



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: STED Guidewires III dated 2019-12-16

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

Examination report: 0_411_18e_Report_TFR_GuidewiresIII_R2020_V1.docx dated 2020-03-19

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 170766848

Effective date 2020-03-19

Expiry date 2024-05-26

Frankfurt am Main 2020-03-19

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 / Micro-Linie/m“

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,
PTFE shrink tube (cover)
Tipform: Straight/J-tip/Angled,
Straight/J-tip/Angled/TAVI
Ends: One end/both ends flexible

Guidewires Productline „NiTi-Line“

Material core: Nitinol
Material coil: stainless steel
Dimension: length 40-650cm,
Coating: PTFE coated/hydrophilic
Dimension: length 190-300cm,
Ø 0.018“-0.052” (0,46-1,32mm)
Tipform: Straight/J-tip/Angled
Design: 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: length 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: Aramid fiber
Material coil: Platinum
Material cover: PTFE
Material tip: synthetic material PEBAX
Dimensions: length: 150-480 cm,
Ø 0.018” – 0,038” (0,46mm – 0,97mm)
Tipform: Straight/J-tip/angled
Design: one end/both ends flexible