Anexa nr. 8
la Documentația standard
nr. ocds-b3wdp1-MD-1729757339018
din 24 octombrie 2024

DECLARAŢIE
privind valabilitatea ofertei

Către IMSP Institutul de Medicina Urgenta
(*MD 2004, MOLDOVA, mun.Chişinău, mun.Chişinău, str.Toma Ciorbă, 1*)

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, **privind achiziționarea Consumabile medicale - 2024 (2), prin procedura de achiziție de valoare mică,** pentru o durată de 60 zile, (șaizeci), respectiv până la data de 30.12.2024 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 28.10.2024

Digitally signed by Gherman Irina
Date: 2024.10.31 09:32:20 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Cu stimă,
Ofertant/candidat
Denolga Medical" SRL
(semnătura autorizată)

Anexa nr. 2
la Regulamentul cu privire la achiziţiile
publice de valoare mică

DECLARAŢIE DE ELIGIBILITATE

Către IMSP Institutul de Medicina Urgenta
(MD 2004, MOLDOVA, mun.Chişinău, mun.Chişinău, str.Toma Ciorbă, 1)

Stimaţi domni,

Subsemnata, Gherman Irina, reprezentant împuternicit al **„Denolga Medical" SRL**, în calitate de ofertant, declar pe propria răspundere, sub sancţiunea excluderii din procedură şi sub sancţiunile aplicate faptei de fals în acte publice, că nu mă aflu în una dintre situaţiile prevăzute la art. 19 din Legea nr. 131/2015 privind achizițiile publice.

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

Data completării 28.10.2024

Ofertant/candidat
„Denolga Medical" SRL
(semnătura autorizată)

Anexa nr. 22
la Documentația standard
nr. ocds-b3wdp1-MD-1729757339018
din 24 OCTOMBRIE 2024

Specificaţii tehnice

Numărul procedurii de achiziție:	**21302252** din 01.11.2024 _conform SIA RSAP / M-Tender
Denumirea procedurii de achiziție:	**Consumabile medicale – 2024 (2)**

Denumirea bunurilor/serviciilor	Model articol	Țara de origine	Producător	Specificarea tehnică deplină solicit. de autoritatea contractantă	Specific tehnică deplină propusă de către ofertant	Standard de referinţă
1	2	3	4	5	6	7
4. Forcepc de litoextractie	27424F/ 27424P – unul la alegere	Germania	Karl Storz	Forcepc de litoextractie rigid, tip alligator 3.3Fr, p/u ureterorenoscop semirigid	Forcepc de litoextractie rigid, tip alligator 4 Fr, p/u ureterorenoscop semirigid, pu model 27001LK	EC, ISO
5. Sonde pneumatice de litotritie de contact	27632635	Germania	Karl Storz	Sonde pneumatice de litotritie de contact, diametrul 1mm, compatibile p/u sursa de energie Calculsplit Kerl Storz	Sonde pneumatice de litotritie de contact, diametrul 1mm, compatibile p/u sursa de energie Calculsplit Kerl Storz	EC, ISO
8. Trocar 11mm	40123NAL	Germania	Karl Storz	Trocar (port toracoscopic) flexibile, capăt distal oval oblic, cu trocar cu vârf conic, reutilizabil, material flexibil medical, nesteril. Diametrul 11mm; Lungime de lucru 100mm.	Trocar (port toracoscopic) flexibile, capăt distal oval oblic, cu trocar cu vârf conic, reutilizabil, material flexibil medical, nesteril. Diametrul 11mm; Lungime de lucru 85 mm.	EC, ISO
9. Trocar 6mm	40120NAL	Germania	Karl Storz	Trocar (port toracoscopic) flexibile, capăt distal oval oblic, cu trocar cu vârf conic, reutilizabil, material flexibil medical, nesteril. Diametrul 6mm; Lungime de lucru 100mm.	Trocar (port toracoscopic) flexibile, capăt distal oval oblic, cu trocar cu vârf conic, reutilizabil, material flexibil medical, nesteril. Diametrul 6mm; Lungime de lucru 85 mm.	EC, ISO

Semnat:_____

Numele, Prenumele: **Gherman Irina**
În calitate de: **Director**
Ofertantul: **„Denolga Medical" SRL**
Adresa: **Mun. Chișinău, str. Grenoble, 149A**

Anexa nr. 23
la Documentația standard
nr. ocds-b3wdp1-MD-1729757339018
din 24 octombrie 2024

Specificații de preț

Numărul procedurii de achiziție:	**21302252** din 01.11.2024 _conform SIA RSAP / M-Tender
Denumirea procedurii de achiziție:	**Consumabile medicale – 2024 (2)**

Cod CPV	Denumirea bunurilor/serviciilor	Cant.	U/M	Preţ unitar (f/TVA)	Preţ unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termen livrare	Clasificație bugetară (IBAN)
1	2	3	4	5	6	7	8	9	10
	Bunuri/servicii								
	4. Forcepc de litoextractie	4	buc.	13 550,00	16 260,00	54 200,00	65 040,00	la comandă, după necesități, în 5 zile, Incoterms 2020DDP	
	5. Sonde pneumatice de litotritie de contact	10	buc.	1 502,08	1 802,50	15 020,80	18 025,00		
	8. Trocar 11mm	3	buc	5 520,00	6 624,00	16 560,00	19 872,00		
	9. Trocar 6mm	3	buc	3 610,00	4 332,00	10 830,00	12 996,00		
	TOTAL					**96 610,80**	**116 933.00**		

Semnat:_____
Numele, Prenumele: **Gherman Irina**
În calitate de: **Director**
Ofertantul: **"Denolga Medical" SRL**
Adresa: **Mun. Chișinău, str. Grenoble, 149A**

ORDIN DE PLATĂ

Nr. 102 | DATA EMITERII 28 octombrie 2024 | TIP.DOC.1

PLĂTIŢI 967.00 LEI Noua sute saizeci si sapte lei 00 bani

PLĂTITOR SC DENOLGA MEDICAL SRL

CODUL IBAN MD69FT222400100003971498

CODUL FISCAL 1005600059558

PRESTATORUL PLĂTITOR 'FINCOMBANK'S.A. SUC.NR.1 CHISINAU

BENEFICIAR IMSP Institutul de Medicina Urgenta

CODUL IBAN MD55VI022510300000002MDL

CODUL FISCAL 1003600152606

PRESTATORUL BENEFICIAR B.C.'VICTORIABANK'S.A.

DESTINAŢIA PLĂŢII Pentru garantia pentru oferta la licitatia publica nr. ocds-b3wdp1-MD-1729757339018 (21302252)

TIPUL TRANSFERULUI NORMAL/URGENT

N

L.Ș.

SEMNĂTURILE EMITENTULUI

CODUL TRANZACŢIEI 001

DATA PRIMIRII 28 octombrie 2024 00:00:00

DATA EXECUTĂRII 28.10.2024 12:50:13

Copia documentului electronic

'FinComBank'S.A.
IDNO 1002600005347

28.10.2024 12:50:13

internet-banking

L.Ș.

MOTIVUL REFUZULUI

I.P. "AGENȚIA SERVICII PUBLICE"
Departamentul înregistrare și licențiere a unităților de drept

Extras
din Registrul de stat al persoanelor juridice
nr. **119574** din **31.10.2023**

Denumirea completă: **Societatea Comercială ”DENOLGA MEDICAL” S.R.L.**
Denumirea prescurtată: **S.C. ”DENOLGA MEDICAL” S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată**
Numărul de identificare de stat și codul fiscal: **1005600059558**
Data înregistrării de stat: **15.12.2005**
Sediu: **MD-2019, strada Grenoble 149A, mun. Chişinău, Republica Moldova**
Genurile de activitate:

1. **Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;**
2. **Acordarea asistenţei medicale de către instituţiile medico-sanitare private;**
3. **Activitatea farmaceutică;**
4. **Comerţul cu ridicata al aparatelor electrice de uz casnic;**
5. **Comerţul cu ridicata al cerealelor, seminţelor şi furajelor pentru animale;**

Capitalul social: **5400 Lei**
Administrator(i): **GHERMAN IRINA IDNP 0960210381510**
Asociați:

1. **GHERMAN IRINA (IDNP 0960210381510), partea socială 5400 Lei, ce constituie 100%**

Beneficiari efectivi: **GHERMAN IRINA (IDNP 0960210381510)**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr.220/2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de 31.10.2023

Specialist coordonator
Ludmila Ciur
tel. 022-207-838

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "DENOLGA MEDICAL" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1005600059558

Data înregistrării **15.12.2005**

Data eliberării **15.12.2005**

Dragomir Ala, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

MD 0048642

otpbank

F/COM/CC/23/02

Nr. CIF9-9564.2024

Data: 29.10.2024

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **OTP Bank S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania DENOLGA MEDICAL SC SRL, cod fiscal (IDNO) 1005600059558, detine următoarele conturi curente in MDL la OTP Bank S.A., Sucursala nr.9 Centru:

MDL-MD59MO2224ASV23107877100

Certificatul este emis în baza solicitării dvs transmisa prin email, înregistrată in cadrul sucursalei cu *nr. COF9-127.2024*

Stratenco Nadejda L.Ș.
Numele, Prenumele si Semnătura
Director sucursalei nr. 9 „Centru"

REPUBLICA MOLDOVA mun. CHIȘINĂU OTP Bank S.A. otpbank Sucursala «Centru» IDNO 1002600006089

Executor : Demianov Dmitri
Tel: 062004913

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 04

Manufacturer:

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
GERMANY

SRN Manufacturer - DE-MF-000005723

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 084462 0072 Rev. 04

Report No.: 713300338

Preceding Certificate No.: G10 084462 0072 Rev. 03

Valid from: 2023-11-23
Valid until: 2025-12-17

Date of Initial Issuance: 2020-12-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-11-23

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 04

Classification:	Class IIa
Device Group:	A018099 - NEEDLES - OTHER ACCESSORIES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	A060102 - SURGICAL DRAINAGE CONNECTION MEDICAL TUBES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	A060399 - FLUID COLLECTION BAGS AND SYSTEMS - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	K010101 - TROCAR, SINGLE-USE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	K030203 - ARTHROSCOPY BLADES, SINGLE-USE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	K030299 - ARTHROSCOPY SURGICAL INSTRUMENTS, SINGLE USE - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L0102 - SURGICAL KNIVES, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L030101 - SUCTION AND IRRIGATION SURGICAL CANNULAS AND HANDPIECES, REUSABLE
Intended Purpose:	./.

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 04

Classification:	Class IIa
Device Group:	L030199 - GENERAL SURGERY SURGICAL CANNULAS AND HANDPIECES, REUSABLE - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L031202 - ABDOMINAL TROCAR, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L031203 - OTOLARYNGOLOGICAL SURGERY TROCAR, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L031301 - GENERAL SURGERY BIOPSY FORCEPS, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L031401 - GENERAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L0399 - GENERAL SURGERY INSTRUMENTS, REUSABLE - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L050903 - GYNECOLOGICAL SURGERY FORCEPS, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L059099 - OBSTETRICS AND GYNECOLOGY INSTRUMENTS, REUSABLE - OTHER
Intended Purpose:	./.

Classification:	Class IIa

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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 04

Device Group:	L080501 - BRONCHUS CLAMPS, REUSABLE
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	L0899 - THORACIC SURGERY INSTRUMENTS, REUSABLE - OTHER
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	L0916 - ORTHOPAEDIC SURGERY BURS AND TIPS, REUSABLE
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	L1206 - LAPAROSCOPIC AND THORACOSCOPIC SURGERY SPREADERS AND RETRACTORS, REUSABLE
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	L140202 - NASAL AND PARANASAL CAVITY SURGERY PLIERS, REUSABLE
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	L140402 - TRACHEOTOMY INSTRUMENTS, REUSABLE
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	L149002 - ENT LEVERS, REUSABLE
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	L149003 - ENT RETRACTORS, REUSABLE
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	L149007 - ENT SPOONS, REUSABLE
Intended Purpose:	./.

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EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 04

Classification:	Class IIa
Device Group:	L149099 - ENT INSTRUMENTS, REUSABLE - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	L180102 - ENDOSCOPIC ELECTROSURGERY DISSECTORS, REUSABLE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Q030302 - ENT SURGERY BURS AND HANDPIECES, SINGLE-USE
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	U090101 - URINARY STONE RETRIEVAL BASKETS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	U090199 - URINARY STONE RETRIEVAL DEVICES - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	U090303 - UROGENITAL ENDOSCOPY BRUSHES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	U090399 - SINGLE-USE INSTRUMENTS FOR UROGENITAL ENDOSCOPY - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose:	./.

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EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 04

Classification:	Class IIa
Device Group:	Z120114 - SURGICAL NAVIGATION INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120202 - MOTORISED INSTRUMENTS FOR ENDOSCOPIC SURGERY
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120205 - UPPER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120206 - LOWER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120207 - GENITOURINARY ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z120208 - PULMONARY ENDOSCOPIC INSTRUMENTS

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(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 04

Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z120210 - ENT ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z120211 - ORTHOPAEDIC ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z120802 - GYNAECOLOGY AND FERTILITY TREATMENT INSTRUMENTS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM INSTRUMENTS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z121601 - EXTRACORPOREAL LITHOTRIPSY INSTRUMENTS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z121690 - VARIOUS INSTRUMENTS FOR UROLOGY
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z129099 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS - OTHER
Intended Purpose:	./.
Classification:	Class IIb

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EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 04

Device Group:	L180602 - ENDOSCOPIC ELECTROSURGERY ELECTRODES, REUSABLE
Intended Purpose:	HF-Electrodes are intended for cutting, coagulation or vaporization of tissue. HF-Electrodes are surgically invasive and meant for short term use.
Classification:	Class IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	Footswitches are intended to activate and control functions of medical devices. Footswitches do not have body contact.
Classification:	Class IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	High-frequency generators are intended to provide electrical power for high-frequency surgical application parts. High-frequency generators do not have body contact.
Classification:	Class IIb
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	Suction/irrigation pumps are intended to irrigate irrigation fluid into organs, joints and on fields of intervention, as weil as to suction off irrigation and body fluids, secretions, tissue and gases. Suction/irrigation pumps do not have body contact.
Classification:	Class IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	The footswitches are used to activate and control the functions of medical devices
Classification:	Class IIb
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	CALCUSPLIT probes are intended to guide pneumatic pulse energy for lithotripsy to the calculus. Probes are surgically invasive and meant tor short term use.
Classification:	Class IIb
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	Laser units are intended to provide laser radiation for cutting, coagulation, vaporization and ablation of biological tissue, as well as for lithotripsy of stones during surgical procedures. Laser units do not have body contact.

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 04

Classification:	Class IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	Insufflators with heating are intended to deliver and heat CO2 for insufflation (creating and maintaining a cavity) or replacement of ambient air in laparoscopy, Othoracoscopy, transanal endoscopy and endoscopic vessel harvesting. Insufflators are non-invasive and meant for short-term use.

Classification:	Class IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	The device is used to centrally display and enable remote control of the parameters.

Classification:	Class IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	Insufflators with heating and smoke evacuation are intended to deliver and heat CO2 for insufflation and smoke evacuation. Insufflators with heating and smoke evacuation are non-invasive and meant for short-term use.

Classification:	Class IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	Heated tubing sets with filter for insufflation are intended for filtration, transfer and heating of CO2 from the insufflator to the patient. Heated tubing sets with filter for insufflation are non-invasive and meant for short-term use

Classification:	Class IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	Heated tubing sets with filter for insufflation and smoke evacuation are intended for filtration, transfer and heating of CO2 from the insufflator to the patient as well as filtration and transfer of smoke from the patient to the insufflator. Heated tubing sets with filter for insufflation and smoke evacuation are non-invasive and meant for short-term use.

Classification:	Class IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

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	MINI-INVASIVE SURGERY
Intended Purpose:	Heated and humidified tubing sets with filter for insufflation and smoke evacuation are intended for filtration, transfer, heating and humidification of CO2 from the insufflator to the patient as well as filtration and transfer of smoke from the patient to the insufflator. Heated and humidified tubing sets with filter for insufflation and smoke evacuation are non-invasive and meant for short-term use.
Classification:	Class IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	Smart Smoke Evacuation is intended to communicate the level of surgical smoke to the insufflator. Smart Smoke Evacuation does not have body contact
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2020-12-18	713169106	-
01	2022-04-14	713224270	-
02	2022-09-22	713249165	-
03	2023-09-27	713253483 / 713274574	Supplemented: Device(s)/group of device(s) added
04	2023-11-23	713300338	Supplemented: Device(s)/group of device(s) added

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

29.10.2024

Către IMSP Institutul de Medicina Urgenta
ocds-b3wdp1-MD-1729757339018

Prin prezenta, “Denolga Medical” SRL declară că va prezenta mostre în timp de 3 zile, la solicitare, care vor fi supuse testării.

Cu stimă şi profund respect,

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Irina I. Gherman

Director, MBA

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