

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNOMEDICA"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1002600053256

Data înregistrării

17.04.2002

Data eliberării

16.02.2005

Bolboceanu Adela, registrator de stat

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

semnătura

MD 0027040



TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

**Către IMSP Spitalul Clinic Republican
„Timofei Moșneaga”**

În atenția Grupului de lucru
al Licităției deschise nr. ocds-b3wdp1-MD-1623927917875,
ID: 21040915

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul Licităției deschise nr. ocds-b3wdp1-MD-1623927917875, ID: 21040915 privind **achiziționarea consumabilelor medicale pentru cabinetul de cardiologie intervențională SUPLIMENTAR pentru anul 2021.**

Cu respect,

Director

Tatiana Roibu

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
Notified Body ID-number: 0124

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

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

optimed Medizinische Instrumente GmbH

Scope of certification:

Development, manufacturing, sterilization and distribution of medical products for vascular interventions, gastroenterology, urology, spine as well as minimally invasive instruments

Certified location:

Ferdinand-Porsche-Straße 11, 76275 Ettlingen, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50066-Z6-00.

Certificate registration no.:	50066-14-01	Certificate valid from:	2019-08-05
Validity of previous certificate:	2019-08-04	Certificate valid to:	2022-08-04

Ruth Delbeck-Bayer



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



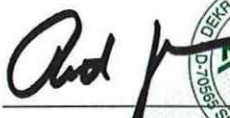
Annex to the Certificate No. 50066-14-01

Revision status: 0

valid from 2019-08-05 to 2022-08-04

The following locations belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	optimed Medizinische Instrumente GmbH	Ferdinand-Porsche-Straße 11 D-76275 Ettlingen	Development, manufacturing, sterilization and distribution of medical products for vascular interventions, gastroenterology, urology, spine as well as minimally invasive instruments
	Subsidiaries	Certified locations	Scope of certification
1.	optimed Medizinische Instrumente GmbH	Ferdinand-Porsche-Straße 9, D-76275 Ettlingen	Development, manufacturing, sterilization and distribution of medical products for vascular interventions, gastroenterology, urology, spine as well as minimally invasive instruments
2.	optimed Medizinische Instrumente GmbH	Otto-Hahn-Straße 18 D-76275 Ettlingen	Development, manufacturing, sterilization and distribution of medical products for vascular interventions, gastroenterology, urology, spine as well as minimally invasive instruments



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



8. Declaration of Conformity

DECLARATION OF CONFORMITY

optimed Medizinische Instrumente GmbH
Ferdinand-Porsche-Straße 11
76275 Ettlingen

hereby declares in its own responsibility that

SINUS-SUPERFLEX-535

Order codes:

*Please refer to the annexed article range
of TD1031_1.1.7, Rev. 2*

is a Class IIb medical device
reviewed in accordance with Annex II excluding section (IV)

0124

DEKRA Certification GmbH
Handwerkstrasse 15
D-70565 Stuttgart

conforming to the relevant provisions of the Directive 93/42/EEC.

This Declaration of Conformity is valid until 26.05.2024.

The validity corresponds to the validity of the CE-certificate number 50066-16-08.

Ettlingen, 25.06.2021



Frank Wohkittel

Head of Regulatory Affairs



Medizinische Instrumente GmbH
Ferdinand-Porsche-Straße 11
76275 Ettlingen · Germany
Phone +49(0)7243 /7633-0
Fax +49(0)7243/7633-99

1.1.7 Complete List of the Various Configurations and Variants

The optimed sinus-SuperFlex-535 stent system is available in stent diameters from 4 mm up to 10 mm and in stent length from 20 mm up to 80 mm.

The following table shows the complete list of stent sizes:

Order Code	Specification
6104-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 30 mm, application device D: 5 F L: 75 cm
6104-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 40 mm, application device D: 5 F L: 75 cm
6104-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 60 mm, application device D: 5 F L: 75 cm
6104-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 80 mm, application device D: 5 F L: 75 cm
6104-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 30 mm, application device D: 5 F L: 120 cm
6104-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 40 mm, application device D: 5 F L: 120 cm
6104-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 60 mm, application device D: 5 F L: 120 cm
6104-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 80 mm, application device D: 5 F L: 120 cm
6105-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 30 mm, application device D: 5 F L: 75 cm
6105-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 40 mm, application device D: 5 F L: 75 cm
6105-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 60 mm, application device D: 5 F L: 75 cm
6105-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 80 mm, application device D: 5 F L: 75 cm
6105-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 30 mm, application device D: 5 F L: 120 cm
6105-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 40 mm, application device D: 5 F L: 120 cm
6105-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 60 mm, application device D: 5 F L: 120 cm
6105-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 80 mm, application device D: 5 F L: 120 cm

6106-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 20 mm, application device D: 5 F L: 75 cm
6106-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 30 mm, application device D: 5 F L: 75 cm
6106-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 40 mm, application device D: 5 F L: 75 cm
6106-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 60 mm, application device D: 5 F L: 75 cm
6106-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 80 mm, application device D: 5 F L: 75 cm
6106-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 20 mm, application device D: 5 F L: 120 cm
6106-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 30 mm, application device D: 5 F L: 120 cm
6106-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 40 mm, application device D: 5 F L: 120 cm
6106-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 60 mm, application device D: 5 F L: 120 cm
6106-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 80 mm, application device D: 5 F L: 120 cm
6107-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 20 mm, application device D: 5 F L: 75 cm
6107-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 30 mm, application device D: 5 F L: 75 cm
6107-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 40 mm, application device D: 5 F L: 75 cm
6107-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 60 mm, application device D: 5 F L: 75 cm
6107-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 80 mm, application device D: 5 F L: 75 cm
6107-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 20 mm, application device D: 5 F L: 120 cm
6107-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 30 mm, application device D: 5 F L: 120 cm
6107-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 40 mm, application device D: 5 F L: 120 cm
6107-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 60 mm, application device D: 5 F L: 120 cm
6107-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 80 mm, application device D: 5 F L: 120 cm
6108-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 20 mm, application device D: 5 F L: 75 cm

6108-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 30 mm, application device D: 5 F L: 75 cm
6108-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 40 mm, application device D: 5 F L: 75 cm
6108-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 60 mm, application device D: 5 F L: 75 cm
6108-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 80 mm, application device D: 5 F L: 75 cm
6108-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 20 mm, application device D: 5 F L: 120 cm
6108-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 30 mm, application device D: 5 F L: 120 cm
6108-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 40 mm, application device D: 5 F L: 120 cm
6108-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 60 mm, application device D: 5 F L: 120 cm
6108-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 80 mm, application device D: 5 F L: 120 cm
6109-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 20 mm, application device D: 5 F L: 75 cm
6109-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 30 mm, application device D: 5 F L: 75 cm
6109-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 40 mm, application device D: 5 F L: 75 cm
6109-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 60 mm, application device D: 5 F L: 75 cm
6109-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 80 mm, application device D: 5 F L: 75 cm
6109-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 20 mm, application device D: 5 F L: 120 cm
6109-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 30 mm, application device D: 5 F L: 120 cm
6109-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 40 mm, application device D: 5 F L: 120 cm
6109-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 60 mm, application device D: 5 F L: 120 cm
6109-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 80 mm, application device D: 5 F L: 120 cm
6110-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 20 mm, application device D: 5 F L: 75 cm
6110-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 30 mm, application device D: 5 F L: 75 cm

6110-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 40 mm, application device D: 5 F L: 75 cm
6110-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 60 mm, application device D: 5 F L: 75 cm
6110-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 80 mm, application device D: 5 F L: 75 cm
6110-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 20 mm, application device D: 5 F L: 120 cm
6110-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 30 mm, application device D: 5 F L: 120 cm
6110-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 40 mm, application device D: 5 F L: 120 cm
6110-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 60 mm, application device D: 5 F L: 120 cm
6110-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 80 mm, application device D: 5 F L: 120 cm