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. Limitations to this certificate are listed in the Annex.

For placing of devices of class IIa, IIb or III 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	1000138066
Effective date	2023-12-06
Expiry date	2027-05-24
Frankfurt am Main,	2023-12-06

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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Head of Certification Body
(active medical devices)

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Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005551
Certificate ID: 1000138066

Device categories covered by this certificate:

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

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Risk classification:	I (reusable)
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**
Risk classification:	I (reusable)
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**
Risk classification:	I (reusable)
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.

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

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Risk classification:	I (reusable)
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.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Risk classification:	I (reusable)
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.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Risk classification:	I (reusable)
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**
Risk classification:	I (reusable)
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.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Risk classification:	I (reusable)
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**
Risk classification:	I (reusable)
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**
Risk classification:	I (reusable)
Intended purpose:	**Tightening screwdriver** 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

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Risk classification:	I (measuring)
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.

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Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Risk classification:	IIb
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**
Risk classification:	IIb
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.

Examinations and tests performed:
210299_A209145MED_QMS_V4 dated 2022-05-05

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
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
In the case of devices with a measuring function, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to the conformity of the devices with the metrological requirements

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 intruments
04	2023-06-22	170782501	Change of company name to KLS Martin SE & Co. KG & Addition of the product „Guiding and Comparative Instruments"