EU Quality Management Certificate

This is to certify that the company

KLS martin GROUP

KLS Martin SE & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

SRN: DE-MF-000005551
has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	210299 MDR2017Q
Certificate ID	1000236412
Effective date	2025-06-24
Expiry date	2027-05-24
Frankfurt am Main,	2025-06-24

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to EU Quality Management Certificate
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Device categories and variants covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	L1 Mandible Resection Guide
Risk classification:	I (reusable)
Basic-UDI-DI:	405760559NZ
Intended purpose:	The **resection guides** are used as aids during mandibular reconstruction with microvascular fibula graft by enabling osteotomies on the mandible and fibula based on a defined and coordinated cutting pattern. While the guides are applied, the created fibula segments can be fixed osteosynthetically in angular position.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Surgical Needles
Risk classification:	I (reusable)
Basic-UDI-DI:	40576053275K
Intended purpose:	The **surgical needles** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient piercing, severing and suturing of tissues, vessels and organs in combination with suture material during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scissors
Risk classification:	I (reusable)
Basic-UDI-DI:	405760535NK
Intended purpose:	The **scissors, osteotomes, chisels and dissecting instruments** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient cutting, piercing, severing, scraping, preparing of tissues, vessels, organs, bones and dressing materials or other medical auxiliary materials during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Osteotomes and bone chisels
Risk classification:	I (reusable)
Basic-UDI-DI:	405760539NT
Intended purpose:	The **scissors, osteotomes, chisels and dissecting instruments** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient cutting, piercing, severing, scraping, preparing of tissues, vessels, organs, bones and dressing materials or other medical auxiliary materials during a surgical use.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Forceps
Risk classification:	I (reusable)
Basic-UDI-DI:	405760549NW
Intended purpose:	The **forceps and pliers** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient dissecting, grasping, fixation of endogenous tissues, skin, organs, bones, implants, dressing materials or other medical auxiliary materials during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Pliers
Risk classification:	I (reusable)
Basic-UDI-DI:	405760560NJ
Intended purpose:	The **forceps and pliers** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient dissecting, grasping, fixation of endogenous tissues, skin, organs, bones, implants, dressing materials or other medical auxiliary materials during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Wound Hooks and Spreaders
Risk classification:	I (reusable)
Basic-UDI-DI:	405760563NQ
Intended purpose:	The **wound hooks, levers and spreader** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient holding, lifting, positioning and retracting of tissues, organs, bones and wound edges during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sliding shaft instruments
Risk classification:	I (reusable)
Basic-UDI-DI:	405760537NP
Intended purpose:	The **slide shaft instruments** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient preparation and removal of cartilage, bones and tissues during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Needle holders
Risk classification:	I (reusable)
Basic-UDI-DI:	405760566NW
Intended purpose:	The **needle holders** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient holding and grasping of needles and sutures during a surgical use.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dissecting Intruments
Risk classification:	I (reusable)
Basic-UDI-DI:	405760538NR
Intended purpose:	The **osteotomes, chisels and dissecting instruments** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient cutting, piercing, severing, scraping, preparing of tissues, vessels, organs, bones and dressing materials or other medical auxiliary materials during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Probes, dilators and bougies
Risk classification:	I (reusable)
Basic-UDI-DI:	40576051485H
Intended purpose:	The **probes, dilators and bougies** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient extending, enlarging, probing, palpating, examination of tissues, organs and foreign bodies during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Trocars
Risk classification:	I (reusable)
Basic-UDI-DI:	405760514255
Intended purpose:	A **trocar** is a surgical instrument to pierce body tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Knives and Handles
Risk classification:	I (reusable)
Basic-UDI-DI:	40576053255F
Intended purpose:	The **knives and their handles** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient cutting, piercing, severing, scraping, and preparing of tissues, vessels and organs during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Saws and manual hand drills
Risk classification:	I (reusable)
Basic-UDI-DI:	40576053285M
Intended purpose:	The **saws and manual hand drills** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient severing and drilling of bones during a surgical use.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dental instruments surgical invasive
Risk classification:	I (reusable)
Basic-UDI-DI:	40576053195L
Intended purpose:	The **dental instruments** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient holding, grasping, cutting and retracting of tissues, teeth and bones during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cutting Guides
Risk classification:	I (reusable)
Basic-UDI-DI:	40576053986A
Intended purpose:	The **cutting guides** are reusable surgically invasive instruments that are not used in combination with an active product and whose function is to temporarily guide saw blades to achieve accurate osteotomies.

evice category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Drill Guides
Risk classification:	I (reusable)
Basic-UDI-DI:	405760514153
Intended purpose:	The **drill guides and protection sleeves** are reusable, surgically-invasive instruments that are not used in conjunction with an active product and whose function is to briefly guide drills and screws, as well as to protect the surrounding tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Instr. for CranioXpand
Risk classification:	I (reusable)
Basic-UDI-DI:	405760553NM
Intended purpose:	**CranioXpand instruments** are reusable, surgically invasive instruments that are not used in conjunction with an active product and whose function is to determine the appropriate size of the CranioXpand implant and to allow its placement and removal during the surgical procedure.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Screwdrivers non active
Risk classification:	I (reusable)
Basic-UDI-DI:	40576051404Z
Intended purpose:	**Tightening screwdrivers** are reusable, surgically invasive devices, the function of which is transient application to insert / remove a screw into / from a patient or device during a surgical procedure.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Guiding and comparative instruments
Risk classification:	I (measuring)
Basic-UDI-DI:	405760516159
Intended purpose:	The **Instruments** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the transient measuring, gauging and comparing of vessels, tissues, organs, implants, shapes and geometries, medical auxiliary materials during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Vigorimeter
Risk classification:	I (measuring)
Basic-UDI-DI:	40576053535L
Intended purpose:	The **Vigorimeter** is a temporary reusable diagnostic medical device for measuring finger or hand strength.

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	maxium
Risk classification:	IIb
Basic-UDI-DI:	40576051775Q
Intended purpose:	The **maxium® electrosurgical unit** is used to deliver high-frequency electrical current for cutting and coagulating human tissue.

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	maxium Beamer
Risk classification:	IIb
Basic-UDI-DI:	40576054145F
Intended purpose:	The **maxium® Beamer** is intended to deliver argon gas for argon plasma coagulation and ablation of tissue as well as argon-assisted cutting of human tissue when used in conjunction with a compatible KLS Martin Electrosurgical Generator and applicators or probes.

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	ME 102 Electrosurgical Unit
Risk classification:	IIb
Basic-UDI-DI:	40576053435H
Intended purpose:	The **ME 102 electrosurgical unit** is used to deliver high frequency electrical current for the cutting and coagulation of human tissue**.**

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	Minicutter
Risk classification:	IIb
Basic-UDI-DI:	40576053425F
Intended purpose:	The **Minicutter electrosurgical unit** is intended to deliver high frequency electrical current for cutting and coagulating of human tissue.

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Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	maxium Sealer
Risk classification:	IIb
Basic-UDI-DI:	40576053475R
Intended purpose:	The **maxium® sealer** is intended to deliver a high frequency bipolar current for compatible instruments intended for vessel sealing applications. The specific application will depend on the compatible surgical instrument connected to the generator.

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	maxium smart C
Risk classification:	IIb
Basic-UDI-DI:	40576051785S
Intended purpose:	The **maxium® smart C electrosurgical unit** is used to deliver high-frequency electrical current for cutting and coagulating human tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Instruments for central nervous systems
Risk classification:	III
Basic-UDI-DI:	405760544 NL
Intended purpose:	The **instruments** are reusable surgically invasive instruments that are not used in connection to an active product and which are specially intended for use in direct contact with the central nervous system and whose function is in the transient holding, grasping, cutting, retracting and sawing of tissues and bones during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Clamps
Risk classification:	IIa
Basic-UDI-DI:	405760558NX
Intended purpose:	The **clamps** are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the short term grasping, fixation of endogenous tissues, skin, organs, bones, implants, dressing materials or other medical auxiliary materials during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Rotating Tools - cutting steril
Risk classification:	IIa
Basic-UDI-DI:	405760513354
Intended purpose:	The **rotating cutting tools** are single-use, surgically invasive products used in con-junction with an active product whose function is the short-term drilling and re-moval of tissue, bone and dentin during a surgical procedure.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Rotating Tools - cutting non-sterile
Risk classification:	IIa
Basic-UDI-DI:	405760513456
Intended purpose:	The **rotating cutting tools** are single-use, surgically invasive products used in con-junction with an active product whose function is the short-term drilling and re-moval of tissue, bone and dentin during a surgical procedure.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Rotating Tools - non cutting
Risk classification:	IIa
Basic-UDI-DI:	40576051365A
Intended purpose:	**Screwdriver blades, holding and extraction sleeves** are reusable, surgically invasive devices that can be used in conjunction with an active device and their function is transient application to insert / remove a screw into / from a patient or device during a surgical procedure.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Templates steril
Risk classification:	IIa
Basic-UDI-DI:	40576051375C
Intended purpose:	**Templates** are surgically invasive single-use devices which are intended for transient use (not intended for connection to an active device). The function of the templates is to determine the correct size, contour and/or positioning of an osteosynthesis implant before or during implantation.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Templates non-sterile
Risk classification:	IIa
Basic-UDI-DI:	40576051385E
Intended purpose:	**Templates** are surgically invasive single-use devices which are intended for transient use (not intended for connection to an active device). The function of the templates is to determine the correct size, contour and/or positioning of an osteosynthesis implant before or during implantation.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sizers
Risk classification:	IIa
Basic-UDI-DI:	40576051395G
Intended purpose:	**Sizers** are reusable, surgically invasive devices which are intended for transient use (not intended for connection to an active device. The function of the sizers is to determine the correct size and/or positioning of an osteosynthesis implant before or during implantation

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Reposition Instruments sterile
Risk classification:	IIa
Basic-UDI-DI:	40576051455B
Intended purpose:	The **instruments** are surgically invasive single-use devices intended for temporary use for reduction and/or fixation of bone fragments and/or implants.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Reposition Instruments non-sterile
Risk classification:	IIa
Basic-UDI-DI:	40576051465D
Intended purpose:	The **instruments** are surgically invasive single-use devices intended for temporary use for reduction and/or fixation of bone fragments and/or implants.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Instruments for suction and irrigation
Risk classification:	IIa
Basic-UDI-DI:	40576051625B
Intended purpose:	The **instruments** are reusable surgically invasive instruments that are used in connection to an active product and whose function is in the transient suction and irrigation of liquids and parts of tissues during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sterile scalpels and scalpel blades
Risk classification:	IIa
Basic-UDI-DI:	40576051855P
Intended purpose:	The sterile **scalpels and scalpel blades** are surgically invasive instruments for single use that are not used in connection to an active product and whose function is in the transient cutting, piercing of vessels, tissues and organs during a surgical use.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	marTract wound spreading system
Risk classification:	IIa
Basic-UDI-DI:	40576053335E
Intended purpose:	The **marTract** wound spreader systems are reusable surgically invasive instruments that are not used in connection to an active product and whose function is the short term holding, lifting, positioning and retracting of tissues, organs, bones and wound edges during a surgical use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Retractors and Wound spreading Systems
Risk classification:	IIa
Basic-UDI-DI:	405760565NU
Intended purpose:	The **retractors and wound spreading** systems are reusable surgically invasive instruments that are not used in connection to an active product and whose function is in the short term holding, lifting, positioning and retracting of tissues, organs, bones and wound edges during a surgical use.

Device category:	**MDN 1102 - Non-active osteo- and orthopaedic joint implants**
Product name:	CapFlex PIP prosthesis
Risk classification:	III
Basic-UDI-DI:	40576052945V
Intended purpose:	**Implantable prosthesis** for long-term use as an endoprosthetic replacement for the proximal interphalangeal joints of the hand.

Examinations and tests performed:
210299_A209145MED_02 dated 2022-09-16
210299_A209145MED_03 dated 2023-03-24
210299_A209145MED_QMS_V4 dated 2022-05-05
210299_A209145MED L1 Mandible Resection Guide dated 2021-10-29
210299_A212895MED_V2 dated 2024-07-03
210299_A212407MED_V3 dated 2024-08-13
210299_A215580MED maXium dated 2024-11-28
210299_A212703MED_Clamps dated 2024-10-31
210299_A212589MED_Templates dated 2024-10-23
210299_A212741MED_Ulnakopfprothese (UHP) dated 2025-02-07
210299_A212893MED_CapFlex PIP prosthesis dated 2025-03-25

Further conditions for or limitations to the validity of the certificate:
In the case of reusable surgical instruments, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing, as well as the related instructions for use.

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Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-05-25	170778446	Addition of the product “maxium”
02	2022-11-02	170781677	Revision Intended Purpose of “maxium”
03	2022-12-08	170782325	Addition of the product “maxium Beamer” and further products class I(reusable) -osteotomes, chisels and dissecting instruments
04	2023-06-22	170782501	Change of company name to KLS Martin SE & Co. KG & Addition of the product „Guiding and Comparative Instruments“
05	2023-12-06	1000138066	New certificate template and Addition of the products “ME 102 Electrosurgical Unit”, „Minicutter“, „maxium smart C“& „maxium Sealer“
06	2024-07-03	1000167068	Addition of the “CranioXpand springs”
07	2024-08-13	1000186560	Addition of the Instruments for central nervous system
08	2024-09-05	1000195923	Extension to software (maXium)
09	2025-01-09	1000202983	Addition of the products “Sizers, Rotating Tools - cutting steril, Rotating Tools - cutting non-sterile, Clamps, Templates non-sterile, Templates Steril, Rotating Tools - non cutting, Reposition Instruments sterile, Reposition Instruments non-sterile, Retractors and Wound spreading Systems, Sterile scalpels and scalpel blades, Sterile scalpels and scalpel blades, Instruments for suction and irrigation, marTract wound spreading system” Correction of intended use of the products: “Pliers” and “Rotating tools cutting sterile and non-sterile”
10	2025-03-06	1000216682	Addition of the products “Ulna head prosthesis (UHP)” and “CapFlex PIP prosthesis“ and Removal of the product “CranioXpand springs” as of 2025-03-31
11	2025-04-03	1000231122	Removal of the product “Ulna head prosthesis (UHP)” as of 2025-05-31