



EC Design Examination Certificate

DQS Medizinprodukte GmbH

hereby certifies to the manufacturer

EPflex Feinwerktechnik GmbH

Im Schwöllbogen 24
72581 Dettingen/Erms
Germany

that the following product

**Guidewires in the variants
according to annex**

is conform to the

Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices

Basis of examination: Technische Dokumentation Führungsdrähte/Guidewire Version 1.4
and TF02_A00_Führungsdrähte_v6_1.doc

Further basis for the examination is referenced in the
undermentioned examination report and relating documents.

Examination report: Reports Produktauslegungsprüfung 780D7_B, Report Führungs-
drähte Rev. 1.doc dated 23.2.2007, 780D7_Bericht Führungsdrähte
Änderungsmeldung 09 2008 Sept. 2008 dated 27.9.2008 and
Report+EG+Auslegungsprüfung+EP+Flex+FD+12+2010.doc dated
30.12.2010

The results of the examination are contained in the above mentioned
report and therein named relating documents.

Validity: This EC Design Examination Certificate is based on the Annex II,
Section 4 of the Council Directive 93/42/EEC concerning medical
devices and is only valid in connection with the valid DQS Certificate
No.: 013536 MR2 according to Annex II, Section 3 of the Council
Directive 93/42/EEC. Changes to the approved design subject to
further approval by the Notified Body.

Certificate registration no.	013536 MRA
Certification ID	170513787
Date of certification	2011-01-05
Valid until	2012-02-26

Frank Graichen
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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC
concerning medical devices with the Notified Body Number 0297.



Annex to Certificate
Registration No. 013536 MRA
Certificate ID 170513787
(Issued: 2011-01-05)

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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; with Pebax tip)