



MESH FOR HERNIA AND INCONTINANCE
TECHNICAL FILE

DOCUMENT NO : TF1
REVISION NO : 00
PUB. DATE : 15.08.2010
PAGE NO : 1/1

KATALOGAS  pirkimo dalis

TECHNICAL SPECIFICATIONS

PRODUCT	Cat.No.	TAPE SIZE
 <p>Supro SUI Vaginal tape</p> <p>Vaginal tape tension free Treatment of Stress Urinary Incontinence</p>	SUPRAPUBIC KIT	10X450mm
	TOT KIT	10X450mm
	HELICAL KIT	10X450mm
	VAGINAL TAPE	10X450mm
	CYSTOCELE KIT	CB80X60X380 mm
	CYSTOCELE FOUR CORNER	CB80X60X380 mm
	RECTOCELE KIT	RB36X280mm



MESH FOR INCONTINANCE:

Raw Material: Polypropylene Monofilament 150 micron thread

Structure : Knitted

Weight : 85 g/m²

Thickness : 420 micron



**MESH FOR HERNIA AND INCONTINANCE
TECHNICAL FILE**

DOCUMENT NO : TF1
REVISION NO : 00
PUB. DATE : 15.08.2010
PAGE NO : 1/1

TECHNINĖ SPECIFIKACIJA

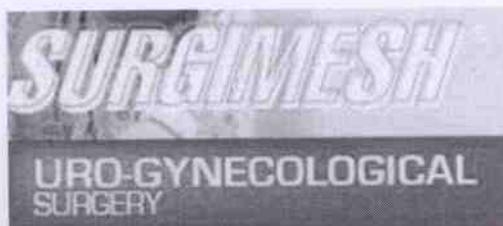
SUPRO SUI ŠLAPIMO NELAIKYMO JUOSTELĖ/VAGINAL TAPE

JUOSTELĖS IŠMATAVIMAI: 10X450 MM (1X45 CM.)

MEDŽIAGA –POLIPROPILENAS

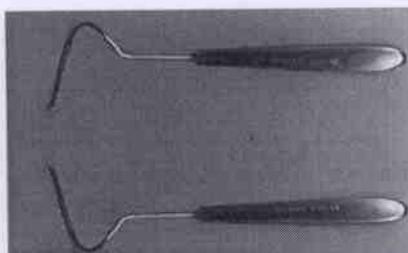
SVORIS – 85 G/M²

STORIS – 420 MIKRONŲ



Implantas įvedamas su:

Daugkartinio naudojimo 2 Transobturatoriniais įvedėjais, S formos, Kodas ATOT-RL:



Daugkartinio naudojimo Retrogaktiniu įvedėju, ¼ apskritimo formos, Kodas AVB:





Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 10 0664 QS/NB/b

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 54/2015 (Collection of Laws), certifies that the products – medical devices of Class IIb

Mesh for Hernia Mesh for Incontinence

manufactured by company

Klas Medikal Cihazlar Sanayi Mumessillik Ic ve Dis Tic Ltd. Sti.
Ramazanoğlu Mahallesi Yıldırım Sokak. No:1 Pendik 34906, İstanbul, Turkey

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Reports No. 803600902a/2010, No. 343602841/2014 and No. 343603256/2015, which are enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 9th August 2017 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023



Paul Vaj
RNDr. Radomír Čevelík

Issued in Zlín, on 30th June 2015
Replaces withdrawn EC Certificate No. 10-0664-QS/NB/a issued on 16th July 2014

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

ASPIDE MEDICAL

246 allée Lavoisier

42350 LA TALAUDIÈRE FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Implants de renfort et de soutènement, à base de polymère ou de silicone, pour les chirurgies générale et plastique, viscérale et digestive, gynécologique et urologique, et ancillaires associés.

Instruments pour les chirurgies générale et plastique, viscérale et digestive, gynécologique et urologique.

Reinforcement and support implants, polymer or silicone based, for general and plastic, visceral and digestive, gynecological and urological surgeries, and associated ancillaries.

Instruments for general and plastic, visceral and digestive, gynecological and urological surgeries.

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé N090171-R, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced N090171-R, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : June 5th, 2013 (included)

Valable jusqu'au / Expiry date : June 4th, 2016 (included)



For the General Director
Laurence DAGALLIER
Deputy Director

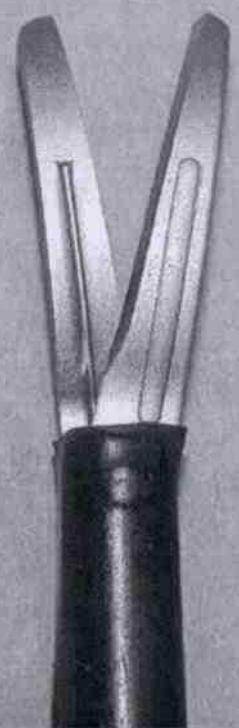
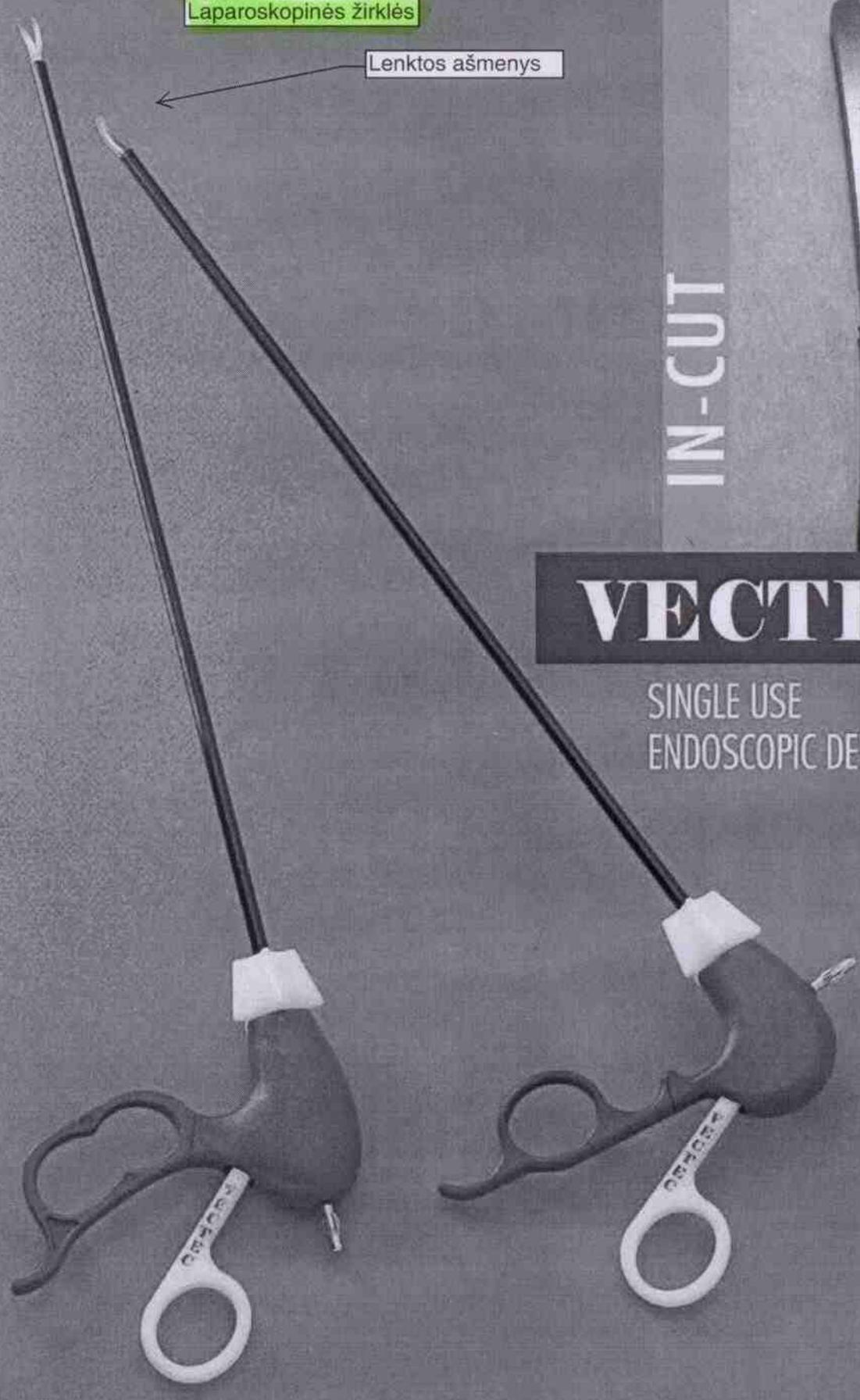
12 pirkimo dalis
Laparoskopinės žirklys

Lenktos ašmenys

IN-CUT

VECTEC

SINGLE USE
ENDOSCOPIC DEVICES



VECTEC

REF: IK5 330



Darbinis ilgis

Diametras

Ašmenų ilgis

IN CUT HIGH QUALITY SINGLE USE LAPAROSCOPIC SCISSORS

Reference	Working length	Diameter	Blade cut length	Connector
IC5 330	330 mm	5 mm	17 mm	Radial
IK5 330	330 mm	5 mm	17 mm	Axial
T5 330	330 mm	5 mm	12 mm	Radial
C5 470 *	470 mm	5 mm	17 mm	Radial
C5 250 *	250 mm	5 mm	17 mm	Radial

* box of 5 individually packaged units

Ergonomic handle allowing a precise surgical gesture.

IK5 330 model developed for gastrointestinal surgery.

IC5 330 model dedicated to gynecological surgery.

Double action curved blades facilitating the dissection.

Monopolar coagulation with extra long electrical insulation up to the active portion of the blades.

Packaging: box of 25 individually packaged units.

Individualiai
supakuotos



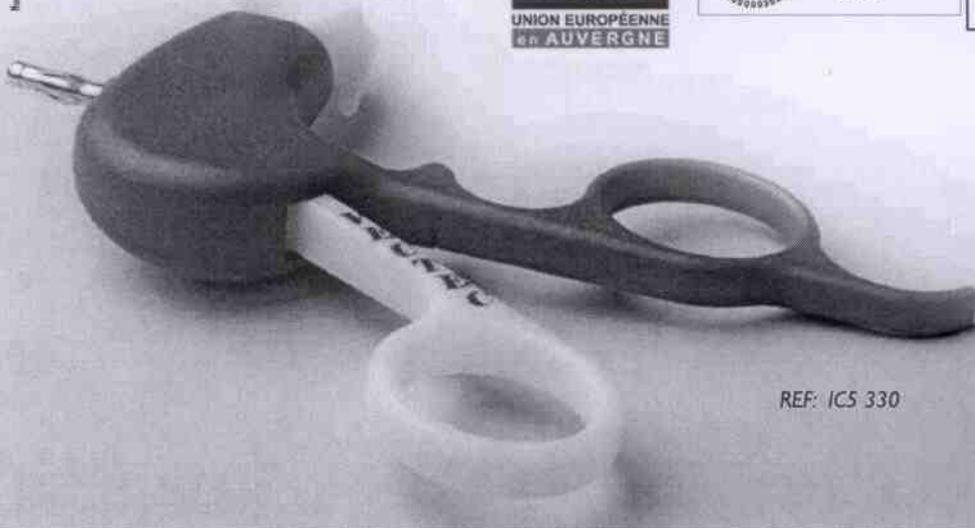
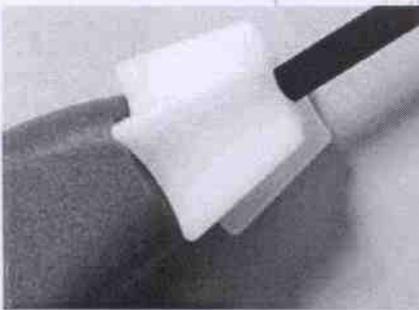
• Certified Management System
• EN ISO 9001
• EN ISO 13485
• ISO 13485 under CMD/CAS

CE
0197

MD Class IIb
Made in France
See instructions for use



REF: CAB 3000
« Single use monopolar cable »



REF: IK5 330

VECTEC

Bioparc - Vichy - Hauterive
03270 Hauterive
FRANCE

Phone : +33 (0)4 70 58 41 70
Fax : +33 (0)4 70 58 41 79
Email : vectec@vectec.fr
<http://www.vectec.fr>

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

VECTEC

Z.A. Bioparc

03270 HAUTERIVE FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Instruments chirurgicaux endoscopiques à usage unique : ciseaux, pinces, crochets, aiguilles de pneumopéritoine, trocars, systèmes de rétractation laparoscopique, manipulateurs utérin et rectal et câbles de connexion électrique pour des applications en chirurgie et électrochirurgie digestive, gynécologique et urologique.

Disposable surgical endoscopic instruments : scissors, forceps, hooks, pneumoperitoneum needles, trocars, laparoscopic retraction systems, uterine and rectal manipulators and electrical connection cables for the area of surgical and electrosurgical applications for digestive, gynaecological and urological surgeries.

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P142535, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P142535, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : **October 12th, 2015 (included)**

Valable jusqu'au / Expiry date : **October 11th, 2018 (included)**



On behalf of the Certification Director

Cécile VAUGELADE

G-MED Certification Division Manager

LNE - 30168 rev. 0

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial

LNE/G-MED • Organisme notifié n° 0459

1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

Identification des dispositifs / Identification of devices

Référence / Reference	Description FR /EN	Classe / Class	Code GMDN
Gamme d'instruments stériles à usage unique <i>Range of single-use sterile instruments</i>			
C5 250	Ciseaux monopolaires « IN CUT » « IN CUT » <i>Monopolar scissors</i>	IIb	37100
C5 330	Ciseaux monopolaires « IN CUT » « IN CUT » <i>Monopolar scissors</i>	IIb	37100
C5 470	Ciseaux monopolaires « IN CUT » « IN CUT » <i>Monopolar scissors</i>	IIb	37100
T5 330	Ciseaux monopolaires « IN CUT » « IN CUT » <i>Monopolar scissors</i>	IIb	37100
IC5 330	Ciseaux monopolaires « IN CUT » « IN CUT » <i>Monopolar scissors</i>	IIb	37100
IK5 330	Ciseaux monopolaires « IN CUT » « IN CUT » <i>Monopolar scissors</i>	IIb	37100
A5 330	Pince atraumatique monopolaire <i>Monopolar atraumatic grasping forceps</i>	IIb	37388
F5 330	Pince atraumatique monopolaire <i>Monopolar atraumatic grasping forceps</i>	IIb	37388
G5 330	Pince monopolaire <i>Monopolar grasping forceps</i>	IIb	37388
D5 330	Dissecteur monopolaire <i>Monopolar dissector</i>	IIb	37388
MD5 330	Dissecteur monopolaire <i>Monopolar dissector</i>	IIb	37388
H5 330	Crochet monopolaire <i>Monopolar hook</i>	IIb	35105
H5 330L	Crochet monopolaire <i>Monopolar hook</i>	IIb	35105

LNE/G-MED

0459



On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

ADD

720 DM 0701-31 rev 5 du 28/07/2015