

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.

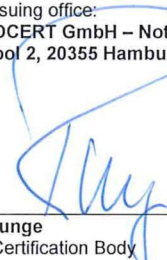
Place and date:
Hamburg, 2022-11-04



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

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



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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



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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

