

Date despre participant:**„Tehnomedica” S.R.L.**

Director – Roibu Tatiana

Adresa poștală: str. Ciuflea 38/1, MD 2001 Chisinau, Moldova**Telefon:** 022 601 087; +373 69 909 500**Telefon/Fax:** 022 601 102**Email:** tehnomedica_md@yahoo.com

tehnomedicamd@gmail.com

Cont de decontare: MD65MO2224ASV98310887100**Banca:** BC „OTP Bank” S.A., fil nr. 26 Negruzzi**Adresa poștală a băncii:** Chisinau, str.Negruzzi 1**Cod:** MOBBMD22**Cod fiscal:** 1002600053256**Cod TVA:** 0207719



I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. 1968 din 01.02.2019

Denumirea completă: **SOCIETATEA CU RĂSPUNDERE LIMITATĂ
«TEHNOMEDICA» .**

Denumirea prescurtată: «TEHNOMEDICA» S.R.L. .

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1002600053256.**

Data înregistrării de stat: **17.04.2002.**

Sediul: **MD-2001, str. Ciuflea, 38/1, mun.Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1 Fabricarea utilajului medical și chirurgical și a dispozitivelor ortopedice;**
- 2 Comerțul cu ridicata al produselor farmaceutice;**
- 3 Comerțul cu amănuntul al produselor farmaceutice;**
- 4 Practica medicală;**
- 5 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 6 Activități de consultare pentru afaceri și management.**

Capitalul social: **5400 lei.**

Administrator: ROIBU TATIANA,

Asociați:

- 1. ROIBU TATIANA 100 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 01.02.2019

Specialist coordonator
tel. 022-20-7838



Clichici Elena



EB 0257484

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, registruator 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>

Anexa nr. 8
la Documentația standard nr.115
din 15.09.2021

DECLARAȚIE privind valabilitatea ofertei

Către IMSP Spitalul Clinic Republican „Timofei Moșneaga”

Stimați domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea consumabilelor medicale specifice angio necesare pentru 10 intervenții TIPS, prin procedura de achiziție valoare mică, pentru o durată de 30 zile, și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 02.05.2024

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

TEHNOMEDICA

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

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

În atenţia Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1714396458662,
ID: 21222867

Declaraţie privind înregistrarea dispozitivelor medicale

Prin prezenta, ne asumăm răspunderea de a notifica produsele oferite în cadrul procedurii prenotate pentru a fi incluse în Registrul de Stat al Dispozitivelor Medicale a Agenţiei Medicamentului şi Dispozitivelor Medicale până la momentul livrării acestora.

Cu respect,

Director

Tatiana Roibu

DECLARAȚIE DE ELIGIBILITATE

Către IMSP SCR „Timofei Moșneaga”

Stimați domni,

Subsemnatul, reprezentant împuternicit al Tehnomedica SRL,
(denumirea operatorului economic)

în calitate de ofertant, declar pe propria răspundere, sub sancțiunea excluderii din procedură și sub sancțiunile aplicate faptei de fals în acte publice, că nu mă aflu în una dintre situațiile prevăzute la art. 19 din Legea nr. 131/2015 privind achizițiile publice.

Mă oblig, la solicitarea autorității/entității contractante, în scopul verificării și confirmării declarației, să prezint orice document doveditor de care dispun.

Data completării 02.05.2024

Ofertant/candidat
Roibu Tatiana
(semnătura autorizată)

DECLARATION OF CONFORMITY

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

hereby declares in its own responsibility that

SINUS-SUPERFLEX-635

Order codes:

*Please refer to the annexed article range
of TD1011_1.1.7_SF635, Rev. 6*

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, 11. 05. 2024



Frank Wohkittel

Head of Regulatory Affairs

 **optimed**

Medizinische Instrumente GmbH
Ferdinand-Porsche-Strasse 11
76275 Ettlingen - Germany
Phone +49 7243/7633-0
Fax +49 7243/7633-624



Person in charge: Christian Eing (Deaktiviert)
 Last amended by: Johannes Mai
 Reviewed by: Unterliegt keiner Prüfung
 Approved by: Zlatka Schüßler-Tankova

1.1.7 Complete List of the Various Configurations and Variants

The optimed sinus-SuperFlex-635 stent system is available in stent diameters from 6 mm up to 12 mm and in stent lengths from 30 mm up to 150 mm.

The following table shows the complete list of stent sizes:

Order code	Short description	Description
8606-6030	sin-SF-635-v/b-06x30-75	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 30 mm, application device 6 F / 75 cm
8606-6040	sin-SF-635-v/b-06x40-75	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 40 mm, application device 6 F / 75 cm
8606-6060	sin-SF-635-v/b-06x60-75	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 60 mm, application device 6 F / 75 cm
8606-6080	sin-SF-635-v/b-06x80-75	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 80 mm, application device 6 F / 75 cm
8606-6100	sin-SF-635-v/b-06x100-75	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 100 mm, application device 6 F / 75 cm
8606-6120	sin-SF-635-v/b-06x120-75	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 120 mm, application device 6 F / 75 cm
8606-6150	sin-SF-635-v/b-06x150-75	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 150 mm, application device 6 F / 75 cm
8606-7030	sin-SF-635-v/b-06x30-120	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 30 mm, application device 6 F / 120 cm
8606-7040	sin-SF-635-v/b-06x40-120	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 40 mm, application device 6 F / 120 cm
8606-7060	sin-SF-635-v/b-06x60-120	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 60 mm, application device 6 F / 120 cm
8606-7080	sin-SF-635-v/b-06x80-120	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 80 mm, application device 6 F / 120 cm
8606-7100	sin-SF-635-v/b-06x100-120	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 100 mm, application device 6 F / 120 cm
8606-7120	sin-SF-635-v/b-06x120-120	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 120 mm, application device 6 F / 120 cm
8606-7150	sin-SF-635-v/b-06x150-120	sinus-SuperFlex-635; stent system, vascular / biliary; 6 mm x 150 mm, application device 6 F / 120 cm
8607-6030	sin-SF-635-v/b-07x30-75	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 30 mm, application device 6 F / 75 cm
8607-6040	sin-SF-635-v/b-07x40-75	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 40 mm, application device 6 F / 75 cm
8607-6060	sin-SF-635-v/b-07x60-75	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 60 mm, application device 6 F / 75 cm

Order code	Short description	Description
8607-6080	sin-SF-635-v/b-07x80-75	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 80 mm, application device 6 F / 75 cm
8607-6100	sin-SF-635-v/b-07x100-75	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 100 mm, application device 6 F / 75 cm
8607-6120	sin-SF-635-v/b-07x120-75	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 120 mm, application device 6 F / 75 cm
8607-6150	sin-SF-635-v/b-07x150-75	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 150 mm, application device 6 F / 75 cm
8607-7030	sin-SF-635-v/b-07x30-120	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 30 mm, application device 6 F / 120 cm
8607-7040	sin-SF-635-v/b-07x40-120	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 40 mm, application device 6 F / 120 cm
8607-7060	sin-SF-635-v/b-07x60-120	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 60 mm, application device 6 F / 120 cm
8607-7080	sin-SF-635-v/b-07x80-120	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 80 mm, application device 6 F / 120 cm
8607-7100	sin-SF-635-v/b-07x100-120	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 100 mm, application device 6 F / 120 cm
8607-7120	sin-SF-635-v/b-07x120-120	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 120 mm, application device 6 F / 120 cm
8607-7150	sin-SF-635-v/b-07x150-120	sinus-SuperFlex-635; stent system, vascular / biliary; 7 mm x 150 mm, application device 6 F / 120 cm
8608-6030	sin-SF-635-v/b-08x30-75	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 30 mm, application device 6 F / 75 cm
8608-6040	sin-SF-635-v/b-08x40-75	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 40 mm, application device 6 F / 75 cm
8608-6060	sin-SF-635-v/b-08x60-75	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 60 mm, application device 6 F / 75 cm
8608-6080	sin-SF-635-v/b-08x80-75	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 80 mm, application device 6 F / 75 cm
8608-6100	sin-SF-635-v/b-08x100-75	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 100 mm, application device 6 F / 75 cm
8608-6120	sin-SF-635-v/b-08x120-75	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 120 mm, application device 6 F / 75 cm
8608-6150	sin-SF-635-v/b-08x150-75	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 150 mm, application device 6 F / 75 cm
8608-7030	sin-SF-635-v/b-08x30-120	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 30 mm, application device 6 F / 120 cm
8608-7040	sin-SF-635-v/b-08x40-120	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 40 mm, application device 6 F / 120 cm
8608-7060	sin-SF-635-v/b-08x60-120	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 60 mm, application device 6 F / 120 cm

Order code	Short description	Description
8608-7080	sin-SF-635-v/b-08x80-120	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 80 mm, application device 6 F / 120 cm
8608-7100	sin-SF-635-v/b-08x100-120	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 100 mm, application device 6 F / 120 cm
8608-7120	sin-SF-635-v/b-08x120-120	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 120 mm, application device 6 F / 120 cm
8608-7150	sin-SF-635-v/b-08x150-120	sinus-SuperFlex-635; stent system, vascular / biliary; 8 mm x 150 mm, application device 6 F / 120 cm
8609-6030	sin-SF-635-v/b-09x30-75	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 30 mm, application device 6 F / 75 cm
8609-6040	sin-SF-635-v/b-09x40-75	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 40 mm, application device 6 F / 75 cm
8609-6060	sin-SF-635-v/b-09x60-75	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 60 mm, application device 6 F / 75 cm
8609-6080	sin-SF-635-v/b-09x80-75	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 80 mm, application device 6 F / 75 cm
8609-6100	sin-SF-635-v/b-09x100-75	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 100 mm, application device 6 F / 75 cm
8609-6120	sin-SF-635-v/b-09x120-75	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 120 mm, application device 6 F / 75 cm
8609-7030	sin-SF-635-v/b-09x30-120	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 30 mm, application device 6 F / 120 cm
8609-7040	sin-SF-635-v/b-09x40-120	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 40 mm, application device 6 F / 120 cm
8609-7060	sin-SF-635-v/b-09x60-120	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 60 mm, application device 6 F / 120 cm
8609-7080	sin-SF-635-v/b-09x80-120	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 80 mm, application device 6 F / 120 cm
8609-7100	sin-SF-635-v/b-09x100-120	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 100 mm, application device 6 F / 120 cm
8609-7120	sin-SF-635-v/b-09x120-120	sinus-SuperFlex-635; stent system, vascular / biliary; 9 mm x 120 mm, application device 6 F / 120 cm
8610-6030	sin-SF-635-v/b-10x30-75	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 30 mm, application device 6 F / 75 cm
8610-6040	sin-SF-635-v/b-10x40-75	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 40 mm, application device 6 F / 75 cm
8610-6060	sin-SF-635-v/b-10x60-75	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 60 mm, application device 6 F / 75 cm
8610-6080	sin-SF-635-v/b-10x80-75	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 80 mm, application device 6 F / 75 cm
8610-6100	sin-SF-635-v/b-10x100-75	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 100 mm, application device 6 F / 75 cm
8610-6120	sin-SF-635-v/b-10x120-75	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 120 mm, application device 6 F / 75 cm
8610-7030	sin-SF-635-v/b-10x30-120	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 30 mm, application device 6 F / 120 cm
8610-7040	sin-SF-635-v/b-10x40-120	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 40 mm, application device 6 F / 120 cm



Order code	Short description	Description
8610-7060	sin-SF-635-v/b-10x60-120	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 60 mm, application device 6 F / 120 cm
8610-7080	sin-SF-635-v/b-10x80-120	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 80 mm, application device 6 F / 120 cm
8610-7100	sin-SF-635-v/b-10x100-120	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 100 mm, application device 6 F / 120 cm
8610-7120	sin-SF-635-v/b-10x120-120	sinus-SuperFlex-635; stent system, vascular / biliary; 10 mm x 120 mm, application device 6 F / 120 cm
8612-6040	sin-SF-635-v/b-12x40-75	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 40 mm, application device 6 F / 75 cm
8612-6060	sin-SF-635-v/b-12x60-75	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 60 mm, application device 6 F / 75 cm
8612-6080	sin-SF-635-v/b-12x80-75	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 80 mm, application device 6 F / 75 cm
8612-6100	sin-SF-635-v/b-12x100-75	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 100 mm, application device 6 F / 75 cm
8612-6120	sin-SF-635-v/b-12x120-75	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 120 mm, application device 6 F / 75 cm
8612-7040	sin-SF-635-v/b-12x40-120	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 40 mm, application device 6 F / 120 cm
8612-7060	sin-SF-635-v/b-12x60-120	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 60 mm, application device 6 F / 120 cm
8612-7080	sin-SF-635-v/b-12x80-120	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 80 mm, application device 6 F / 120 cm
8612-7100	sin-SF-635-v/b-12x100-120	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 100 mm, application device 6 F / 120 cm
8612-7120	sin-SF-635-v/b-12x120-120	sinus-SuperFlex-635; stent system, vascular / biliary; 12 mm x 120 mm, application device 6 F / 120 cm

DECLARATION OF CONFORMITY

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

hereby declares in its own responsibility that

TIPS PUNCTURE SET STANDARD
TIPS PUNCTURE SET SPECIAL

Order codes:

*Please refer to the annexed article range
of TD1025_1.1.7 Section _STANDS, Rev. 3
and TD1025_1.1.7 Section _SPECS, Rev. 3*

is a Class IIa 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, 11.05.2024



Frank Wohkittel

Head of Regulatory Affairs



Medizinische Instrumente GmbH

Ferdinand-Porsche-Strasse 11
76275 Ettlingen · Germany

Phone +49 7243/7633-0

Fax +49 7243/7633-624



Person in charge: Christian Eing
 Last amended by: Christian Eing
 Reviewed by: Unterliegt keiner Prüfung
 Approved by: Frank Nagl (Deaktiviert), Zlatka Schüßler-Tankova

1.1.7 Complete List of the Various Configurations and Variants

The range of products for TIPS interventions offered by optimed consists of the following product categories:

- TIPS Puncture Sets Standard with pencil-cut (guide wire straight or curved)
 - Needle 30 ° angled
 - Needle 60 ° angled
- TIPS Puncture Set Special with colapinto-cut or reversed colapinto-cut (guide wire straight)
 - Needle 30 ° angled
 - Needle 60 ° angled
- TIPS Puncture Needles:
 - Standard with pencil-cut (30 ° or 60 ° angled)
 - Special 1 with colapinto-cut (30 ° or 60 ° angled)
 - Special 2 with reversed colapinto-cut (30 ° or 60 ° angled)
- TIPS Guiding Catheters

Extension	Reference	Specification
_STANDS	1490-1000	TIPS Puncture Set Standard 30 °; needle: angled, pencil-cut, guide wire: straight, guiding catheter; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 30 °
_STANDN	1490-1100	TIPS Puncture Needle Standard 30 °; needle: angled, pencil-cut; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 30 °
_TIGC	1490-1201	TIPS Guiding Catheter; guiding catheter adapted to TIPS Needle; D: 8 F, L: 45 cm
_TIGC	1490-1202	TIPS Guiding Catheter; guiding catheter adapted to TIPS Needle; D: 8 F, L: 50 cm
_STANDS	1490-2000	TIPS Puncture Set Standard 60 °; needle: angled, pencil-cut, guide wire: straight, guiding catheter; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 60 °
_STANDN	1490-2100	TIPS Puncture Needle Standard 60 °; needle: angled, pencil-cut; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 60 °
_STANDS	1490-3000	TIPS Puncture Set Standard 30 °; needle: angled, pencil-cut, guide wire: curved, guiding catheter; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 30 °
_STANDS	1490-4000	TIPS Puncture Set Standard 60 °; needle: angled, pencil-cut, guide wire: curved, guiding catheter; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 60 °



Summary Technical Documentation

TD1025_1.1.7

Revision:3

Approved on: 22.10.2020 10:08

Page 2 of 2

Extension	Reference	Specification
_SPECS	1490-6000	TIPS Puncture Set Special 1 30 °; needle: angled, colapinto-cut, guide wire: straight, guiding catheter; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 30 °
_SPECN	1490-6100	TIPS Puncture Needle Special 1 30 °; needle: angled, colapinto-cut; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 30 °
_SPECS	1490-7000	TIPS Puncture Set Special 1 60 °; needle: angled, colapinto-cut, guide wire: straight, guiding catheter; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 60 °
_SPECN	1490-7100	TIPS Puncture Needle Special 1 60 °; needle: angled, colapinto-cut; needle: D: 15 G (1.8 mm), L: 580 mm, angle: 60 °
_SPECN	1490-8000	TIPS Puncture Needle Special 2 30 °; needle: angled, reversed colapinto-cut; needle: D: 15 G (1.8 mm), L: 500 mm, angle: 30 °
_SPECN	1490-9000	TIPS Puncture Needle Special 2 60 °; needle: angled, reversed colapinto-cut; needle: D: 15 G (1.8 mm), L: 500 mm, angle: 60 °

Key:

_STANDS	TIPS Puncture Set Standard
_STANDN	TIPS Puncture Needle Standard
_SPECS	TIPS Puncture Set Special
_SPECN	TIPS Puncture Needle Special
_TIGC	TIPS Guiding Catheter



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



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
www.zlg.de
ZLG-BS-295.10.02

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.



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