7 pirkimo dalis - PTA vielos pravedėjai be markerių

Intervention Accessories

INT MEDICAL

Vienos dalies konstrukcija

Guide Wire-PTFE

- High quality PTFE pre-coated stainless steel. Dengta teflonu (PTFE)
- Highly flexible and smoothly rounded wire tip.
- Special designed dispenser to achieve easy flush.
- Designed to provide true 1:1 torque response to facilitate navigation and rapid vessel selection.
- J tip radius: 3.0 mm or 1.5mm. J formos tipo galiukas
- X-ray contrast tip - 3 cm 3 cm ilgio rentgenokontrastinis galiukas

Skersmuo Galiuko forma Ilgis

Ref.No.	Diameter	Tip shape	Length	Ref.No.	Diameter	Tip shape	Length
GW181JF	0.018" (0.46mm)	3mm J	150cm	GW221JF	0.021" (0.53mm)	3.0 mm J	150cm
GW182JF			180cm	GW212JF			180cm
GW183JF			260cm	GW213JF			260cm
GW181SF		Straight	150cm	GW211SF		Straight	150cm
GW182SF			180cm	GW212SF			180cm
GW183SF			260cm	GW213SF			260cm
GW351JF	0.035" (0.89mm)	3mm J	150cm	GW381JF	0.038" (0.97mm)	3.0 mm J	150cm
GW352JF			180cm	GW382JF			180cm
GW353JF			260cm	GW383JF			260cm
GW351SF		Straight	150cm	GW381SF		Straight	150cm
GW352SF			180cm	GW382SF			180cm
GW353SF			260cm	GW383SF			260cm
GW351BJF		1.5mm J	150cm	GW381BJF		1.5 mm J	150cm
GW352BJF			180cm	GW382BJF			180cm
GW353BJF			260cm	GW383BJF			260cm

Guide Wire-Hydrophilic

- High quality Niti core wire enables1:1 torque control for better navigation and faster vessel selection.
- TPU jacket with tungsten providing excellent visibility under X-ray.
- Unique coating technology ensure a lubricant surface durable.

Standard Guidewire

Ref NO.	Wire Type	Diameter	Flexible Taper Length	Tip Shape	Length
HG353AF	Standard	0.035" (0.89 mm)	10cm	Angled	150cm
HG354AF					180cm
HG355AF					260cm
HG353SF				Straight	150cm
HG354SF					180cm
HG355SF					260cm
HG353JF				3.0 mm J	150cm
HG354JF					180cm
HG355JF					260cm
HG383AF	Standard	0.038" (0.97 mm)	10cm	Angled	150cm
HG384AF					180cm
HG385AF					260cm
HG383SF				Straight	150cm
HG384SF					180cm
HG385SF					260cm
HG383JF				3.0 mm J	150cm
HG384JF					180cm
HG385JF					260cm

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2020.106.14142-1 Desingn Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Shanghai Kindly Medical Instruments Co., Ltd.
Company Address	: No.925 Jinyuan yi Road, 201803,Shanghai, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Cardiovascular Angiography Catheter - Class III Sterile Guiding Catheter - Class III Sterile Micro Catheter - Class III Sterile Cardiovascular Guidewire - Class III
GMDN	: 10688, 17846, 36205, 31668

Product Types are attached.

Certificate Number	: M.2020.106.14142
Report Number	: MD.4077.IB
Initial Assessment Date	: 22.10.2020
Registration Date	: 29.12.2020
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc.Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive 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 audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

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EC DESIGN EXAMINATION CERTIFICATE

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2020.106.14142 the validity of the certificate M.2020.106.14142-1 will also end.

Company Name	: Shanghai Kindly Medical Instruments Co., Ltd.
Company Address	: No.925 Jinyuan yi Road, 201803,Shanghai, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Section 4)
Product	: Sterile Cardiovascular Angiography Catheter - Class III Sterile Guiding Catheter - Class III Sterile Micro Catheter - Class III Sterile Cardiovascular Guidewire - Class III
GMDN	: 10688, 17846, 36205, 31668

Product Types are attached.

Certificate Number	: M.2020.106.14142-1
Report Number	: MD.4077.IB
Initial Assessment Date	: 22.10.2020
Registration Date	: 29.12.2020
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive 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 audits, defined by Annex II, section 5 of the aforementioned directive. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

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