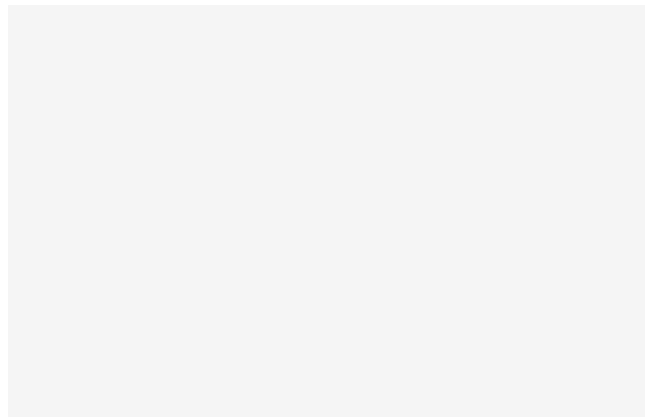




Überreicht durch
With compliments
Atentamente
Avec les compliments de
Con i complimenti



Surgical Innovation is our Passion

max. 134 °C

Hinweis zur Sterilisation:

Unsere wiederverwendbaren Produkte werden im unsterilen Zustand angeliefert und können bei max. 134 °C sterilisiert werden. Einmalprodukte sind hiervon ausgenommen und entsprechend gekennzeichnet.

Note on sterilization:

Our reusable products are supplied in non-sterile condition and can be sterilized at 134°C max. Single-use products are excluded from this and are labeled accordingly.

Nota sobre la esterilización:

Nuestros productos reutilizables se suministran no estériles y se pueden esterilizar a una temperatura máxima de 134 °C. Quedan excluidos de ello los productos desechables que están etiquetados correspondientemente.

Remarque relative à la stérilisation :

Nos produits réutilisables sont fournis à l'état non stérile et peuvent être stérilisés à 134 °C max. Les produits à usage unique en sont exclus et sont marqués en conséquence.

Nota relativa alla sterilizzazione:

I nostri prodotti riutilizzabili sono forniti non sterili e possono essere sterilizzati ad una temperatura massima di 134 °C. Sono esclusi dalla sterilizzazione i prodotti monouso, opportunamente contrassegnati.

Kombi-Instrument für die offenchirurgische Gefäßversiegelung
 Combination instrument for open surgical vessel sealing
 Instrumento combinado para el sellado vascular en cirugía abierta
 Instrument combiné de scellement de vaisseaux sanguins pour la chirurgie ouverte
 Strumento combinato per la sigillatura vascolare nella chirurgia a cielo aperto

marClamp® Cut IQ



- | | | | | |
|----------------------------|---------------------------------|----------------------------------------|--------------------------------------------------|---------------------------------------|
| ✓ Präparieren | Dissect | Disecionar | Disséquer | Sezionare |
| ✓ Versiegeln | Seal | Sellar | Clamper | Sigillare |
| ✓ Trennen | Cut | Cortar | Couper | Separare |
| ✓ Plug & Play | Plug & Play | Plug & Play | Plug & Play | Plug & Play |
| ✓ Kein Instrumentenwechsel | No need to exchange instruments | No es necesario cambiar de instrumento | Il n'est pas nécessaire de changer d'instruments | Senza necessità di cambiare strumento |
| ✓ Wiederverwendbar | Reusable | Reutilizable | Réutilisable | Riutilizzabile |

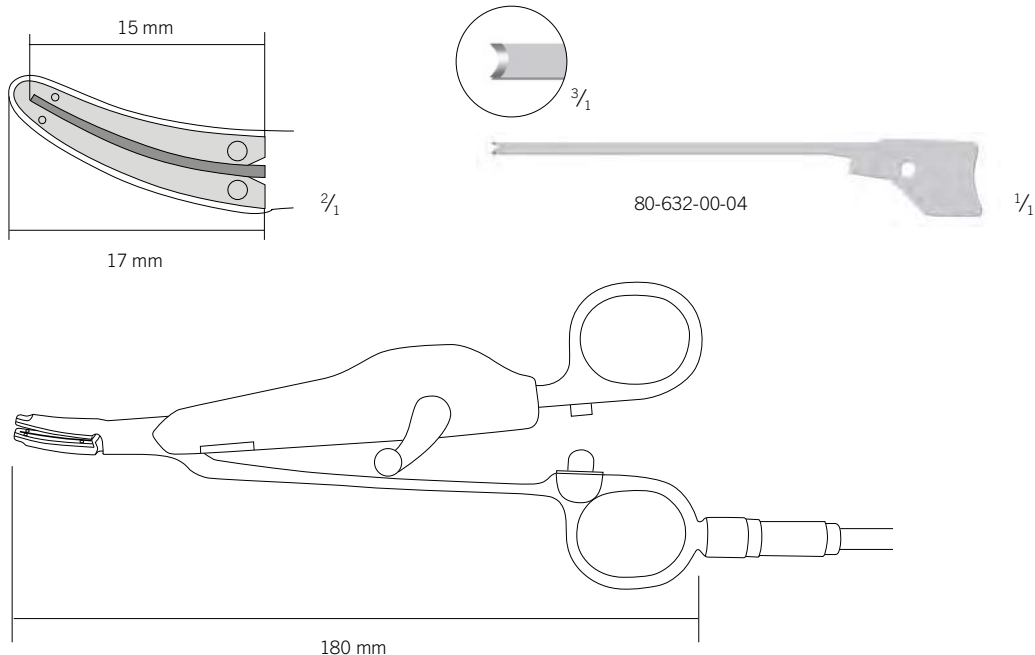
| | marClamp®-Cut-IQ-System Instrument, komplett*, ohne Klingen | marClamp® Cut IQ System Instrument, complete*, without blades | Sistema marClamp® Cut IQ Instrumento, completo*, sin cuchillas |
|--------------|-----------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|
| 80-632-18-04 | marClamp® Cut IQ, 18 cm | marClamp® Cut IQ, 18 cm | marClamp® Cut IQ, 18 cm |

| | Komponenten | Components | Componentes |
|--------------|--------------------------------------------|-------------------------------------------------|------------------------------------------------|
| 80-632-00-04 | Klinge für marClamp® Cut IQ, steril, VE=10 | Blade for marClamp® Cut IQ, sterile, pack of 10 | Cuchilla para marClamp® Cut IQ, estéril, UE=10 |
| 80-630-58-04 | Reinigungswerkzeug | Cleaning tool | Herramienta de limpieza |
| 80-632-01-04 | Set Reinigungsbürsten, 3 Stück | Set of cleaning brushes, 3 pcs. | Juego de cepillos de limpieza, 3 unidades |

* inkl. 80-630-58-04, 80-632-01-04
Klingen müssen separat bestellt werden

* incl. 80-630-58-04, 80-632-01-04
Blades have to be ordered separately

* incl. 80-630-58-04, 80-632-01-04
Las cuchillas se deben encargar por separado



Instrumentarium zur bipolaren Gefäßversiegelung
 Instruments for bipolar vessel sealing
 Instrumentos para el sellado vascular bipolar
 Instruments pour la clampage vasculaire bipolaire
 Strumenti di sigillatura vascolare bipolare



Integrierter Schalter zur Handaktivierung
 Integrated switch for manual activation
 Interruptor integrado para la activación manual
 Interrupteur intégré pour l'activation manuelle
 Interruttore integrato per l'attivazione manuale



5

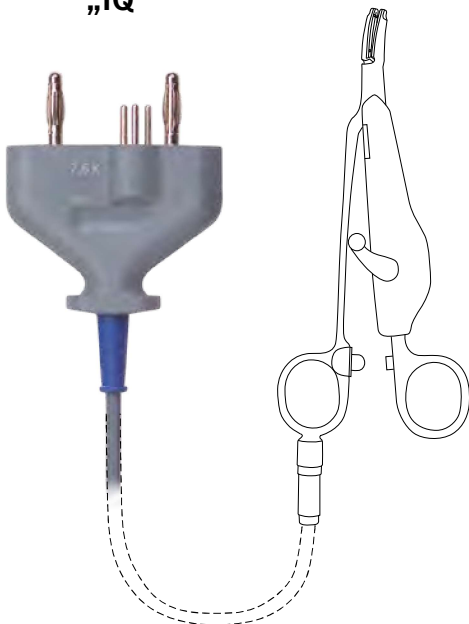
| | | |
|--------------|---------------------------------------------------------------------|---------------------------------------------------------------------|
| | Système marClamp® Cut IQ Instrument, complet*, sans lames | Sistema marClamp® Cut IQ Strumento, completo*, senza lame |
| 80-632-18-04 | marClamp® Cut IQ, 18 cm | marClamp® Cut IQ, 18 cm |

| | | |
|--------------|-------------------------------------------------------|---------------------------------------------------------|
| | Composants | Componenti |
| 80-632-00-04 | Lame pour instrument marClamp® Cut IQ, stérile, UC=10 | Lama per marClamp® Cut IQ, sterile, confezione=10 unità |
| 80-630-58-04 | Outil de nettoyage | Strumento di pulizia |
| 80-632-01-04 | Jeu de brosses de nettoyage, 3 unités | Set di spazzolini di pulizia, 3 pezzi |

* incl. 80-630-58-04, 80-632-01-04
 Les lames doivent être commandées séparément

* incl. 80-630-58-04, 80-632-01-04
 Le lame devono essere ordinate a parte

„IQ“



Weitere Informationen entnehmen Sie bitte der separaten Broschüre.

For further information please refer to our separate product brochure.

Encontrará informaciones adicionales en el folleto individual.

Vous trouverez des informations supplémentaires dans la brochure.

Per ulteriori informazioni vedasi il prospetto separato.

marSeal5 plus – bipolares Gefäßversiegelungssystem
 marSeal5 plus – bipolar vessel sealing system
 marSeal5 plus – sistema de sellado vascular bipolar
 marSeal5 plus – système bipolaire de clampage de vaisseaux
 marSeal5 plus – sistema bipolare di sigillatura dei vasi

marSeal5 plus



Vessel Sealing in a new Dimension!



| | | | | |
|----------------------------|---------------------------------|----------------------------------------|--------------------------------------------------|---------------------------------------|
| ✓ Präparieren | Dissect | Disecionar | Disséquer | Sezionare |
| ✓ Versiegeln | Seal | Sellar | Clamper | Sigillare |
| ✓ Trennen | Cut | Cortar | Couper | Separare |
| ✓ Plug & Play | Plug & Play | Plug & Play | Plug & Play | Plug & Play |
| ✓ Kein Instrumentenwechsel | No need to exchange instruments | No es necesario cambiar de instrumento | Il n'est pas nécessaire de changer d'instruments | Senza necessità di cambiare strumento |
| ✓ Wiederverwendbar | Reusable | Reutilizable | Réutilisable | Riutilizzabile |

| | marSeal5-plus-System Instrument, komplett*, ohne Klinsen | marSeal5 plus System Instrument, complete*, without blades | Sistema marSeal5 plus Instrumento, completo*, sin cuchillas |
|--------------|--------------------------------------------------------------------|----------------------------------------------------------------------|-----------------------------------------------------------------------|
| 80-633-00-04 | marSeal5 plus IQ Schaftlänge 370 mm | marSeal5 plus IQ shaft length 370 mm | marSeal5 plus IQ longitud del vástago 370 mm |

| | Einzelkomponenten | Individual components | Componentes individuales |
|--------------|------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| 80-633-04-04 | Handgriff | Handle | Mango |
| 80-633-05-04 | Rohrschaft, Ø 5 mm, Schaftlänge 370 mm, bestehend aus Außen- und Innenrohr** | Tubular shaft, Ø 5 mm, shaft length 370 mm, consisting of outer and inner tube** | Vástago tubular, Ø 5 mm, longitud del vástago 370 mm, compuesto por tubo externo e interno** |

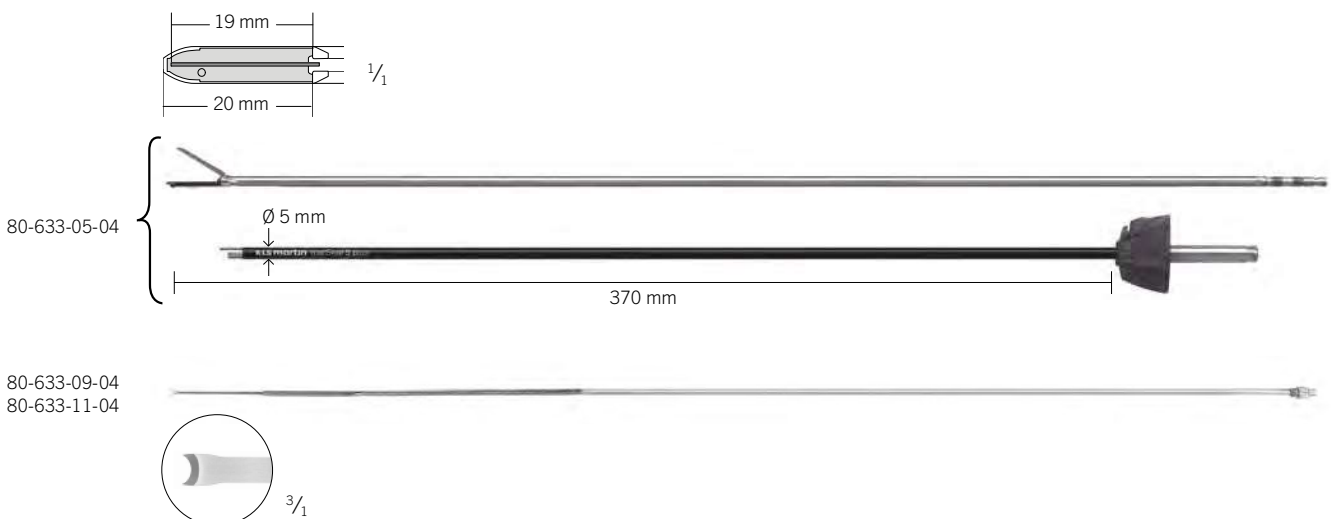
| | Verbrauchsmaterial | Consumables | Consumibles |
|--------------|----------------------------------------------|-------------------------------------------------|----------------------------------------------------|
| 80-633-09-04 | Klingenträger, 370 mm, steril, VE=10 Stück | Blade holder, 370 mm, sterile, PU=10 pieces | Portacuchillas, 370 mm, estéril, UE=10 unidades |
| 80-633-11-04 | Klingenträger, 370 mm, unsteril, VE=10 Stück | Blade holder, 370 mm, non-sterile, PU=10 pieces | Portacuchillas, 370 mm, no estéril, UE=10 unidades |

| | Reinigungs- und Aufbereitungs-Tools | Cleaning and reprocessing tools | Herramientas de limpieza y acondicionamiento |
|--------------|--------------------------------------------|------------------------------------------|-----------------------------------------------------|
| 80-633-12-04 | Reinigungswerkzeug | Cleaning tool | Herramienta de limpieza |
| 80-633-13-04 | Spüladapter für Außen- und Innenrohr | Rinsing adapter for outer and inner tube | Adaptador de lavado por tubo externo e interno |

* inkl. 80-633-12-04, 80-633-13-04
 ** inkl. 80-633-12-04
 Klinsen müssen separat bestellt werden

* incl. 80-633-12-04, 80-633-13-04
 ** incl. 80-633-12-04
 Blades have to be ordered separately

* incl. 80-633-12-04, 80-633-13-04
 ** incl. 80-633-12-04
 Las cuchillas se deben encargar por separado





EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

KLS martin
GROUP

Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Active and non active medical devices, surgical instruments and units, implants, medical devices for RF- and laser surgery, Smoke evacuation systems, Accessories for Smoke evacuation systems, ceiling-mounted supply systems and accessories according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

| | |
|------------------------------|------------|
| Certificate registration no. | 210299 MR2 |
| Certificate unique ID | 170763177 |
| Effective date | 2020-01-13 |
| Expiry date | 2024-05-26 |
| Frankfurt am Main | 2020-01-13 |

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
Certificate registration No.: 210299 MR2
Certificate unique ID: 170763177
Effective date: 2020-01-13



Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

| Device family | Devices | Class |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| RF-surgery units | Medical RF-surgery units for general and special applications Argon Beamer | IIb |
| Accessories for RF-surgery units | Handles for RF-surgery Electrodes Forceps and scissors Clamps, forceps, NervScout | IIa / IIb |
| Laser surgery units | surgical laser units for common and particular use | IIb |
| Accessories for laser surgery units | Laser contact probe Adapter for laser fibres Connection fibres Fibre optics Bipolar suction and irrigation units Micromanipulator | IIa / IIb |
| Smoke evacuation systems | products for smoke evacuation | IIa |
| Accessories for Smoke evacuation systems | adapters | IIa |
| Implants and Instruments | Distractor Trocar tip for activation arm Condylar implant Washers Meshes (for cranioplasty) Bone plates Bone screws Bone nails Fixation screws Fixation screws (lug) UHP (prosthesis for wrist joint) Tantal wire (orthodontic) Bone clips Bone wire Finger joint CranioXpand marPOR Polyethylene Implants | IIa / IIb |



Annex to certificate
Certificate registration No.: 210299 MR2
Certificate unique ID: 170763177
Effective date: 2020-01-13



Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

| Device Family | Device | Class |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Resorbable Implants | Resorb X meshes Resorb X plates Resorb X screws Resorb X Pins | III |
| Surgical instruments and units | Sterile scalpels Sterile blades Guide pins Guide wires | Ila Ila Ilb Ilb |
| | Drill bits OMF surgery BOS driver SonicWeld Rx (basis device, handpieces) SonicWeld Rx (sonotrodes) Drill bits / Saw blades orthopaedic BOS-Battery pack sterile Bending Templates | Ila Ila Ila Ila Ila Is Is |
| Pendants | Service Head | Ilb |
| Wound spreading systems | marTract | Ila |
| Surgical Instruments and units | Suction Units, Suction Cannulae, Irrigation Cannulae | Ila |



CERTIFICATE



This is to certify that

KLS martin
GROUP

Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

has implemented and maintains a **Quality Management System**.

Scope:

Development, manufacturing and distribution of medical products, surgical instruments and devices, non-active implants, RF surgery units, operation theatre light systems, ceiling-mounted surgery stands, surgical laser devices and container systems for sterilization and accessories for the above mentioned products.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

| | |
|------------------------------|-------------|
| Certificate registration no. | 210299 QM15 |
| Certificate unique ID | 170738717 |
| Effective date | 2020-07-29 |
| Expiry date | 2023-07-28 |
| Frankfurt am Main | 2020-07-29 |



Deutsche
Akkreditierungsstelle
D-ZM-16021-02-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de



CERTIFICATE



This is to certify that the company

KLS martin
GROUP

Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

has implemented and maintains a **Quality Management System**.

Scope:

Development, manufacturing and distribution of medical products, surgical instruments and devices, non-active implants, RF surgery units, operation theatre light supply units, ceiling-mounted supply systems, surgical laser devices and container systems for sterilization and accessories for the above mentioned products.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2016

| | |
|------------------------------|---------------|
| Certificate registration no. | 210299 MP2016 |
| Certificate unique ID | 170738702 |
| Effective date | 2019-08-29 |
| Expiry date | 2022-08-28 |
| Frankfurt am Main | 2020-03-06 |



DQS Medizinprodukte GmbH

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Managing Director

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Head of Certification Body

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Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de