

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
optimed Medizinische Instrumente GmbH

Ferdinand-Porsche-Straße 11, 76275 Ettlingen, Germany

Certified location:

Ferdinand-Porsche-Straße 11, 76275 Ettlingen, 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. 50066-Z6-00, the decision dated 2019-06-26 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-08-05 to 2024-05-26

Registration No.: 50066-16-08

Handwritten signature of Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-06-26
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



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

Annex to the EC Certificate No. 50066-16-08

Valid from 2019-08-05 to 2024-05-26

Revision status of the annex: 1 dated 2020-04-22

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Ureteral Catheters and Sets
- Non-Invasive Accessories
 - Connectors
 - Adapters

Class II a:

- Radiological Catheters
 - Balloon Catheters
 - Lysis Catheters
 - Aspiration Catheters and Sets
- CO₂-Angioset
- Needles and Systems
 - Interventional Needles
- TIPS Puncture Needles and Sets
- Stone Baskets
- Invasive / surgical invasive Accessories
 - Dilators
 - Pushers
 - Introducers
- Non-invasive Accessories
 - Stopcocks
 - Haemostatic Valves
- Percutaneous Drainages
 - Catheters and Sets
- Drainages and Sets
 - Biliary Endoprotheses
 - Pancreatic Stent
- Urological Balloon Catheters and Sets
- Hydrophilic coated Nitinol Guide Wires

Class II b:

- Implants: Nitinol Stents
 - sinus-Endoscopic
 - sinus-Repo-Visual 6F
 - sinus-Reduction
 - sinus-SuperFlex-418
 - sinus-SuperFlex-518
 - sinus-SuperFlex 535
 - sinus-SuperFlex-635
 - sinus-Venous
 - sinus-Obliquus
 - Tentos 4F / Tentos 5F

Annex to the EC Certificate No. 50066-16-08

Valid from 2019-08-05 to 2024-05-26

Revision status of the annex: 1 dated 2020-04-22

Devices/device categories included in the certificate:

Class II b:

- Ureteral Stents and Sets
- Spine
 - Injection Instruments and Sets
 - Adapters
 - Needles and Accessories

Class III:

- Implants: Nitinol Stents
 - sinus-XL, sinus-XL Flex, sinus-XL 6F
 - sinus-SuperFlex-DS, sinus-Repo-DS
- Radiological Catheters
 - DSA Premium Catheters and Sets
 - Angiography Catheters and Sets
 - Balloon Catheters
- PTFE-coated Guide Wires (Stainless Steel, Nitinol)
- Exchange Guide Wires (Stainless Steel)

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.



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-22
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