



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

EPflex Feinwerktechnik GmbH

Im Schwöllbogen 24
72581 Dettingen/Erms
Germany

that the design of the following device(s)

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.

This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 013536 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: Technische_Akte Ila_III_DQS dated 2016-11-16

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

Examination report: 411_18e_Report_TFR_Guidewires III dated 2016-11-27

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

Certificate registration no. 013536 MRA

Certificate unique ID 170666323

Effective date 2017-02-27

Expiry date 2022.02.26

Frankfurt am Main 2016-11-27

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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Guidewires Productline „Basic Line“	Material core: stainless steel Material coil: stainless steel Coating: PTFE/hydrophilic Dimension: length 20-650 cm, Ø 0.018-0.094“ (0,46-2,39 mm) Tipform: Straight/J-tip/Angled ends: One end/both ends flexible
Guidewires Productline „Micro-Line“	Material core: stainless steel/Nitinol Material coil: stainless steel/Platin/Tungsten, Dimension: length 20-650cm, Ø 0.010-0.038“ (0,25-0,97mm) Coating: PTFE/hydrophilic Tipform: Straight/J-tip/Angled Ends: One end/both ends flexible
Guidewires Productline „PTCA-Line“	Material core: stainless steel/Nitinol Material coil: stainless steel/Platin/Tungsten Coating: PTFE/hydrophilic Dimension: length 190-300cm, Ø 0.014“ (0,36mm) Tipform: Straight/J-tip/Angled ends: one end flexible
Guidewires Productline „Movable-Line“	Material core: stainless steel Material coil: stainless steel Dimension: Länge 80-400cm, Ø 0.028-0.038“ (0,71-0,97mm) Coating: PTFE/hydrophilic Tipform: Straight/J-tip/Angled Ends: One end flexible
Guidewires Productline „MR-Line“	Material core: Polyamide/Nitinol Material coil: Polyamide/PTFE/Nitinol/Tungsten Dimension: length 150 cm, Ø 0.035“ (0,89 mm) Coating: PTFE/hydrophilic Tipform: Straight/J-tip/Angled Ends: One end/both ends flexible