EU Technical Documentation Assessment Certificate

This is to certify that the company

KLS martin GROUP

Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

SRN: DE-MF-000005551
has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

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

Certificate registration no.	210299 MDR2017B
Certificate ID	1000116756
Effective date	2023-06-15
Expiry date	2027-05-24
Frankfurt am Main,	2023-06-15

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
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.

420.91 Version 5.0

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005551
Certificate ID: 1000116756

Device categories and variants covered by this certificate:

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	maxium
Models:	n/a
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
Models:	n/a
Risk classification:	IIb
Basic-UDI-DI:	40576051775Q
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_02 dated 2022-09-16
210299_A209145MED_03 dated 2023-03-24

Further conditions for or limitations to the validity of the certificate:
Products listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-11-02	170778427	Revision Intended purpose of “maxium”
02	2022-12-08	170782324	Product name of “maxium” without article number
03	2022-12-27	170782567	Addition of the product “maxium® Beamer”