Certificate

Full Quality Assurance System Approval
Annex II excluding (4) of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

Stapleline Medizintechnik GmbH
Bessemer Straße 30, 44793 Bochum, Germany

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Audit Report Number	Registered under	Valid until
671-14-122	Z/15/03646E	May 28th, 2020

Aachen, August 26th, 2015

Certification Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-240.10.12

Annex I of Certificate Z/15/03646E

ecm
Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code
Single use device	Suture Units, Automatic:	15-065
	- Circular Stapler	
	- PPH Stapler	
	- STARR Stapler	
	- Linear Stapler	
	- Linear Cutter	
	- Cartridges Stapler	
	- Cartridges Cutter	
	- Hernia Stapler	

Special terms of validity:

None.

UMDS Code is optional