EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Divus Medical GmbH

Take-off Gewerbepark 9
78579 Neuhausen ob Eck
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:

Endospcopic Instruments and trocars 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.	453998 MR2
Certificate unique ID	170690223
Effective date	2018-03-20
Expiry date	2023-03-19
Frankfurt am Main	2018-01-26

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.

411.20 Version 1.0

Annex to certificate
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Device family	Device	Class
LAP Instruments	LAP Instruments, Scissors Endoscopic	IIb
	LAP Instruments, Forceps Endoscopic	IIb
HF-Instruments	HF-Instruments, bipolar MIC Instruments	IIb
	HF-Instruments, bipolar electrodes	IIb
	HF-Instruments, bipolar forceps	IIb
	HF-Instruments, bipolar instruments	IIb
Trocars	Arthroscopy sheath	IIa
	Trocar sleeve	IIa
	Verres- insufflation	IIa
	Puncture and injection needle	IIa
	Cholangiography Needle	IIa
	Guide tube for cholangiography catheter	IIa
	Puncture needle	IIa
	Suction- and Irrigation Cannula	IIa