



# EC Design-Examination Certificate

## DQS GmbH

Deutsche Gesellschaft zur Zertifizierung von Managementsystemen

hereby certifies to the manufacturer

### EPflex Feinwerktechnik GmbH

Im Schwöllbogen 24  
D-72581 Dettingen/Erms

that the following products

### Guidewires in the variants according to annex

are conform to the

### essential requirements of Annex I of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

**Examination Basis:** Technische Dokumentation Führungsdrähte/Guidewire Version 1.4

The further examination basis is detailed in the following named report and the relating documents.

**Examination reports:** Reports Produktauslegungsprüfung 780D7\_B, Report Führungsdrähte Rev. 1.doc dated 23.2.2007 and 780D7\_Bericht Führungsdrähte Änderungsmeldung 09 2008 Sept. 2008 dated 27.9.2008

The results of the examination are detailed in the above mentioned report(s) and the therein named relating documents.

**Validity:** This EC Design-Examination Certificate is based on section 4 of Annex II of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and is only valid in connection with the valid DQS Certificate No.: 013536 MR2 according to Annex II of the Council Directive 93/42/EEC. Changes to the approved design must receive further approval from the notified body.

This certificate is valid until 2012-02-26

Certificate Registration No. 013536 MRA

Frankfurt am Main 2007-02-27, revision 2009-10-09

Ass. iur. M. Drechsel

MANAGING DIRECTORS

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Number of DQS as notified body according to Council Directive 93/42EWG: 0297



**Annex to EC Design-Examination Certificate Registration No.: 013536 MRA  
dated 2007-02-27, revision 2009-10-09**

**EPflex Feinwerktechnik GmbH**

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**Guidewires with safety wire**

(J-tip, both ends flexible; J-tip, one end flexible; J-tip, movable core; straight tips, both ends flexible; straight tips, one end flexible; straight tips, movable core)

**Guidewires without safety wire**

(J-tip, both ends flexible; J-tip, one end flexible; straight tips, both ends flexible; straight tips, one end flexible; straight tips, both ends rigid; with handle)

**Guidewires with monofil element**

(J-tip; J-tip, second end flexible; straight tips; straight tips, second end flexible; PTCA-guidewires)

**Nitinol guidewires**

(completely covered with shrink sleeve; partly covered with shrink sleeve; without shrink sleeve)