



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company



## SurgicEye GmbH

Friedenstr. 18a  
81671 München  
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:

Intraoperative Imaging and Navigation System as well as medical image processing (class IIa) 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.	466372 MR2
Certificate unique ID	170774367
Effective date	2021-05-16
Expiry date	2024-05-26
Frankfurt am Main	2021-05-16

### DQS Medizinprodukte GmbH

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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**  
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## **SurgicEye GmbH**

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<b>Device</b>	<b>Class</b>
declipseSPECT Confident Surgery Suite 300	Ila
declipse®SPECT Imaging Probe system	Ila
DosePlan 1.0	Ila