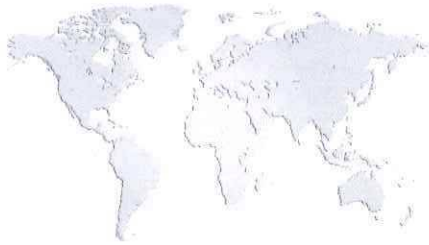
EC CERTIFICATE

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

Digitally signed by Ostapciuc Alexandr
Date: 2023.09.13 15:46:56 EEST
Reason: MoldSign Signature
Location: Moldova

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

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-06-26
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

844460

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
- CO_2-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 Endoprostheses
    - 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.

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-22
Notified Body ID-number: 0124