

EU Quality Management System Certificate

Certificate no.
20320GB448240215

Final Assessment Report no.
20320AU01F

Effective date
2024-02-15

Expiry date
2027-05-11

This is to certify that the quality system of

KLS Martin SE & Co. KG

KLS Martin Platz 1, 78532 Tuttlingen, Germany

SRN: DE-MF-000005551

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,
Chapters I and III 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, 2024-02-15

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



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

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com


Lorenz Runge
Director Certification Body



Certificate no.: 20320GB448240215
Place and date: Hamburg, 2024-02-15

Preceding certificate

Certificate no.	Issue date	Identification of changes
20320GB448220825	2022-08-25	CN 12 (WO-012114), CN 16 (WO-012438)
20320GB448231113	2023-11-13	Class IIb listed per intended purpose
20320GB448240212	2024-02-12	CN 08 (WO-011351)

Sites covered by this certificate

KLS Martin SE & Co. KG, KLS Martin Platz 1, 78532 Tuttlingen, Germany
KLS Martin SE & Co. KG, Am Flughafen 18, 79108 Freiburg im Breisgau, Germany
KLS Martin SE & Co. KG, Kolbinger Straße 10, 78570 Mühlheim an der Donau, Germany
KLS Martin SE & Co. KG, Am Gewerbering 7, 78570 Mühlheim an der Donau, Germany



Products covered by this certificate

Class IIb medical devices, excluding implantable non-WET

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120503	Osteosynthesis screw-plate systems

Intended purpose

The L1 Rib Plating System is indicated for osteosynthesis in the thoracic anatomy.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120503	Osteosynthesis screw-plate systems

Intended purpose

The Osteosynthesis systems include implantable single-use devices that are used for internal fixation after alignment, reconstruction and stabilization of bone tissue.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120503	Osteosynthesis screw-plate systems

Intended purpose

The products are non-active implants, which are intended to temporary stabilize bone or bone fragments

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120599	Bone fixation plates - other

Intended purpose

The maxillary distractors are implantable single-use products designed to distract the maxillary bone.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120599	Bone fixation plates - other

Intended purpose

The cranial distractors are implantable single-use products designed to distract the cranial bone.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120599	Bone fixation plates - other

Intended purpose

The midface distractors are implantable single-use products designed to distract the midfacial bones.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120599	Bone fixation plates - other

Intended purpose

The mandibular transversal distractors are implantable single-use products designed to transversally distract the mandibular bone.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120599	Bone fixation plates - other

Intended purpose

The alveolar distractors are implantable single-use products designed to distract the mandibular or maxillary bone.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120599	Bone fixation plates - other

Intended purpose

Distractors for hand and foot surgery are implantable single-use products designed to distract bones of the extremities.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P09120599	Bone fixation plates - other

Intended purpose

The mandibular transport distractors are implantable single-use products designed to distract mandibular bones by means of segmental transport.



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Class III custom-made implantable medical devices

Category	Medical devices/groups of medical devices
MDN 1102	Non-active osteo- and orthopaedic implants
MDN 1104	Non-active soft tissue and other implants

