EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

CARL HAAS GmbH

Dr. Konstantin-Hank-Str.18
78713 Schramberg
Germany

that the design of the following device(s)

Guidewires in different variants according to annex

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 016561 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: Akte PTCA-Führungsdraht v. Mai 2013

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

Examination report: Bericht DE_370_1_3_Bericht_EGA_2013-05-08+final v. 01.06.2013

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

Certificate registration No.	016561 MRA
Certificate unique ID	170571970
Effective date	2013-06-01
Expiry date	2018-05-31
Frankfurt am Main	2013-06-01

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.

20120803/2/EN380310

Annex to Certificate
Certificate registration No.: 016561 MRA
Certificate unique ID: 170571970
Effective date: 2013-06-01

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Device

Guidewires

- **with or without monofil element**
- **with or without safety wire**
- **with fixed or movable core**
- **core made of stainless steel or Nitinol**
- **with or without handle**
- **with different configurations of the guidewire ends (J -tip, angled, straight, rigid, flexible)**
- **coated or uncoated**
- **with or without marking**