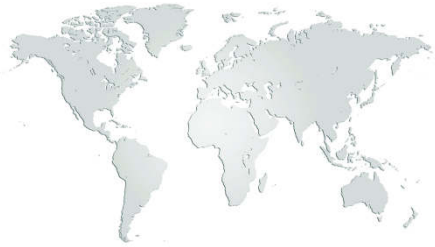
EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

medicut stent Technology GmbH

Christinstraße 15, 75177 Pforzheim, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 51121-Z3-00, the decision dated 2016-11-16 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-01-25 to 2020-01-24

Registration No.: 51121-16-03

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565 Stuttgart

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2016-11-16
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 51121-16-03

Revision status: 0

Valid from 2017-01-25 to 2020-01-24

Devices/device categories included in the certificate:

Class II a:

Non-active peripheral vascular products

- Ballon-Catheter
  mc-PTA Balloon catheter .014inch
- Ballon-Catheter
  mc-PTA Balloon catheter .035inch

Class II b:

Non-active cardiovascular implants
Stent delivery system, self-expandable
Product family mc-peripheral

- mc-p 5F
  Standard, long and transradial/transbrachial
- mc-p 6F
- mc-p II 6F
- mc-p LRF 6F
- multi-LOC 6F

Class III:

Non-active endoluminal cardiovascular implants
Stent delivery system, self-expandable
mc-aortic-stent

- mc-a 12F
- mc-a 14F
- mc-a 16F

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2016-11-16
Notified Body ID-number: 0124