



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 IIa 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.

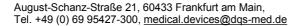
Certificate registration no. 013536 MRA Certificate unique ID 170666323 Effective date 2017-02-27

Expiry date 2022.02.26 Frankfurt am Main 2016-11-27

DQS Medizinprodukte GmbH

Sigrid Uhlemann

Dr. Thomas Feldmann Head of Certification Body









Annex to certificate

Certificate registration No.: 013536 MRA

Certificate unique ID: 170666323

Effective date: 2017-02-27

EPflex Feinwerktechnik GmbH

Im Schwöllbogen 24 72581 Dettingen/Erms Germany

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" ends: One end/both ends flexible

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

Guidewires Productline "Movable-Line"

ends: one end flexible

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

