mm HA
52400817	MUTARS® humerus stem cementless 17/75mm HA

Class	III
Basic UDI-DI	4048844MUTHUSTOP2UNC4M
Intended purpose	Ulna Stop HD intended to be used in combination with the MUTARS® Distal Humerus HD 30mm and 50mm in order to prevent hyperextension of the elbow joint.
Model (REF#)	Device name
52511100	MUTARS® ulna stop HD

Class	III
Basic UDI-DI	4048844MUTHUSTOPUNCZ3
Intended purpose	Ulna Stop intended to be used in combination with the MUTARS® Distal Humerus 30mm and 50mm in order to prevent hyperextension of the elbow joint.
Model (REF#)	Device name
52501100	MUTARS® ulna stop



DNV

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Class	III
Basic UDI-DI	4048844MUTHUSTTINCDX7
Intended purpose	Stem for cemented fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
Model (REF#)	Device name
52400408N	MUTARS® humerus stem cemented 8/75 mm TiN
52400409N	MUTARS® humerus stem cemented 9/75 mm TiN
52400410N	MUTARS® humerus stem cemented 10/75 mm TiN
52400411N	MUTARS® humerus stem cemented 11/75 mm TiN
52400412N	MUTARS® humerus stem cemented 12/75 mm TiN
52400413N	MUTARS® humerus stem cemented 13/75mm TiN
52400414N	MUTARS® humerus stem cemented 14/75mm TiN
52400415N	MUTARS® humerus stem cemented 15/75mm TiN
52400416N	MUTARS® humerus stem cemented 16/75mm TiN
52401008N	MUTARS® humerus stem cemented 8/100mm TiN
52401009N	MUTARS® humerus stem cemented 9/100mm TiN
52401010N	MUTARS® humerus stem cemented 10/100mm TiN
52401011N	MUTARS® humerus stem cemented 11/100mm TiN
52401012N	MUTARS® humerus stem cemented 12/100mm TiN
52401013N	MUTARS® humerus stem cemented 13/100mm TiN
52401014N	MUTARS® humerus stem cemented 14/100mm TiN
52401015N	MUTARS® humerus stem cemented 15/100mm TiN
52401016N	MUTARS® humerus stem cemented 16/100mm TiN
52401508N	MUTARS® humerus stem cemented 8/150mm TiN
52401509N	MUTARS® humerus stem cemented 9/150mm TiN
52401510N	MUTARS® humerus stem cemented 10/150mm TiN
52401511N	MUTARS® humerus stem cemented 11/150mm TiN
52401512N	MUTARS® humerus stem cemented 12/150mm TiN
52401513N	MUTARS® humerus stem cemented 13/150mm TiN
52401514N	MUTARS® humerus stem cemented 14/150mm TiN
52401515N	MUTARS® humerus stem cemented 15/150mm TiN
52401516N	MUTARS® humerus stem cemented 16/150mm TiN

Class	III
Basic UDI-DI	4048844MUTHUSTUNCCDWW
Intended purpose	Stem for cemented fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
Model (REF#)	Device name
52400408	MUTARS® humerus stem cemented 8/75 mm
52400409	MUTARS® humerus stem cemented 9/75 mm
52400410	MUTARS® humerus stem cemented 10/75 mm
52400411	MUTARS® humerus stem cemented 11/75 mm
52400412	MUTARS® humerus stem cemented 12/75 mm
52400413	MUTARS® humerus stem cemented 13/75mm
52400414	MUTARS® humerus stem cemented 14/75mm
52400415	MUTARS® humerus stem cemented 15/75mm
52400416	MUTARS® humerus stem cemented 16/75mm
52401008	MUTARS® humerus stem cemented 8/100mm
52401009	MUTARS® humerus stem cemented 9/100mm
52401010	MUTARS® humerus stem cemented 10/100mm
52401011	MUTARS® humerus stem cemented 11/100mm
52401012	MUTARS® humerus stem cemented 12/100mm
52401013	MUTARS® humerus stem cemented 13/100mm
52401014	MUTARS® humerus stem cemented 14/100mm
52401015	MUTARS® humerus stem cemented 15/100mm
52401016	MUTARS® humerus stem cemented 16/100mm
52401508	MUTARS® humerus stem cemented 8/150mm
52401509	MUTARS® humerus stem cemented 9/150mm
52401510	MUTARS® humerus stem cemented 10/150mm
52401511	MUTARS® humerus stem cemented 11/150mm
52401512	MUTARS® humerus stem cemented 12/150mm
52401513	MUTARS® humerus stem cemented 13/150mm
52401514	MUTARS® humerus stem cemented 14/150mm
52401515	MUTARS® humerus stem cemented 15/150mm
52401516	MUTARS® humerus stem cemented 16/150mm

Class	III
Basic UDI-DI	4048844MUTHUSTUNCCLXE
Intended purpose	Stem for cementless fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.
Model (REF#)	Device name
52400707	MUTARS® humerus stem cementless 7/75mm
52400708	MUTARS® humerus stem cementless 8/75mm
52400709	MUTARS® humerus stem cementless 9/75mm
52400710	MUTARS® humerus stem cementless 10/75mm
52400711	MUTARS® humerus stem cementless 11/75mm
52400712	MUTARS® humerus stem cementless 12/75mm
52400713	MUTARS® humerus stem cementless 13/75mm
52400714	MUTARS® humerus stem cementless 14/75mm
52400715	MUTARS® humerus stem cementless 15/75mm
52400716	MUTARS® humerus stem cementless 16/75mm
52400717	MUTARS® humerus stem cementless 17/75mm

Class	III
Basic UDI-DI	4048844MUTHUUA2CPHACLME
Intended purpose	Hinged elbow joint component intended to serve as cementless osseous anchorage in the ulna in case of a distal or total humerus replacement.
Model (REF#)	Device name
52501040	MUTARS® ulnar component HD cementless right
52501045	MUTARS® ulnar component HD cementless left

Class	III
Basic UDI-DI	4048844MUTHUUACPHACLPR
Intended purpose	Hinged elbow joint component intended to serve as cementless osseous anchorage in the ulna in case of a distal or total humerus replacement.
Model (REF#)	Device name
52501015	MUTARS® ulna anchorage cementless left cpTi/HA
52501020	MUTARS® ulna anchorage cementless right cpTi/HA

Class	III
Basic UDI-DI	4048844MUTHUUATINBNCL9H
Intended purpose	Hinged elbow joint component intended to serve as cementless osseous anchorage in the ulna in case of a distal or total humerus replacement.
Model (REF#)	Device name
52501015N	MUTARS® ulna anchorage cementless left TiNbN
52501020N	MUTARS® ulna anchorage cementless right TiNbN

Class	III
Basic UDI-DI	4048844MUTHUUC2UNCCDM6
Intended purpose	Hinged elbow joint component intended to serve as cemented osseous anchorage in the ulna in case of a distal or total humerus replacement.
Model (REF#)	Device name
52510070	MUTARS® ulnar component HD cemented 70mm right
52510100	MUTARS® ulnar component HD cemented 100mm right
52510130	MUTARS® ulnar component HD cemented 130mm right
52515070	MUTARS® ulnar component HD cemented 70mm left
52515100	MUTARS® ulnar component HD cemented 100mm left
52515130	MUTARS® ulnar component HD cemented 130mm left

Class	III
Basic UDI-DI	4048844MUTHUUCITINCD7X
Intended purpose	Hinged elbow joint component intended to serve as cemented osseous anchorage in the ulna in case of a distal or total humerus replacement.
Model (REF#)	Device name
52510070N	MUTARS® ulnar component HD cemented 70mm right TiN
52510100N	MUTARS® ulnar component HD cemented 100mm right TiN
52510130N	MUTARS® ulnar component HD cemented 130mm right TiN
52515070N	MUTARS® ulnar component HD cemented 70mm left TiN
52515100N	MUTARS® ulnar component HD cemented 100mm left TiN
52515130N	MUTARS® ulnar component HD cemented 130mm left TiN

Class	III
Basic UDI-DI	4048844MUTHUUCTINBNCD7
Intended purpose	Hinged elbow joint component intended to serve as cemented osseous anchorage in the ulna in case of a distal or total humerus replacement.
Model (REF#)	Device name
52505070N	MUTARS® ulnar component cemented 70mm left TiNbN
52500070N	MUTARS® ulnar component cemented 70mm right TiNbN
52505100N	MUTARS® ulnar component cemented 100mm left TiNbN
52500100N	MUTARS® ulnar component cemented 100mm right TiNbN

Class	III
Basic UDI-DI	4048844MUTHUUCUNCCDR3
Intended purpose	Hinged elbow joint component intended to serve as cemented osseous anchorage in the ulna in case of a distal or total humerus replacement.
Model (REF#)	Device name
52505070	MUTARS® ulnar component cemented 70mm left
52500070	MUTARS® ulnar component cemented 70mm right
52505100	MUTARS® ulnar component cemented 100mm left
52500100	MUTARS® ulnar component cemented 100mm right

Class	III
Basic UDI-DI	4048844MUTHUULNA2TINTY
Intended purpose	Hinged elbow joint component intended to replace the part of the proximal ulna in a proximal ulna replacement or total elbow replacement.
Model (REF#)	Device name
5251003001N	MUTARS® prox. ulna HD TiN

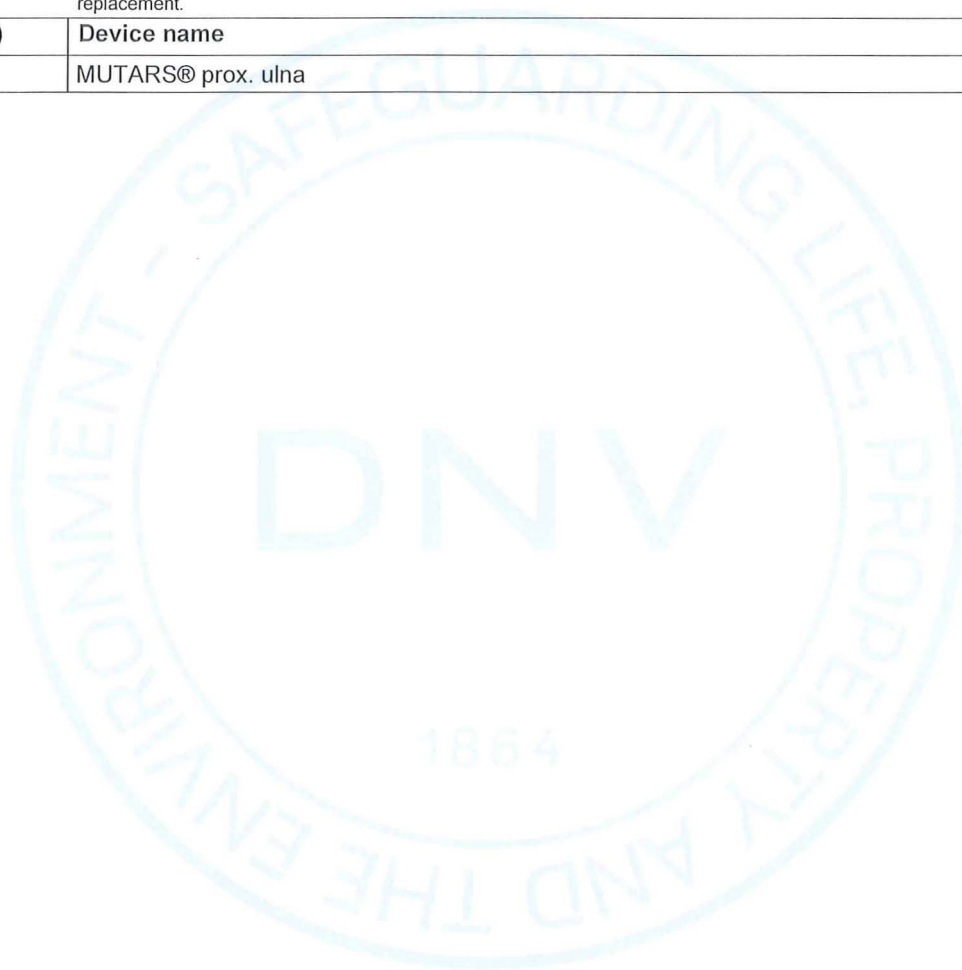


DNV

Certificate no.: 13266GB450221104
Place and date: Hamburg, 2022-11-04

Class	III
Basic UDI-DI	4048844MUTHUULNA2UNCTW
Intended purpose	Hinged elbow joint component intended to replace the part of the proximal ulna in a proximal ulna replacement or total elbow replacement.
Model (REF#)	Device name
5251003001	MUTARS® prox. ulna HD

Class	III
Basic UDI-DI	4048844MUTHUULNAUNCT9
Intended purpose	Hinged elbow joint component intended to replace the part of the proximal ulna in a proximal ulna replacement or total elbow replacement.
Model (REF#)	Device name
5250003000	MUTARS® prox. ulna



Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului), Modelul	Denumire comercială (brand)*	Cod GMDN*
1	52400707	52400707 MUTARS® humerus stem cementless 7/75mm	MUTARS®	P 48090
2	52400708	52400708 MUTARS® humerus stem cementless 8/75mm	MUTARS®	P 48090
3	52400709	52400709 MUTARS® humerus stem cementless 9/75mm	MUTARS®	P 48090
4	52400710	52400710 MUTARS® humerus stem cementless 10/75mm	MUTARS®	P 48090
5	52400711	52400711 MUTARS® humerus stem cementless 11/75mm	MUTARS®	P 48090
6	52400712	52400712 MUTARS® humerus stem cementless 12/75mm	MUTARS®	P 48090
7	52400713	52400713 MUTARS® humerus stem cementless 13/75mm	MUTARS®	P 48090
8	52400714	52400714 MUTARS® humerus stem cementless 14/75mm	MUTARS®	P 48090
9	52400715	52400715 MUTARS® humerus stem cementless 15/75mm	MUTARS®	P 48090
10	52400716	52400716 MUTARS® humerus stem cementless 16/75mm	MUTARS®	P 48090
11	52400717	52400717 MUTARS® humerus stem cementless 17/75mm	MUTARS®	P 48090
12	52400807	52400807 MUTARS® humerus stem cementless 7/75mm HA	MUTARS®	P 48090
13	52400808	52400808 MUTARS® humerus stem cementless 8/75mm HA	MUTARS®	P 48090
14	52400809	52400809 MUTARS® humerus stem cementless 9/75mm HA	MUTARS®	P 48090
15	52400810	52400810 MUTARS® humerus stem cementless 10/75mm HA	MUTARS®	P 48090
16	52400811	52400811 MUTARS® humerus stem cementless 11/75mm HA	MUTARS®	P 48090
17	52400812	52400812 MUTARS® humerus stem cementless 12/75mm HA	MUTARS®	P 48090
18	52400813	52400813 MUTARS® humerus stem cementless 13/75mm HA	MUTARS®	P 48090
19	52400814	52400814 MUTARS® humerus stem cementless 14/75mm HA	MUTARS®	P 48090
20	52400815	52400815 MUTARS® humerus stem cementless 15/75mm HA	MUTARS®	P 48090
21	52400816	52400816 MUTARS® humerus stem cementless 16/75mm HA	MUTARS®	P 48090
22	52400817	52400817 MUTARS® humerus stem cementless 17/75mm HA	MUTARS®	P 48090
23	52400408	52400408 MUTARS® humerus stem cemented 8/75mm	MUTARS®	P34197
24	52400409	52400409 MUTARS® humerus stem cemented 9/75mm	MUTARS®	P34197
25	52400410	52400410 MUTARS® humerus stem cemented 10/75mm	MUTARS®	P34197
26	52400411	52400411 MUTARS® humerus stem cemented 11/75mm	MUTARS®	P34197
27	52400412	52400412 MUTARS® humerus stem cemented 12/75mm	MUTARS®	P34197
28	52400413	52400413 MUTARS® humerus stem cemented 13/75mm	MUTARS®	P34197
29	52400414	52400414 MUTARS® humerus stem cemented 14/75mm	MUTARS®	P34197
30	52400415	52400415 MUTARS® humerus stem cemented 15/75mm	MUTARS®	P34197
31	52400416	52400416 MUTARS® humerus stem cemented 16/75mm	MUTARS®	P34197
32	52401008	52401008 MUTARS® humerus stem cemented 8/100mm	MUTARS®	P34197
33	52401009	52401009 MUTARS® humerus stem cemented 9/100mm	MUTARS®	P34197
34	52401010	52401010 MUTARS® humerus stem cemented 10/100mm	MUTARS®	P34197
35	52401011	52401011 MUTARS® humerus stem cemented 11/100mm	MUTARS®	P34197
36	52401012	52401012 MUTARS® humerus stem cemented 12/100mm	MUTARS®	P34197
37	52401013	52401013 MUTARS® humerus stem cemented 13/100mm	MUTARS®	P34197
38	52401014	52401014 MUTARS® humerus stem cemented 14/100mm	MUTARS®	P34197
39	52401015	52401015 MUTARS® humerus stem cemented 15/100mm	MUTARS®	P34197
40	52401016	52401016 MUTARS® humerus stem cemented 16/100mm	MUTARS®	P34197
41	52401508	52401508 MUTARS® humerus stem cemented 8/150mm	MUTARS®	P34197
42	52401509	52401509 MUTARS® humerus stem cemented 9/150mm	MUTARS®	P34197
43	52401510	52401510 MUTARS® humerus stem cemented 10/150mm	MUTARS®	P34197
44	52401511	52401511 MUTARS® humerus stem cemented 11/150mm	MUTARS®	P34197
45	52401512	52401512 MUTARS® humerus stem cemented 12/150mm	MUTARS®	P34197
46	52401513	52401513 MUTARS® humerus stem cemented 13/150mm	MUTARS®	P34197
47	52401514	52401514 MUTARS® humerus stem cemented 14/150mm	MUTARS®	P34197
48	52401515	52401515 MUTARS® humerus stem cemented 15/150mm	MUTARS®	P34197
49	52401516	52401516 MUTARS® humerus stem cemented 16/150mm	MUTARS®	P34197
50	52500000	52500000 MUTARS® dist. humerus 50mm incl. axle, safety screw and 2 locking screws	MUTARS®	P40124
51	52500004	52500004 MUTARS® accessories for dist. humerus: axle, counter- and locking screws	MUTARS®	P40124
52	52510000	52510000 MUTARS® dist. Humerus HD 50mm incl. axle, safety screw and 2 locking screws	MUTARS®	P40124
53	52502300	52502300 MUTARS® dist. humerus 30mm incl. axle, covers and safety screw	MUTARS®	P40124
54	52512300	52512300 MUTARS® dist. humerus HD 30mm incl. axle, covers and safety screw	MUTARS®	P40124
55	52300125	52300125 MUTARS® screw for dist. humerus M6x12.5mm SW5	MUTARS®	P40124
56	52300200	52300200 MUTARS® screw for dist. humerus M6x20mm SW5	MUTARS®	P40124
57	52300225	52300225 MUTARS® screw for dist. humerus M6x22.5mm SW5	MUTARS®	P40124
58	52300250	52300250 MUTARS® screw for dist. humerus M6x25mm SW5	MUTARS®	P40124
59	52300275	52300275 MUTARS® screw for dist. humerus M6x27.5mm SW5	MUTARS®	P40124
60	52300300	52300300 MUTARS® screw for dist. humerus M6x30mm SW5	MUTARS®	P40124
61	52501015	52501015 MUTARS® ulna anchorage cementless left cpTi/HA	MUTARS®	P40124
62	52501020	52501020 MUTARS® ulna anchorage cementless right cpTi/HA	MUTARS®	P40124
63	52501040	52501040 MUTARS® ulnar component HD cementless right	MUTARS®	P40124
64	52501045	52501045 MUTARS® ulnar component HD cementless left	MUTARS®	P40124
65	52505070	52505070 MUTARS® ulnar component cemented 70mm left	MUTARS®	P40124
66	52505100	52505100 MUTARS® ulnar component cemented 100mm left	MUTARS®	P40124
67	52500070	52500070 MUTARS® ulnar component cemented 70mm right	MUTARS®	P40124

68	52500100	52500100 MUTARS® ulnar component cemented 100mm right	MUTARS®	P40124
69	52500030	52500030 MUTARS® prox. ulna incl. safety screw	MUTARS®	P40124
70	52510030	52510030 MUTARS® prox. ulna HD incl. safety screw	MUTARS®	P40124
71	52501100	52501100 MUTARS® ulna stop	MUTARS®	P40124
72	52200020	52200020 MUTARS® humerus extension piece 20mm	MUTARS®	P40124
73	52200040	52200040 MUTARS® humerus extension piece 40mm	MUTARS®	P40124
74	52200060	52200060 MUTARS® humerus extension piece 60mm	MUTARS®	P40124
75	52210080	52210080 MUTARS® humerus connecting part 80mm	MUTARS®	P40124
76	52300015	52300015 MUTARS® humerus screw M8x15mm	MUTARS®	P40124
77	52300035	52300035 MUTARS® humerus screw M8x35mm	MUTARS®	P40124
78	52300055	52300055 MUTARS® humerus screw M8x55mm	MUTARS®	P40124
79	52300075	52300075 MUTARS® humerus screw M8x75mm	MUTARS®	P40124
80	52000000	52000000 MUTARS® humerus head 50mm incl. safety screw	MUTARS®	P40124
81	52000099	52000099 MUTARS® humerus safety screw	MUTARS®	P40124
82	52100000	52100000 MUTARS® humerus cap small TiN	MUTARS®	P40124
83	52100005	52100005 MUTARS® humerus cap medium TiN	MUTARS®	P40124
84	52100010	52100010 MUTARS® humerus cap large TiN	MUTARS®	P40124
85	52101000	52101000 MUTARS® humerus cap invers TiN	MUTARS®	P40124
86	52101002	52101002 MUTARS® glenosphere symmetric 40mm	MUTARS®	P40124
87	52210000	52210000 MUTARS® humerus reducer 10mm	MUTARS®	P40124
88	52210099	52210099 MUTARS® humerus screw for connecting part	MUTARS®	P40124
89	52210100	52210100 MUTARS® humerus reducer 100mm	MUTARS®	P40124
90	52300815	52300815 MUTARS® screw for dist. humerus 30mm length: 15mm	MUTARS®	P40124
91	52301815	52301815 MUTARS® screw for dist. humerus M6x15mm	MUTARS®	P40124
92	52301820	52301820 MUTARS® screw for dist. humerus M6x20mm	MUTARS®	P40124
93	52301825	52301825 MUTARS® screw for dist. humerus M6x25mm	MUTARS®	P40124
94	52301830	52301830 MUTARS® screw for dist. humerus M6x30mm	MUTARS®	P40124
95	52500001	52500001 MUTARS® axle for dist. humerus	MUTARS®	P40124
96	52500003	52500003 MUTARS® locking screw for dist. humerus	MUTARS®	P40124
97	52500030	52500030 MUTARS® prox. ulna incl. safety screw	MUTARS®	P40124

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:

- 1 Proteze pentru articulații:
 - MUTARS® Humerus System

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Semnătura _____

Kojevnikov Dmitrii, director

Data 04/12/2023