

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chişinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Anexa nr. 8
la Documentația standard nr.115
din 15.09.2021

DECLARAȚIE privind valabilitatea ofertei

Către **IMSP Institutul de Medicină Urgentă**

Stimați domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea Consumabilelor pentru craniotom - Elan 4, Aesculap Inc, prin procedura de achiziție nr.ocds-b3wdp1-MD-1727953226106, ID: 21287487 din 15.10.2024, pentru o durată de 60 zile (șaizeci zile) din data deschiderii, și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 09.10.2024

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)



I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. 1968 din 01.02.2019

Denumirea completă: **SOCIETATEA CU RĂSPUNDERE LIMITATĂ
«TEHNOMEDICA»** .

Denumirea prescurtată: «TEHNOMEDICA» S.R.L. .

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1002600053256.**

Data înregistrării de stat: **17.04.2002.**

Sediul: **MD-2001, str. Ciuflea, 38/1, mun.Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1 Fabricarea utilajului medical și chirurgical și a dispozitivelor ortopedice;**
- 2 Comerțul cu ridicata al produselor farmaceutice;**
- 3 Comerțul cu amănuntul al produselor farmaceutice;**
- 4 Practica medicală;**
- 5 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 6 Activități de consultare pentru afaceri și management.**

Capitalul social: **5400 lei.**

Administrator: ROIBU TATIANA,

Asociați:

- 1. ROIBU TATIANA 100 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 01.02.2019

Specialist coordonator
tel. 022-20-7838



Clichici Elena



EB 0257484

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNOMEDICA"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1002600053256

Data înregistrării

17.04.2002

Data eliberării

16.02.2005

Bolboceanu Adela, registruator de stat

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

semnătura

MD 0027040



Nr. CIF26-842.2020
Data: 13 Februarie 2020

**CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE**

Prin prezentul, **Mobiasbanca - OTP Group S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **TEHNOMEDICA S.R.L.** cod fiscal (IDNO) **1002600053256**, detine următoarele conturi curente la Mobiasbanca - OTP Group S.A., Sucursala. 26 Negruzzi:

1. **MDL - MD65MO2224ASV98310887100**
2. **EUR - MD06MO2224ASV98311097100**


L.S.
Numele, Prenumele si Semnătura
Director sucursalei „Gheorghe Mocanu”



Executor :Eduard Cilic
Tel: 022-812-150

TEHNOMEDICA

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e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către IMSP Institutul de Medicină Urgentă

În atenția Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1727953226106,
ID: 21287487

DECLARAȚIE

privind înregistrarea în Registrul de Stat al Dispozitivelor Medicale al Agenției Medicamentului și Dispozitivelor Medicale

Prin prezenta, declarăm că produsele oferite în cadrul procedurii prenotate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale.

Dovada înregistrării dispozitivelor medicale se regăsește pe pagina web a Agenției Medicamentului și Dispozitivelor Medicale www.amdm.gov.md.

DM000411415	ELAN 4 ELECTRO CONTROL UNIT	GA800	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-00013
DM000411424	ELAN 4 ELECTRO CRANIOTOME 2-RING	GA849	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-00013
DM000515040	ELAN 4 2-RING CRANIOTOME CUTTER STANDARD	GP342R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000513925	CRANIAL PERFORATOR 12/15MM HUDSON SHANK	GB304R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514780	ELAN 4 1-RING ROSEN BURR D3.0	GP124R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514786	ELAN 4 1-RING ROSEN BURR D4.0	GP126R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514796	ELAN 4 1-RING ROSEN BURR D6.0	GP129R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514774	ELAN 4 1-RING ROSEN BURR+ D2.3	GP121R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514830	ELAN 4 1-RING DIAMOND BURR+ D2.7	GP152R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514832	ELAN 4 1-RING DIAMOND BURR D3.0	GP153R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514836	ELAN 4 1-RING DIAMOND BURR D4.0	GP155R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514842	ELAN 4 1-RING DIAMOND BURR D6.0	GP158R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514884	ELAN 4 1-RING TWIST DRILL D2.0	GP189R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514898	ELAN 4 1-RING NEURO CUTTER+ SOFT D2.0	GP202R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514904	ELAN 4 1-RING NEURO CUTTER+ SOFT D3.0	GP205R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514956	ELAN 4 1-RING REVERSE TAPER BURR D4.0	GP238R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123
DM000514942	ELAN 4 1-RING BARREL BURR SOFT D5.0	GP229R	Germania	AESULAP AG	TEHNOMEDICA S.R.L.	Rg04-000123

Cu respect,

Director

Tatiana Roibu

Attachment to Declaration of 2014-11-26

Aesculap Product Groups
Surgical, diagnostic and dental instruments
Joint implants (hip, knee)
Spinal implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor systems
Sterilization containers and accessories
High frequency surgery devices
Endoscopic systems
Navigation systems
Surgical suction pumps
Special suture-sets
Implants for replacement of connective tissue
Tissue adhesives
Vascular prostheses and accessories
Local haemostatics
Other surgical accessories

EU Quality Management System Certificate

Certificate no.
7400GB448230921

Final Assessment Report no.
7400AU08F

Effective date
2023-09-21

Expiry date
2025-11-15

This is to certify that the quality system of

Aesculap AG

Am Aesculap-Platz, 78532 Tuttlingen, Germany

SRN: DE-MF-000005504

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX Chapter I 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 certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2023-09-21



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

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



Lorenz Runge
Director Certification Body

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



Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

Preceding certificate

Certificate no.	Issue date	Identification of changes
7400GB448220414	2022-04-14	Extension by class IIa + Intended purpose class IIb, WO-009751, WO-010862

Sites covered by this certificate

Aesculap AG, Am Aesculap-Platz, 78532 Tuttlingen, Germany



Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

Products covered by this certificate

Class I medical devices

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	Class	Medical devices/groups of medical devices
MDN 1208	Ir	Non-active non-implantable instruments

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0202	Z120111	Instruments for operative microscopy
MDN 1208	K010201	Minimally invasive surgery surgical instruments, single-use
MDN 1208	L031205	Orthopaedic surgery trocar, reusable
MDN 1208	L070702	Cardiac dilators and retractors, reusable
MDN 1208	L091099	Osteosynthesis instruments, reusable - other
MDN 1208	L091102	Orthopaedic prostheses reamers and burs, reusable
MDN 1208	L091199	Orthopaedic prosthetics instruments, reusable - other
MDN 1208	L110501	Vertebral surgery spreaders and retractors, reusable
MDN 1208	P091203	Bone fixation wires
MDN 1208	P091303	Orthopaedic implant drill bits, single-use
MDN 1208	P091399	Orthopaedic implant instruments, single-use - other
MDN 1208	V0199	Cutting devices, single-use - other
MDN 1208	Z120114	Surgical navigation instruments
MDN 1208	Z120190	Various instruments for general and multidisciplinary surgery
MDN 1208	Z120207	Genitourinary endoscopy instruments
MDN 1208	Z120209	Neuroendoscopy instruments
MDN 1208	Z120211	Orthopaedic endoscopy instruments
MDN 1208	Z120290	Various instruments for endoscopy and mini-invasive surgery
MDN 1208	Z121305	Motorised orthopaedic surgery system instruments

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090701	Spinal fusion systems

Intended purpose

TA012095: PEEK Cages are used as follows:

- CeSPACE® PEEK: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® PEEK: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- TSPACE® PEEK: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

TA012353: Titanium cages are used as follows:

- CeSPACE® Ti: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® Ti PLIF: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- PROSPACE® Ti TLIF: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental
- TSPACE® Ti: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

TA013625: PLASMAPORE XP® Cages are used as follows:

- CeSPACE® XP: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® XP: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- TSPACE® XP: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

TA015914: 3D Cages are used as follows:

- CeSPACE® 3D: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® 3D: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- PROSPACE® 3D Oblique: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental
- TSPACE® 3D: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090703	Implantable vertebral stabilisation or fixation systems

Intended purpose

TA009693: The ABC implants are used exclusively for anterior monosegmental and multisegmental stabilization of the cervical spine in the region from C2 to Th1.

TA011187: The S4 Spinal System Implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. They comprise: ■ Mono/polyaxial screws ■ Rods ■ Hook ■ Cross connector ■ Rod connectors – parallel, axial and lateral offset ■ appropriate fixation elements. Special instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the lumbar and thoracic spine.

TA011700: The ABC implants are used exclusively for anterior monosegmental and multisegmental stabilization of the cervical spine in the region from C2 to Th1.

TA012865: The S4 Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. The S4 Spinal System – augmentation screw can be fixed with bone cement to increase anchoring stability. In this case, the injection cannula is inserted in the S4 Spinal System – augmentation screw for application of the bone cement. The S4 Spinal System - augmentation screw comprises: ■ S4 Monoaxial/polyaxial screws (augmentation screw), supplied in sterile condition ■ S4 Element monoaxial/polyaxial screws (augmentation screw), supplied in sterile condition ■ Cement injection cannula (sterile), see TA013132 ■ for percutaneous application with S4 Element monoaxial/polyaxial screws (augmentation screws): S4 Element Augmentation instruments, see TA014315.

Note: There are special S4 instruments provided for the implantation of these system components and for the augmentation, distraction, compression, and reduction of the lumbar and thoracic spine.

TA013366: The Quintex cervical plating system is used for the anterior monosegmental and multisegmental stabilization of the cervical spine.

TA013579: Note: The S4 Spinal System – in sterile condition is addressed in general in the operating instructions for the S4 Spinal System – Lumbar/Deformity TA011187. This information on the sterile-packaged S4 implants supplements the respective information in the instructions for use of the S4 Spinal System – Lumbar/Deformity. The S4 Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. The parallel (closed and open) and axial rod connectors are connected to S4 Spinal System rods in order to connect a rod parallel or in line with another rod. The lateral offset connectors are connected to the S4 Spinal System rods in order to place a screw offset. The rod connectors thus extend the rod to the adjacent spinal column segments. The S4 Spinal System – sterile-packaged comprises: ■ Rod connector – parallel (closed and open), axial and lateral offset connectors.

Note: Special S4 instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the lumbar and thoracic spine.

TA014887: The Ennovate Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar, thoracic and sacral spine.

TA015555: The ArcadiusXP L Interbody Fusion System is a stand alone device intended to be used with four bone screws if no supplement fixation is used to stabilize the lumbar spine through an anterior approach. The system contains: ■ Cages in different heights, angles and footprints ■ Bone screws in different lengths.

TA015777: The Ennovate Cervical Spinal System implants are used for the posterior monosegmental and multisegmental stabilization of the occipitocervical junction and of the cervical and upper thoracic spine. The system consists of: Occiput plates and screws, Rods, Polyaxial screws, Bone screws, Set screws, Hook, Cross connectors (head-to-head cross connectors, rod-to-rod cross connectors), Other connectors, Laminoplasty plate. The Ennovate Cervical laminoplasty plate is intended for use in the cervical spine (C3-C6) after a unilateral laminoplasty has been performed. It is fixated to the lamina with the SecureSpan screws. Surgically installed implants serve to support the normal healing process. They are not supposed to replace normal body structures or to support permanent loads that occur in cases where healing does not occur. The laminoplasty plate should be used with a stabilization block (by e.g. a bone graft). Appropriate implant components from Ennovate Spinal System (e.g. rods) can also be used. Special instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the thoracolumbar spine.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090703	Implantable vertebral stabilisation or fixation systems

Intended purpose

TA018000: The ArcadiusXP C spinal system is intended to be used as an intervertebral body fusion cage as a standalone system used with two bone screws. It is inserted between the vertebral bodies into the disc space from C2 to T1 in skeletally mature patients.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090803	Hip prostheses acetabular components

Intended purpose

TA013800: The implant is used: ■ As a component of a human hip endoprosthesis: Hip endoprosthesis cup, consisting of outer cup Plasmafit® Poly or Plasmafit® Plus, possibly central screw plug, possibly anchoring screws and modular Plasmafit® inserts (standard, asymmetrical or with shoulder) ■ In combination with Aesculap hip endoprosthesis components ■ In combination with implant components explicitly approved by Aesculap ■ For implantation without bone cement.

Note: The options of patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090880	Hip prostheses - accessories

Intended purpose

TA008056: The Centralizer is used as an additional guide when using cemented Aesculap endoprosthesis stems. It acts as a guide for the distal tip of the prosthesis when inserting the stem into the bone cement. If the correct size has been selected, the Centralizer guarantees a closed and uniform cement socket.

Different outer diameters are available for centralizers; they are marked on the packaging. The selection of the correct centralizer depends on the Aesculap hip implant stem used or the Aesculap knee implant component used, and the operative preparation and size of the medullary cavity. Observe the instructions for use for the Aesculap endoprosthesis components used.

The Centralizer is used with Aesculap Endoprosthesis Centrament, Bicontact, Excia, SLA, Vega and Columbus.

TA009897: The anchoring screws are used in combination with Aesculap acetabular implants. They are used to increase stability in the event of insufficient primary stability in Plasmacup® and Plasmafit® press fit cups and to secure the Aesculap reconstruction cup and the acetabular Structan® Augment in the bone. The 6.5 mm anchoring screws may only be used as explained below: ■ in combination with Aesculap hip endoprosthesis components ■ in combination with implant components explicitly approved by Aesculap ■ in compliance with the instructions for use of the individual implant components ■ in the listed implant systems according to their color coding. Color coding of anchoring screws / Permissible use - Yellow oxide layer Plasmacup® and Aesculap recon ring - Blue oxide layer Plasmafit® and acetabular Structan® Augment. Anchoring screws are available in different lengths. Note: The options of patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

TA012315: For use with a cemented Trilliance or CoreHip hip endoprosthesis stem.
See instructions for use of Trilliance-/CoreHip hip endoprosthesis stems.

TA012526: The implant is used: ■ as a component part of a human hip endoprosthesis: Locking screw ■ in combination with Aesculap hip endoprosthesis stems with locking holes ■ in combination with implant components explicitly approved by Aesculap ■ in compliance with the instructions for use of the individual implant components.

The locking screws are intended for the fixation of above-mentioned implant components that allow distal locking. The operating surgeon decides, depending on the indication, if and to what degree implant locking is necessary. Note: The options of patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

TA013723: The implant is used: ■ as a component of a human hip endoprosthesis: augmentation implant for filling of acetabular bone defects ■ in combination with Aesculap hip endoprosthesis components: Plasmafit, Plasmafit Revision, Plasmacup, cemented PE cups ■ in combination with implant components explicitly approved by Aesculap ■ in combination with hip endoprosthesis cups with the same nominal diameter, or one that is a maximum of 4 mm smaller/larger ■ in combination with bone cement at the interface to the hip cup.

The anchoring screws must only ever be used as follows: ■ In compliance with the instructions for use of the individual implant components ■ In the stated implant systems according to their color coding.

Yellow oxide layer - Plasmacup; Blue oxide layer - Plasmafit Plus, Plasmafit Revision, Structan acetabulum augmentation implant; Pink oxide layer - Structan acetabulum augmentation implant.

Note: The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

TA015599: The 4.5 mm anchoring screws are used in conjunction with Aesculap acetabulum implants. It serves to secure the Structan® acetabulum augmentation in the bone. The 4.5 mm anchoring screws may only be used as follows: ■ In compliance with the instructions for use of the individual implant components ■ In the stated implant systems according to their color coding.

Pink oxide layer - Structan® acetabulum augmentation.

The anchoring screws are available in various lengths.



Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090908	Knee prostheses spacers

Intended purpose

TA016100: The implant is used:

- as a component of a human knee endoprosthesis that consists of a femoral, tibial and meniscal implant component and possibly patella, extension stems and augment implants
- in combination with implant components explicitly approved by Aesculap
 - univation® X
 - Columbus®
 - e.motion®
 - VEGA System®
 - EnduRo
- for implantation without bone cement with PLASMAPORE® or PLASMAPORE® µ-CaP coated implants and cementless extension stems
- for implantation with bone cement for other knee implants including All-poly tibia implants except meniscal components.

Note: The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090980	Knee prostheses - accessories

Intended purpose

TA016100: The implant is used:

- as a component of a human knee endoprosthesis that consists of a femoral, tibial and meniscal implant component and possibly patella, extension stems and augment implants
- in combination with implant components explicitly approved by Aesculap
 - univation® X
 - Columbus®
 - e.motion®
 - VEGA System®
 - EnduRo
- for implantation without bone cement with PLASMAPORE® or PLASMAPORE® µ-CaP coated implants and cementless extension stems
- for implantation with bone cement for other knee implants including All-poly tibia implants except meniscal components.

Note: The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems

Category	EMDN code	Medical devices/groups of medical devices
MDN 1104	H030102	Singular clips for open surgery

Intended purpose

TA013486: The DS titanium ligation-clips are used for the ligation of vessels and hollow organs and for marking anatomical structures

Class III custom-made implantable medical devices

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



Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

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
MDA 0312	Other active non-implantable surgical devices
MDN 1101	Non-active cardiovascular, vascular and neurovascular implants
MDN 1102	Non-active osteo- and orthopaedic implants
MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1208	Non-active non-implantable instruments