

The crosslapped edge made of MANI's original hard fiber stainless steel produces the ultimate sharpness.

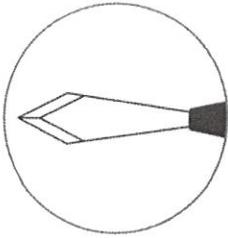
## Slit Knife

Angle = 45°

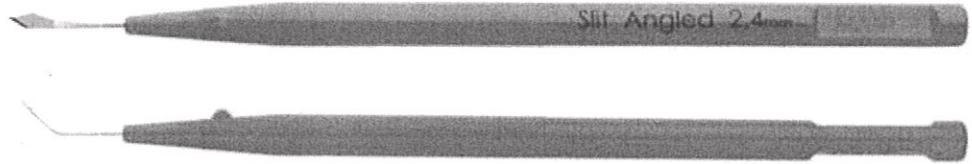
KONFIDENCIALU

6pcs/box

○Main Application: Corneal Incision, Scleral Incision



MSL·MSS



Actual size

Product Name	ORDER#
Slit Angled 1.0mm	MSL10
Slit Angled 1.1mm	MSL11
Slit Angled 1.2mm	MSL12
Slit Angled 1.3mm	MSL13
Slit Angled 1.4mm	MSL14
Slit Angled 1.6mm	MSL16
Slit Angled 1.8mm	MSL18
Slit Angled 1.9mm	MSL19
Slit Angled 2.0mm	MSL20
Slit Angled 2.1mm	MSL21
Slit Angled 2.2mm	MSL22
Slit Angled 2.3mm	MSL23
Slit Angled 2.4mm	MSL24
Slit Angled 2.5mm	MSL25
Slit Angled 2.65mm	MSL26
Slit Angled 2.75mm	MSL27
Slit Angled 2.8mm	MSL28
Slit Angled 2.9mm	MSL29
Slit Angled 3.0mm	MSL30
Slit Angled 3.2mm	MSL32
Slit Angled 3.5mm	MSL35
Slit Straight 1.0mm	MSS10
Slit Straight 2.8mm	MSS28
Slit Straight 3.0mm	MSS30

20.



KOPIJA TIKRA

Direktorė  
Vestina Strakšytė



PERIPHERAL  
VASCULAR



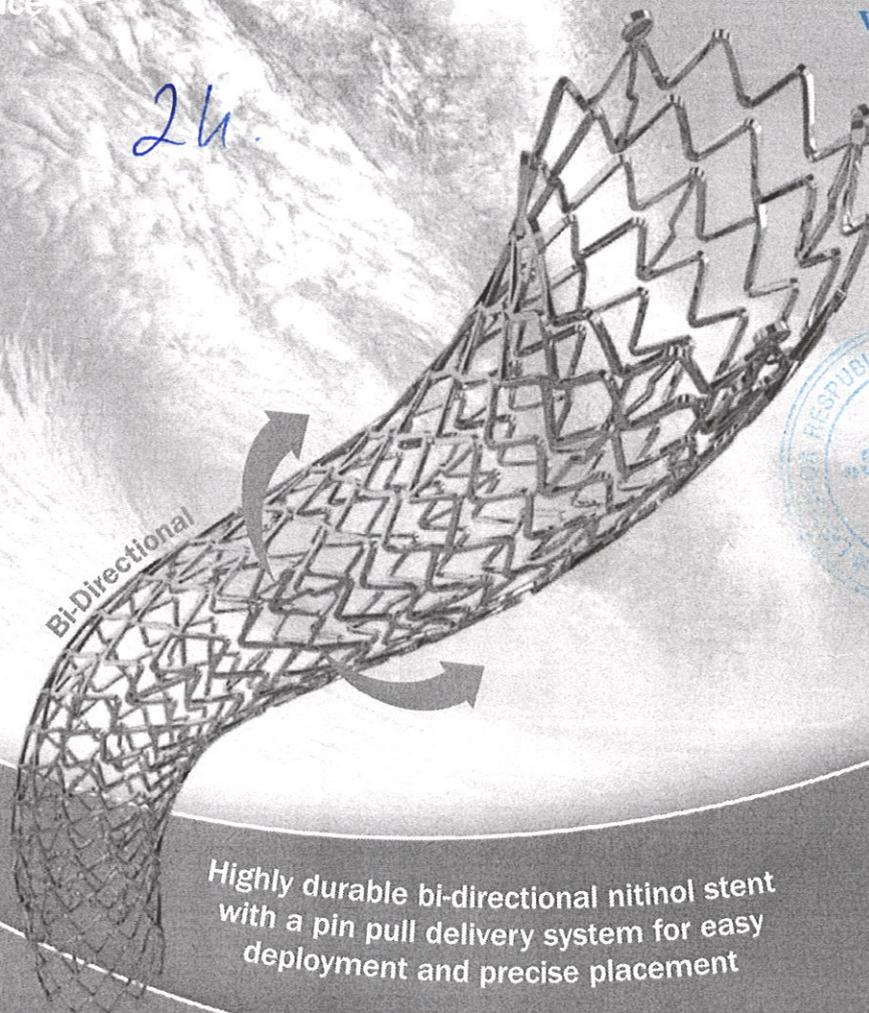
# NAVALIS-pp ADVANCE

Peripheral Vascular Self-Expanding Stent System  
Pin Pull Device

KOPIJA TIKRA

Direktorė  
Vestina Strakšytė

24.



Bi-Directional



Highly durable bi-directional nitinol stent  
with a pin pull delivery system for easy  
deployment and precise placement

Regulatory Status  
CE Mark Approved



# NAVALIS-pp ADVANCE

Peripheral Vascular Self-Expanding Stent System  
Pin Pull Device

The **NAVALIS-pp** Self-Expanding Peripheral Vascular Stent System combines **highly durable** nitinol stent with a **flexible** delivery system to provide **proven clinical results**<sup>1</sup>.

## ACCURACY & EASE OF USE

- > Nitinol Stent with tantalum markers provides excellent visibility under fluoroscopy
- > Minimal Foreshortening ensures accurate positioning and placement
- > Delivery Catheter ensures accurate and easy 1:1 delivery

## ENHANCED CATHETER

- > Durability for greater shelf life and improved pushability
- > Accuracy provided through lower deployment force for more accurate stent placement
- > Integrated Connector Port for ease of flushing and injection of contrast material
- > Usable working Lengths of 80 and 120cm, guided over 0.035" guidewire

## FLEXIBILITY & STRENGTH

- > Unique Wave Design provides flexibility without sacrificing radial strength
- > Flexible Connectors provide high resistance against bending, torsion, and compression stress
- > Highly Flexible Delivery Catheter facilitates navigation of tortuous anatomy

24



KOPIJA TIKRA

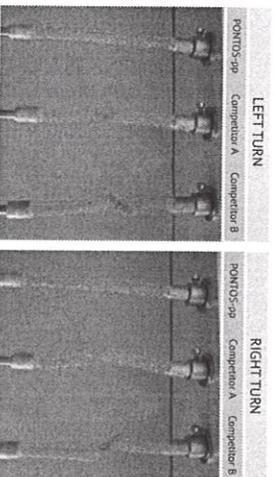
Directorius  
Vestina Strakšytė

KONFIDENCIALU

**85.7%**  
FREEDOM FROM TLR  
AFTER 24 MONTHS<sup>1</sup>



TORSION AND DIRECTIONALITY TESTING  
One Full Turn



<sup>1</sup> Krankenberg, H., et al (JACC 2019). Bi-directional, Self-Expanding Stent for Superficial Femoral Artery Lesions - 2-year Interim-Results from the Q3 Registry.

24

KONFIDENCIALU

# NAVALIS-pp ADVANCE

## Peripheral Vascular Self-Expanding Stent System Pin Pull Device

KOPIJA TIKRA

Direktorė  
Vestina Strakšytė

### TECHNICAL SPECIFICATIONS

#### Stent

Description	Self-Expandable Nitinol Stent
Material	Nickel titanium alloy
Diameter	5.0 6.0 7.0 8.0 9.0 10.0 11.0 mm
Lengths	20   40   60   80   100   120   150   175   200 mm
Visibility	4 x-ray markers at each end Tantalum marker

#### Stent Delivery System

Recommended Guidewire	0.035" ( 0.89 mm)
Recommended Introducer	6 F
Usable Catheter Lengths	80 cm and 120 cm
Delivery Device	Pin Pull Delivery System

### ORDER INFORMATION

#### Short

Usable catheter length 80 cm

Diameter (mm)	Length (mm)								
	20	40	60	80	100	120	150	175	200
5	08 APS 05020	08 APS 05040	08 APS 05060	08 APS 05080	08 APS 05100	08 APS 05120	08 APS 05150	08 APS 05175	08 APS 05200
6	08 APS 06020	08 APS 06040	08 APS 06060	08 APS 06080	08 APS 06100	08 APS 06120	08 APS 06150	08 APS 06175	08 APS 06200
7	08 APS 07020	08 APS 07040	08 APS 07060	08 APS 07080	08 APS 07100	08 APS 07120	08 APS 07150	08 APS 07175	08 APS 07200
8	08 APS 08020	08 APS 08040	08 APS 08060	08 APS 08080	08 APS 08100	08 APS 08120	08 APS 08150	08 APS 08175	08 APS 08200
9	08 APS 09020	08 APS 09040	08 APS 09060	08 APS 09080	08 APS 09100	08 APS 09120	08 APS 09150		
10	08 APS 10020	08 APS 10040	08 APS 10060	08 APS 10080	08 APS 10100	08 APS 10120	08 APS 10150		
11	08 APS 11020	08 APS 11040	08 APS 11060	08 APS 11080	08 APS 11100	08 APS 11120	08 APS 11150		

#### Long

Usable catheter length 120 cm

Diameter (mm)	Length (mm)								
	20	40	60	80	100	120	150	175	200
5	12 APS 05020	12 APS 05040	12 APS 05060	12 APS 05080	12 APS 05100	12 APS 05120	12 APS 05150	12 APS 05175	12 APS 05200
6	12 APS 06020	12 APS 06040	12 APS 06060	12 APS 06080	12 APS 06100	12 APS 06120	12 APS 06150	12 APS 06175	12 APS 06200
7	12 APS 07020	12 APS 07040	12 APS 07060	12 APS 07080	12 APS 07100	12 APS 07120	12 APS 07150	12 APS 07175	12 APS 07200
8	12 APS 08020	12 APS 08040	12 APS 08060	12 APS 08080	12 APS 08100	12 APS 08120	12 APS 08150	12 APS 08175	12 APS 08200
9	12 APS 09020	12 APS 09040	12 APS 09060	12 APS 09080	12 APS 09100	12 APS 09120	12 APS 09150		
10	12 APS 10020	12 APS 10040	12 APS 10060	12 APS 10080	12 APS 10100	12 APS 10120	12 APS 10150		
11	12 APS 11020	12 APS 11040	12 APS 11060	12 APS 11080	12 APS 11100	12 APS 11120	12 APS 11150		

The product official name is: NAVALIS-pp Peripheral Vascular Self-Expanding Stent System



www.tsunamed.com

MANUFACTURED BY

**QualiMed**  
A Q3 Medical Company

QualiMed Innovative Medizinprodukte GmbH  
Boschstraße 16, 21423 Winsen, Germany  
Phone +49 4171 6578 0  
Fax +49 4171 6578 11  
Web www.qualimed.de

BRO\_NAVALIS-pp ADV REV. A  
JUNE 2020

**Qualimed NAVALIS-pp Advanced periferiniai stentai 0.035“ vielai****Periferiniai savaimė išsiplečiantys stentai, naudojami su 0.035“ pravedimo viela.**

Savaimė išsiplečiantys dvikrypčiai (angl. *Bi-directional*) nitaliniai periferiniai stentai;

Bangos formos segmentinė stento konstrukcija su lanksčiomis jungtimis;

Labai lankstūs, pasižymintys didele radialine jėga;

Stento išskleidžiamo mechanizmas PIN-PULL tipo;

Kiekviename stento gale integruota po 4 tantalo rentgenokonstrastinius žymeklius;

Integruota Y formos jungtis praplovimui ar kontrastinės medžiagos įšvirkštimui;

Naudojami su 0.035“ pravedimo viela;

Naudojami su 6 F introduiseriu visiems dydžiams;

Stentų diametrai: 5, 6, 7, 8, 9, 10, 11 mm;

Stentų ilgiai: 20, 40, 60, 80, 100, 120, 150, 175, 200 mm;

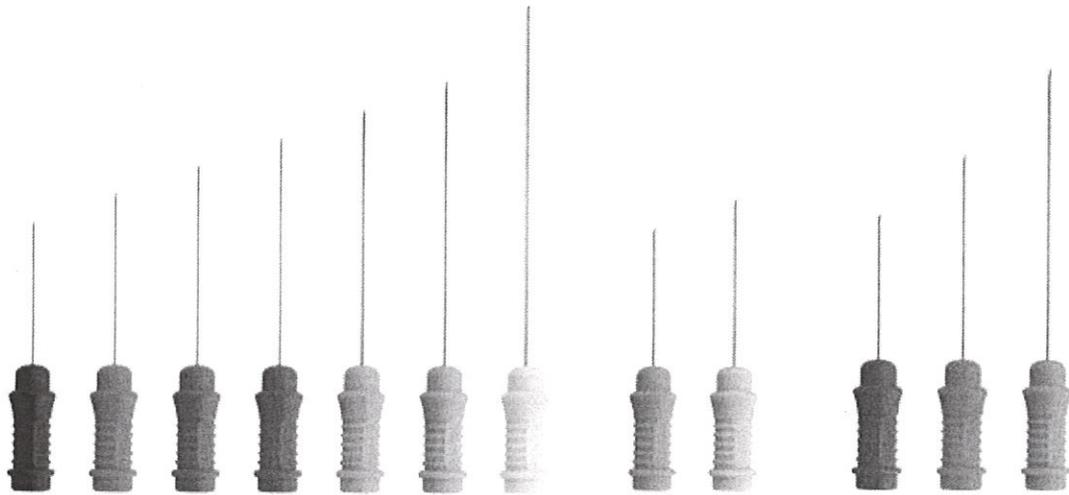
Įvedimo kateterio ilgiai: 80 cm ir 120 cm.

Vertimas tikras

Direktorė  
Vestina Strakšytė



## NEEDLE ELECTRODES



### BIONEN QUALITY NEEDLE STANDARD

REF	TYPE	L	Ø	QTY	COLORS
0028.012	BQNS-4625	25 mm	0,46 mm (26G)	25/box	●
0028.013	BQNS-4630	30 mm	0,46 mm (26G)	25/box	●
41. 0028.014	BQNS-4637	37 mm	0,46 mm (26G)	25/box	●
0028.015	BQNS-4640	40 mm	0,46 mm (26G)	25/box	●
0028.016	BQNS-4645	45 mm	0,46 mm (26G)	25/box	●
0028.018	BQNS-4650	50 mm	0,46 mm (26G)	25/box	●
0028.017	BQNS-5565	65 mm	0,55 mm (25G)	25/box	●
0028.112	BQNS-3525	25 mm	0,35 mm (28G)	25/box	●
0028.113	BQNS-3530	30 mm	0,35 mm (28G)	25/box	●

### BIONEN QUALITY NEEDLE PREMIUM

REF	TYPE	L	Ø	QTY	COLORS
0028.612	BQNP-4625	25 mm	0,46 mm (26G)	25/box	●
0028.614	BQNP-4637	37 mm	0,46 mm (26G)	25/box	●
0028.618	BQNP-4650	50 mm	0,46 mm (26G)	25/box	●

### NEEDLE HOLDER FOR BQN

REF	L CABLE	INSTRUMENT SIDE
0030.0115	100 cm	5 pole DIN



KOPIJA TIKRA

Direktorė  
Vestina Strakšytė



**Adatiniai elektrodai**

Kodas	Tipas	Ilgis	Diametras	Pakuotė
0028.012	BQNS-4625	25 mm	0,46 mm (26G)	25 vnt./dėž.
0028.013	BQNS-4630	30 mm	0,46 mm (26G)	25 vnt./dėž.
0028.014	BQNS-4637	37 mm	0,46 mm (26G)	25 vnt./dėž.
0028.015	BQNS-4640	40 mm	0,46 mm (26G)	25 vnt./dėž.
0028.016	BQNS-4645	45 mm	0,46 mm (26G)	25 vnt./dėž.
0028.018	BQNS-4650	50 mm	0,46 mm (26G)	25 vnt./dėž.
0028.017	BQNS-5565	65 mm	0,55 mm (25G)	25 vnt./dėž.
0028.112	BQNS-3525	25 mm	0,35 mm (28G)	25 vnt./dėž.
0028.113	BQNS-3530	30 mm	0,35 mm (28G)	25 vnt./dėž.

**Laidas prie koncentrinųjų elektrodų**

Kodas	Ilgis	Instrumento pusė
0030.011S	100 cm	5 kontaktų DIN

Vertimas tikras

Direktorė  
Vestina Strakšytė



**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60142912 0001

**Report No.:** 12022703 018

**KOPIJA TIKRA**

**Manufacturer:** MANI, INC.  
8-3 Kiyohara Industrial Park,  
Utsunomiya,  
Tochigi, 321-3231,  
- Japan

Direktorė  
**Vestina Strakšytė**



**Products:** Medical Devices and Instruments in Surgical and  
Dental Fields  
(see attachment for sites and products included)

Replaces Approval, Registration No.: HD 60097627 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-09-20

**Date:** 2019-09-20



**Notified Body**

*M. Sc. M. Aihara*  
**M.Sc. M. Aihara**

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Doc. 1/3, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HD 60142912 0001  
**Report No.:** 12022703 018

**Manufacturer:** MANI, INC.  
8-3 Kiyohara Industrial Park,  
Utsunomiya,  
Tochigi, 321-3231,  
- Japan

**KOPIJA TIKRA**

Direktorė  
**Vestina Strakšytė**

**Products included:**

- Surgical Needles
- Surgical Sutures
- Surgical Suturing Devices
- Dental Rotary Instruments
- Dental Endodontic Instruments
- Dental Pins and Posts
- Medical Knives
- Bone Fixation Devices
- Medical Saws
- Ophthalmic Cannulae
- Dental Root Canal Filling Materials



**Notified Body**

*M. Aihara*  
**M.Sc. M. Aihara**

**Date: 2019-09-20**

TUV

**APROBAVIMAS**  
**EC Direktyva 93/42/EEC Priedas II, išskyrus skyrių 4**  
**Visiškos Kokybės Užtikrinimo Sistema**  
**Medicininiai Prietaisai**

**Registracijos Nr.: HD 60142912 0001**

**Protokolo Nr.: 12022703 018**

**Gamintojas: Mani Inc.**  
**8-3 Kiyohara Industrial Park**  
**Utsunomiya**  
**Tochigi, 321-3231**  
**Japonija**

**Produktai:** Medicinos priemonės ir instrumentai chirurgijai ir stomatologijai  
(nurodyta priede)

**Galioja iki:** 2024-05-26

Notifikuotoji įstaiga pareiškia, kad išvardytiems gaminiams buvo įvykdyti II priedo, išskyrus Direktyvos 93/42 / EEB 4 skirsnį, reikalavimai. Pirmiau minėtas gamintojas sukūrė ir taiko kokybės užtikrinimo sistemą, kuriai taikoma periodinė priežiūra, apibrėžta minėtos direktyvos II priedo 5 skirsnyje. Pateikiant rinkai III klasės įtaisus, kuriems taikomas šis pažymėjimas ir EB projekto tyrimo sertifikatas pagal II priedo 4 skirsnį, būtina.

Notifikavimo organizacija  
Parašas  
Antspaudas

Efektyvi data: 2019-09-20

Data: 2019-09-20

Vertimas tikras

Direktorė  
Vestina Strakšytė



TUV

TUV Rheinland  
LGA Products Products GmbH  
Tillystrase 2, 90431 Nurnberg

Priedas prie  
sertifikato

Registracijos Nr.: HD 60142912 0001

Protokolo Nr.: 12022703 018

Gamintojas: **Mani Inc.**  
**8-3 Kiyohara Industrial Park**  
**Utsunomiya**  
**Tochigi, 321-3231**  
**Japonija**

Produktai:

- Chirurginės adatos
- Chirurginiai siūlai
- Chirurginiai siuvimo prietaisai
- Stomatologiniai rotoriniai instrumentai
- Stomatologiniai endodontiniai instrumentai
- Stomatologiniai kaiščiai ir strypai
- Medicininiai ašmenys
- Kaulų tvirtinimo priemonės
- Medicininiai pjūklai
- Oftalmologinės kaniulės
- Stomatologinės dantų kanalų užpildymo medžiagos

Notifikavimo organizacija  
Parašas  
Antspaudas

Data: 2019-09-20

Direktorė  
**Vestina Strakšytė**



# 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  
**QualiMed Innovative Medizinprodukte GmbH**

Boschstraße 16, 21423 Winsen, Germany

**Certified location:**

Boschstraße 16, 21423 Winsen, Germany

KOPIJA TIKRA

Direktoriė  
Vestina Strakšytė



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. 50289-Z7-00, the decision dated 2020-03-19 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is only valid in connection with the main certificate no. 50289-16-07.

This certificate is valid from 2020-03-19 to 2024-05-26

Registration No.: 50289-16-07-2

*Ruth Delbeck-Bayer*



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2020-03-19  
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. 50289-16-07-2

Valid from 2020-03-19 to 2024-05-26

Revision status of the annex: 0 dated 2020-03-19

Devices/device categories included in the certificate:

## **Brand: TsunaMed**

### Class II a:

- JUTURNA-vq PTA Balloon Catheter
- JUTURNA-e PTA Balloon Catheter

### Class II b:

- NAVALIS Peripheral Vascular Self Expanding Stent System
- NAVALIS-pp Peripheral Vascular Self Expanding Stent System
- LITUS<sup>Xi</sup> Peripheral Balloon Expandable Stent System
- LITUS<sup>Xi</sup> 6F Peripheral Balloon Expandable Stent System
- LITUS<sup>Xi</sup> Peripheral Balloon Expandable Stent System

### Class III:

- EMAX Aspiration Catheter
- MAGMA Rapamycin-Eluting Coronary Stent System
- JUTURNA-c PTCA Balloon Catheter

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.

**KOPIJA TIKRA**

Direktorė  
**Vestina Strakšytė**



  
Ruth Delbeck-Bayer



DEKRA Certification GmbH, Stuttgart, 2020-03-19  
Notified Body ID-number: 0124

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

# CE SERTIFIKATAS

DEKRA

Remiantis direktyvos 93/42/EEC Priedu II išskyrus 4 skyrių

kompanija

**Qualimed Innovative Medizinprodukte GmbH**  
**Boschstrase 16, 21423 Winsen, Vokietija**

atitinka kokybės sistemą medicinos prietaisų, nurodytų direktyvos 93/42/EEC II priede.  
Patvirtinimas yra priimtas 2018-04-03 ir rezultatai apibendrinti raporte Nr. 50289-Z6-00.

Šis sertifikatas galioja nuo 2020-03-19 iki 2024-05-26

Registracijos Nr.: 50289-16-07-2



Parašas  
Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2020-03-19  
Sertifikavimo tarnybos ID numeris: 0124

Vertimas tikras

Direktorė  
**Vestina Strakšytė**

A handwritten signature in blue ink, appearing to be "Vestina Strakšytė", written over the printed name.

**Priedas prie sertifikato 50289-16-07-2**

Galioja nuo 2020-03-19 iki 2024-05-26

Priemonės, nurodytos sertifikate

Prekinis ženklas: TsunaMed

Klasė IIa:

JUTURNA-vq PTA balioniniai kateteriai

JUTURNA-e PTA balioniniai kateteriai

Klasė IIb:

NAVALIS savaimė išsiskleidžiantys periferiniai kraujagyslių stentai

NAVALIS-pp savaimė išsiskleidžiantys periferiniai kraujagyslių stentai

LITUS<sup>Xi</sup> periferiniai balionu išplečiami stentai

LITUS<sup>Xi 6F</sup> periferiniai balionu išplečiami stentai

LITUS<sup>Xi-</sup> periferiniai balionu išplečiami stentai

Klasė III:

EMAX atsiurbimo kateteriai

MAGMA rapamicinu dengti koronariniai stentai

JUTURNA-c PTCA balioniniai kateteriai



Vertimas tikras

Direktorė  
**Vestina Strakšytė**

A handwritten signature in blue ink, appearing to be "Vestina Strakšytė".

Parašas

Ruth Delbeck-Bayer

DEKRA Certification GmbH Stuttgart; 2020-03-19

Sertifikavimo tarnybos ID numeris: 0124

**DICHIARAZIONE DI CONFORMITA' CE**  
*CE DECLARATION OF CONFORMITY*

**BIONEN S.A.S. DI BARBARA NENCIONI & C.**

**in qualità di fabbricante, dichiara sotto la propria responsabilità che il prodotto:**  
*as manufacturer, declares under its own responsibility that the device:*

**ELETTRODI AD AGO SUBDERMALE, sterili e non sterili**  
*SUBDERMAL NEEDLE ELECTRODES, sterile and not sterile*

**ELETTRODI AD AGO CONCENTRICO, sterili e non sterili**  
*CONCENTRIC NEEDLE ELECTRODES, sterile and not sterile*

**ELETTRODI AD AGO MONOPOLARE, sterili**  
*MONOPOLAR NEEDLE ELECTRODES, sterile*

**come da Doc. n° 042 Rev. F del 20.11.2017**  
*see Doc. n° 042 Rev. F dated 20.11.2017*

**BIOFEEDBACK PRESSORIO – ref. 0032.001**  
*PRESSURE BIOFEEDBACK – ref. 0032.001*

**Appartiene alla Classe IIa**  
*Is a Class IIa device*

**è stato costruito applicando il sistema di garanzia della qualità, approvato dall'organismo notificato IMQ, numero identificativo 0051, per la fabbricazione e controllo finale del prodotto e risponde ai requisiti presenti nell'Allegato I della Direttiva 93/42/CEE sui dispositivi medici per la classe IIa.**

*Is manufactured according to the Quality Assurance System, approved by IMQ n° 0051, for manufacturing and final control of the product and complies with the requirements of 93/42/EEC Directive, Annex I.*

**Rif.:**

**Certificato IMQ n.1493/MDD**      **norma**  
*IMQ Certificate n. 1493/MDD*      *norm*

**Allegato II, della direttiva 93/42/CEE e s.m.i**  
*Annex II of the Directive 93/42/EEC and its revised version*

FIRENZE 16/04/2020

**KOPIJA TIKRA**

Direktorė  
**Vestina Strakšytė**

TIMBRO E FIRMA DEL LEGALE RAPPRESENTANTE

Monia Nencioni

BIONEN s.a.s. di Barbara Nencioni & C.  
Sede: Via P. Petrocchi, 42/1 – 50127 FIRENZE (FI)  
Tel. / Fax: +39 055 412188 – Mobile 335 8458876  
Cod. Fisc. Part. IVA: 04132210487

## CE Atitikties Deklaracija

### BIONEN S.A.S. DI BARBARA NENCIONI & C.

kaip gamintojas savo atsakomybe pareiškia, kad prietaisai:

Sterilūs ir nesterilūs poodiniai adatiniai elektrodai  
Sterilūs ir nesterilūs koncentriniai adatiniai elektrodai  
Sterilūs monopoliniai adatiniai elektrodai

Žiūrėti Doc. nr. 042 Rev. F, data 20.11.2017

Slėgio atsakikliai – ref. 0032.001

Yra IIa klasės prietaisai

Gaminami pagal kokybės užtikrinimo sistemą, patvirtintą IMQ Nr. 0051, gamybai ir produkto kontrolei atitinka 93/42/EEC Direktyvos I priedo reikalavimus.

IMQ Sertifikato Nr. 1493/MDD

II priedas Direktyvis 93/42/EEC ir jo pakeista versija

FIRENZE 16/04/2020

Monia Nencioni  
/Parašas/

Vertimas tikras

Direktorė  
Vestina Strakšytė

