



# EC-CERTIFICATE

(Production quality assurance)



This is to certify that the company

## mediDOK Software Entwicklungsgesellschaft mbH

Handschuhsheimer Landstraße 11  
69221 Dossenheim  
Germany

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

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

### Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Software for medical applications mediDOK<sup>®</sup> 2.X Class IIa

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the 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.	066450 MR5
Certificate unique ID	170631444
Effective date	2015-10-05
Expiry date	2020-10-04
Frankfurt am Main	2015-10-05

### 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.

