SC "DENOLGA MEDICAL" SRL

Republica Moldova, Chisinau
Adresa: str. Grenoble 149A
Adresa postala: Str. Bănulescu Bodoni, Nr. 45, of. 315
Tel.: +373 22 260-602; fax: +373 22 260-601
e-mail: irina@denolga.com
IBAN: **MD59MO2224ASV23107877100**
Bank: OTP BANK S.A.
SWIFT: MOBBMD22
Cod fiscal: 1005600059558
Cod TVA: 0206317

Digitally signed by Gherman Irina
Date: 2023.12.08 16:34:00 EET
Reason: MoldSign Signature
Location: Moldova

Cu respect,

_____

Irina I. Gherman

Director, MBA

SC "DENOLGA MEDICAL" SRL

Specificaţii tehnice

Numărul procedurii de achiziție **ocds-b3wdp1-MD-1701864806092** din **06.12.2023**						
Obiectul achiziției: consumabile specifice pentru cabinetul chirurgie enduorologică						
Denumirea bunurilor/serviciilor	**Denumirea modelului bunului**	**Ţara de origine**	**Produ-cătorul**	**Specificarea tehnică deplină solicitată de către autoritatea contractantă**	**Specificarea tehnică deplină propusă de către ofertant**	**Standarde de referinţă/Nr. de înregistrare AMDM**
1	2	3	4	5	6	7
Bunuri						
Electrod de taiere bipolar	27040GP140	Germania	Karl Storz	Electrod de tăiere, cu capătul de lucru unghiular, tip ansă, bipolar,cu 2 tije, pentru utilizare cu teaca 24/26 Fr (compatibil cu dispozitivul aflat în dotare - K. Storz), diametrul 0,40 mm	Electrod de tăiere, cu capătul de lucru unghiular, tip ansă, bipolar,cu 2 tije, pentru utilizare cu teaca 24/26 Fr (compatibil cu dispozitivul aflat în dotare - K. Storz), diametrul 0,40 mm	EC, ISO
Cablu electric pentru rezecție	UH801	Germania	Karl Storz	Cablu electric pentru rezecție in mediul salin, bipolar (compatibil cu dispozitivul aflat în dotare K. Storz)	Cablu electric pentru rezecție in mediul salin, bipolar (compatibil cu dispozitivul aflat în dotare K. Storz)	EC, ISO

Semnat:_____ Numele, Prenumele: **Gherman Irina** În calitate de: **Director**

Ofertantul: **“Denolga Medical” SRL** Adresa: **Mun. Chișinău, str. Bănulescu Bodoni, 45, of. 316**

Specificații de preț

Numărul procedurii de achiziție **ocds-b3wdp1-MD-1701864806092** din **06.12.2023**								
Obiectul achiziției: consumabile specifice pentru cabinetul chirurgie enduorologică								
Cod CPV	**Denumirea bunurilor/serviciilor**	**Unitatea de măsură**	**Canti-tatea**	**Preţ unitar (fără TVA)**	**Preţ unitar (cu TVA)**	**Suma fără TVA**	**Suma cu TVA**	**Termenul de livrare/prestare**
1	2	3	4	5	6	7	8	9
	Bunuri							
33190000-8	Electrod de taiere bipolarArc ghid diagnostic stiff	buc	12	2 566,80	3 080,16	**30 801,60**	**36 961,92**	Pînă la 25 decembrie 2023;
	Cablu electric pentru rezecție	buc	5	4 056,50	4 867,80	**20 282,50**	**24 339,00**	Pînă la 25 decembrie 2023;
	Total:					**51 084,10**	**61 300,92**	

Semnat:_____ Numele, Prenumele: Gherman Irina În calitate de: Director

Ofertantul: “Denolga Medical” SRL Adresa: Mun. Chișinău, str. Bănulescu Bodoni, 45, of. 316

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

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

Extras
din Registrul de stat al persoanelor juridice
nr. **115168** din **24.07.2023**

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 24.07.2023

Specialist coordonator
Aurelia Racu
tel. 022-207839

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

DECLARAŢIE DE ELIGIBILITATE

Către IMSP SCR „Timofei Moșneaga”

Stimaţi domni,

Subsemnatul, 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 08.12.2023

Ofertant/candidat
Denolga Medical SRL
(semnătura autorizată)

Electrodes, bipolar

Two-stem electrodes with stabilizers, for Working Elements 27040DB, 27040EB

KARL STORZ — ENDOSKOPE

For use with 24 – 28 Fr. resectoscope sheaths

The cutting loops are delivered with a wire diameter of 0.35 mm.
Loops with 30 as the last digit of the order number and orange insulation indicate a wire diameter of 0.30 mm.

bipolar
NaCl

27040GP1

Working end	24 / 26 Fr. color code: yellow	27 / 28 Fr. color code: brown	Instrument description
	**27040GP1**	**27040GPB1**	**Cutting Loop,** bipolar
	**27040GP140**	–	**Cutting Loop,** bipolar
	**27040GD1**	–	**Cutting Loop,** bipolar, small
	**27040BL1**	–	**Coagulation Electrode,** bipolar, pointed
	**27040GP130**	–	**Cutting Loop,** bipolar, diameter 0.30 mm
	**27040JB130**	–	**Cutting Loop,** bipolar, longitudinal, diameter 0.30 mm
	**27040JBE130**	–	**Cutting Loop,** bipolar, rectangular, longitudinal, diameter 0.30 mm
	**27040NB**	–	**Vaporization Electrode HALF MOON®,** bipolar, ball-shaped
	**27040VE**	–	**VapoEnucleation Electrode,** hemispherical

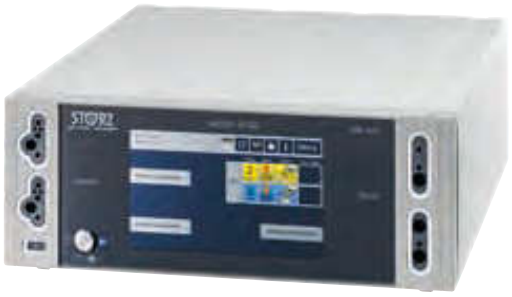
280 **Protection Tube,** for sterilization and storage of electrodes, loops, curettes and knives

07-22

Electrodes are delivered in packages of 6.

Note: Electrodes, in sterile packaging, are also available for single use.

High Frequency Surgery Units



UH 400 — **AUTOCON® III 400 High-End,** with KARL STORZ-SCB control NEO, power supply 220-240 VAC, 50/60 Hz, including mains cord

UH 400U — **AUTOCON® III 400 High-End,** with KARL STORZ-SCB control NEO, power supply 100-127 VAC, 50/60 Hz, including mains cord

UH 801 — **Bipolar High Frequency Cord,** length 400 cm, for KARL STORZ AUTOCON® III 400 SCB, for use with KARL STORZ bipolar resectoscopes

UF 902 — **Two-Pedal Footswitch,** with button for switchover function, for use with HF generators

KARL STORZ — ENDOSKOPE

EU-Declaration of Conformity

EU-Konformitätserklärung

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.
Diese Europäische Konformitätserklärung wird in alleiniger Verantwortung des Herstellers ausgestellt.

MANUFACTURER
HERSTELLER

Name of Company ***Firmen Name***	**Address** ***Adresse***	**SRN** ***SRN***
KARL STORZ SE & Co. KG	Dr.-Karl-Storz-Str. 34 78532 Tuttlingen Germany	DE-MF-000005723

PRODUCT IDENTIFICATION
PRODUKTIDENTIFIZIERUNG

Device Description ***Produkt Bezeichnung***	**Basic UDI-DI** ***Basis UDI-DI***
Unipolar High Frequency Cord, different sizes	4048551000505TF

Intended use
Zweckbestimmung

Connecting cable between HF equipment and unipolar or bipolar HF instruments as well as neutral electrodes for transporting high-frequency currents.

REF Number(s), Short text
REF Nummer(n), Kurztext

26004ML Unipolar High Frequency Cord, 500 cm, 26005ML Unipolar High Frequency Cord, 500 cm, 26006M Unipolar High Frequency Cord, 300 cm, 279A Unipolar High Frequency Cord, 300 cm, 26005M Unipolar High Frequency Cord, 300 cm, 26006ML Unipolar High Frequency Cord, 500 cm, 26176LE Bipolar High Frequency Cord, 300 cm, 279KA Unipolar High Frequency Cord, 300 cm, 279KB Unipolar High Frequency Cord, 300 cm, 279KBL Unipolar High Frequency Cord, 500 cm, 279KE Unipolar High Frequency Cord, 300 cm, UH801 Bipolar High Frequency Cord, 400 cm, 26002M Unipolar High Frequency Cord, 300 cm, 26002ML Unipolar High Frequency Cord, 500 cm, 26004M Unipolar High Frequency Cord, 300 cm, 26176LEL Bipolar High Frequency Cord, 500 cm, 26176LM Bipolar High Frequency Cord, 300 cm, 26176LML Bipolar High Frequency Cord, 500 cm, 26176LV Bipolar High Frequency Cord, 300 cm, 26176LVL Bipolar High Frequency Cord, 500 cm, 26176LW Bipolar High Frequency Cord, 300 cm, 277 Unipolar High Frequency Cord, 300 cm, 277A Unipolar High Frequency Cord, 300 cm, 277AL Unipolar High Frequency Cord, 500 cm, 277KA Unipolar High Frequency Cord, 300 cm, 277KB Unipolar High Frequency Cord, 300 cm, 277KBL Unipolar High Frequency Cord, 500 cm, 277KE Unipolar High Frequency Cord, 300 cm, 277KEL Unipolar High Frequency Cord, 500 cm, 277L Unipolar High Frequency Cord, 500 cm, 279 Unipolar High Frequency Cord, 300 cm, 847000E Bipolar High Frequency Cord, 300 cm, 847000M Bipolar High Frequency Cord, 300 cm, 847000V Bipolar High Frequency Cord, 300 cm, 847000W Bipolar High Frequency Cord, 300 cm, 847002V Bipolar High Frequency Cord, 450 cm, 26002MR Unipolar High

KARL STORZ — ENDOSKOPE

EU-Declaration of Conformity

EU-Konformitätserklärung

Frequency Cord, 600 cm, 26176LER Bipolar High Frequency Cord, 600 cm

RISK CLASS (according Annex VIII (EU) 2017/745)
RISIKOKLASSE (gemäß Anhang VIII (EU) 2017/745)

Class ***Klasse***	I	**Conformity Assessment Procedure** ***Konformitätsbewertungsverfahren***
Rule ***Regel***	1	Art. 52, Para. 7 *Art. 52, Para. 7*

A complete listing of applied standards is available upon request.
Eine vollständige Liste der angewandten Normen ist auf Anfrage verfügbar.

The Manufacturer declares that the above-mentioned products meet the provision of the following EU legislation.
Der Hersteller erklärt, dass die oben genannten Produkte den Bestimmungen folgender EU-Gesetzgebung entsprechen.

(EU) 2017/745 MDR
2011/65/EU RoHS

This declaration is valid until / *Diese Erklärung ist gültig bis zum*: 17.12.2025.

Tuttlingen, 06.07.2021

p.p. Karim Djamshidi-Gilani
Executive Director / Global Regulatory Affairs

This declaration instantly loses all validity in consequence of any product change not authorized by KARL SE & Co. KG in written form, in case of product change affects the conformity to the General Safety and Performance Requirements, so that a new placing on the market must be assumed.

Diese Erklärung verliert sofort ihre Gültigkeit in Folge jeder nicht durch KARL STORZ SE & Co. KG schriftlich autorisierten Änderung am Produkt, bei der die Konformität mit den Grundlegenden Sicherheits- und Leistungsanforderungen beeinflusst wird, so dass von einem neuen Inverkehrbringen auszugehen ist.

SAP ID: 300000427175
Version: BC

KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

Device Name Produkt Name	Cutting Loop, bipolar, 24/26 Fr.
Model Number(s) Modell Nummer(n)	27040GP140
Classification Klassifizierung	Class IIb per Annex IX, Rule 9 of Council Directive 93/42/EEC Klasse IIb gemäß Anhang IX, Regel 9 der Richtlinie 93/42/EWG des Rates

We issue the present Declaration of Conformity on our sole responsibility and herewith declare self-dependent that the device mentioned above meets the Essential Requirements as defined in Annex I MDD 93/42/EEC .
Wir stellen die vorliegend Konformitätserklärung in Eigenverantwortung aus und erklären hiermit unter alleiniger Verantwortung, dass das oben genannte Produkt die Grundlegenden Anforderungen gemäß Anhang I MDD 93/42/EWG erfüllt.

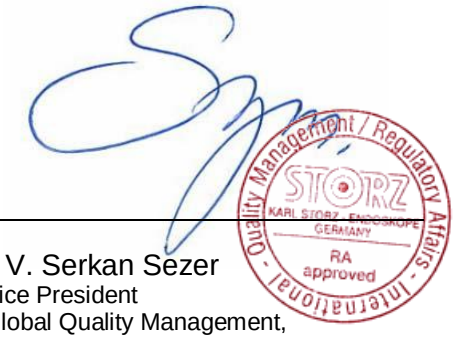
This Declaration of Conformity is issued according to Annex II excluding (4) Council Directive 93/42/EEC for Medical Devices (for class IIa and IIb devices).
Diese Konformitätserklärung ist erstellt gemäß Anhang II ohne Abschnitt (4) Richtlinie 93/42/EWG des Rates über Medizinprodukte (für Klasse IIa und IIb Produkte).
Notified Body / Registration Number / Benannte Stelle / Registrierungsnummer:
TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München / 0123

Full list of applied standards, directives and laws (12-C2.3.F013-LOAS-CM002) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3.F013-LOAS-CM002) auf Anfrage.

The validity of this declaration is determined by EC certificate number: G1 18 04 84462 012
Die Gültigkeit dieser Erklärung bestimmt sich nach dem EG Zertifikat mit der Nummer: G1 18 04 84462 012

CE 0123

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



Tuttlingen, 17 Juli 2018

i. V. Serkan Sezer
Vice President
Global Quality Management,
Regulatory Affairs, RSB & Service

This declaration loses all validity if KARL STORZ SE & Co. KG performs a product change which affects the Conformance to the Essential Requirements or an alteration of any kind not approved by KARL STORZ SE & Co. KG was made at the device mentioned above.
Diese Erklärung verliert ihre Gültigkeit sobald KARL STORZ SE & Co. KG Produktänderungen durchführt, welche die Konformität mit den Grundlegenden Anforderungen beeinflusst oder eine Änderung jeglicher Art ohne Freigabe durch die KARL STORZ SE & Co. KG am oben genannten Produkt durchgeführt wird.

Product Service

Add value.
Inspire trust.

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

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

Munich, 2023-06-29
Order No.: 713300646_2

Confirmation concerning EC Certificate G1 084462 0012 Rev. 01 and G2S 084462 0013 Rev. 01

We confirm that the following certificates:

G1 084462 0012 Rev. 01 (valid until 2023-07-16)
G2S 084462 0013 Rev. 01 (valid until 2023-07-16)

issued to the legal medical device manufacturer:

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

cover the Directive 93/42/EEC on Medical Devices with the scope:

G1 084462 0012 Rev. 01:

- Light Sources
- Light Carrier (adaptable)
- Optics (Telescopes) with channel
- Optics (Telescopes) without channel
- Fiberscopes with channel
- Fiberscopes without channel
- Semiflexible endoscopes with channel
- Rigid Videoscopes with channel
- Rigid Videoscopes without channel
- Flexible Videoscopes with channel
- Flexible Videoscopes without channel
- Sheaths
- Trocars
- Instruments with movable jaws
- Instruments without movable jaws
- Working Elements/ Working Inserts
- Cannulas

Product Service

- HF Instruments with movable jaws
- HF Instruments without movable jaws/ HF Electrodes
- HF Suction/ Irrigation Instruments
- HF Generators
- HF Foot Switches
- HF Working Elements
- Nonactive implants for ENT
- Nonactive bone implants for arthroscopic procedures
- Insufflators with Accessories
- Tubing Sets Insufflators
- Laser Devices
- Foot Switch Laser
- Laser Fibers
- Lithotripsy Devices
- Foot Switches Lithotripsy Devices
- Lithotripsy Probes
- Pumps
- Suction/ Irrigation Instruments
- Foot Switches with Pumps
- Tubing Sets Pumps
- Motor Control Unit
- Handpieces/ Motors
- Foot Switches Motor Control Unit
- Shaver/ Drills
- Morcellator Systems
- EM Navigation
- Active controlling systems, components of software

G2S 084462 0013 Rev. 01

- Medical equipment drape
- Suction/irrigation tubing
- ENT probe
- Adhesive bandage
- Laparoscopic cholangiography catheter
- Surgical plume evacuation system filter
- Laparoscopic access cannula seal
- Surgical instrument assist arm system, manually-adjusted
- Surgical irrigation/aspiration tubing set

and the following devices:

see:
order number 713300646_2:
Attachment 1 _Devices covered by G1 084462 0012 Rev. 01
Attachment 2 _Devices covered by G2S 084462 0013 Rev. 01

Product Service

With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

In accordance with Article 120 (2) Regulation (EU) 2017/745 (as amended by Regulation (EU) 2023/607 – hereafter referred to as MDR) the above-mentioned certificate remains valid after the end of the period indicated on the certificate at the latest until the date set out in Article 120 (3a) MDR applicable for the relevant risk class of the devices and subject to the manufacturer's compliance with the conditions specified in Article 120 (3c) MDR.

Especially no later than **26 May 2024**, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

According to Article 120 (3a) MDR Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:
(a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;
(b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

The above-mentioned certificates are valid.

MÜNCHEN TÜV SÜD PRODUCT SERVICE

Georg Bauer
TÜV SÜD PRODUCT SERVICE GMBH
PS-MHS-FA-0
Foreign Affairs

Article Number	Device Name	MDD classification
27040DB	Arbeitselement, bipolar	IIa
27040DO	Arbeitselement, bipolar	IIa
27040E	Arbeitselement	IIa
27040EB	Arbeitselement, bipolar	IIa
27040EO	Arbeitselement, bipolar	IIa
27040F	Schneideschlinge, abgewinkelt, 27 Charr.	IIb
27040FP	Schneideschlinge, bipolar, 27/28 Charr.	IIb
27040G	Schneideschlinge, abgewinkelt, 24 Charr.	IIb
27040GD	Schneideschlinge, bipolar, klein	IIb
27040GD1	Schneideschlinge, bipolar, klein	IIb
27040GDV	Schneideschlinge, bipolar, klein	IIb
27040GP	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040GP1	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040GP130	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040GP140	Schneideschlinge bipolar, 24/26 Charr.	IIb
27040GP30	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040GP40	Schneideschlinge, bipolar	IIb
27040GPB1	Schneideschlinge bipolar, 27/28 Charr.	IIb
27040GPO	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040GPO1	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040GPV	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040GPV40	Schneideschlinge, bipolar	IIb
27040JB	Schneideschlinge, bipolar, 24 Charr.	IIb
27040JB1	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040JB130	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040JB30	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040JBE130	Schneideschlinge, bipolar, 24/26 Charr.	IIb
27040K	Koagulationselektrode, 27 Charr.	IIb
27040L	Koagulationselektrode, 24 Charr.	IIb

08.12.2023

Către IMSP Spitalul Clinic
Republican„Timofei Moşneaga”
LP nr. ocds-b3wdp1-MD-1701864806092

Prin prezenta, “Denolga Medical” SRL confirmă următoarele:

- îşi asumă pe propria răspundere obligativitatea ca la livrare produsele vor fi înregistrate la AMDM.
- termenul de valabilitate al produselor livrate va fi cel puțin 80% din termenul total de valabilitate

Cu stimă şi profund respect,

_____

Irina I. Gherman

Director, MBA

SC “DENOLGA MEDICAL” Ltd

SC “DENOLGA MEDICAL” Ltd
Bănulescu Bodoni Str.,45/416; Chisinau, MD-2001; R Moldova
Tel: + 373 22 260-602; Fax: + 373 22 260-601
irina@denolga.com; www.denolga.com