Republika e Kosovës
Komuna e Prishtinës

Departamenti i Prokurimit

Prishtinë: datë, 03.01.2020

Zyrtari Përgjegjës i Prokurimit i Komunës së Prishtines, në mbështetje të nenit 108/A (paragrafi 10.1) të Ligjit per Prokurimin Publik nr. 04/L-042, i ndryshuar dhe plotësuar me ligjin Nr. 04/L-237, ligjin Nr. 05/L-068 dhe ligjin Nr. 05/L-092, duke u bazuar në nenin 8 (paragrafi 8.1.2) të Rregullave për Parashtrimin e Ankesave të aprovuara nga Komisioni Rregullativ i Prokurimit Publik, duke vendosur sipas **kërkesës për ri-shqyrtim** të datës 21.12.2019 të parashtruar nga Operatori Ekonomik "INTERLAB SHPK për aktivitetin: "Furnizim me paisje mjekesore per QKMF dhe AMU-ritender-pjesa I"dhe me numër të prokurimit: **616 -19-8612-111** nxjerr:

VENDIM

1.Refuzohet kërkesa për ri-shqyrtim e Operatori Ekonomik **"INTERLAB SHPK"**e datës 31.12.2019 lidhur me aktivitetin e prokurimit"Sherbimet e veçanta kontraktuale per perfaqesim ligjor per nevojat e Komunes se Prishtines" dhe me numër të prokurimit: **616 -19-9412-221** , kundër Njoftimit *për Vendimin e AK-se per dhenje të kontratës-pjesa e dyte* te AK –së, të datës 26.12.2019, te publikuar ne web-faqe te KRPP-së.

1. **Mbetet ne fuqi Vendimi për dhenje te kontrates per pjesen e dyte publikuar me datë: 26.12.2019;**

2. Ky vendim hyn në fuqi ditën e nënshkrimit dhe do të publikohet për të gjitha palët në platformën elekronike në adresën : https://e-prokurimi.rks-gov.net.

Arsyetim

Operatori Ekonomik "Lego SHPK"" me datë 31.12.2019 ka parashtruar kërkesën për ri-shqyrtim, lidhur me aktivitetin e prokurimit me titull: "Furnizim me paisje mjekesore per QKMF dhe AMU-ritender-pjesa I"dhe me numër të prokurimit: **616 -19-8612-111**.
Autoriteti Kontraktues, me datë 03.01.2020, ka shqyrtuar kërkesën në fjalë dhe ka konstatuar si vijon:

-Pretendimet jane te pa bazuara pasiqe Autoriteti Kontraktues ka analizuar me kujdes tenderin e pretenduesit dhe ka konstatuar se rekomandimet e komisionit te vleresimit jane te bazuara per arsyet ne vijim:

-Komisioni me te drejte ka konstatuar se pretenduesi nuk ka ofruar deshmi te mjaftueshme per furnizime te ngjajshme ne vleren e kerkuar,pasi qe deshmite e e

dorezuara kane te bejne kryesisht me materiale shpenzuese,kemikalie,qelqurina,paisje laboratorike,paisje per veterinari dhe paisje te TI-se,ndersa lidhur me kerkesat teknike nuk ka asnje koment nga komisioni;
-Lidhur me pretendimet se tenderuesi i propozuar per kontrate nuk ka deshmi per pozicionet 1,2 dhe 6 poashtu jane te pa bazuara pasiqe ne tenderin e tij eshte paraqitur katalogu per artikujt,se bashku me specifikat dhe deklaratat e prodhuesit per konformitetin e tyre me specifikimet teknike te kerkuara.

Ne baze te sqarimeve paraprake u vendos si ne Dispozitiv te Vendimit.

Zyrtarja e prokurimit qe administron kete lende duhet te publikoj kete Vendim ne E Prokurim.

Këshilla juridike:
Kundër këtij vendimi, ankuesi mund të paraqesë ankesë pranë OSHP-së. **Ankesa prane OSHP-se duhet te dorezohet brenda 10 (dhjetë) diteve pas pranimit te ketij vendimi.**

Shtese:Deshmite nga katalogu i tenderuesit "Made Kos".

Zyrtari përgjegjës i Prokurimit

CE EC Declaration of Conformity CE

Manufacturer:

ARI Medical Technology Co., Ltd.
Add: Block A, Lotus Industrial Park, Economic Development Zone, Hefei City, Anhui, China.

According to EC Declaration of Conformity set out in Annex VII of the Council Directive 93/42/EEC (MDD93/42/EEC) concerning medical devices for the following products Series:

Item No	Products Name	UMDNS Code	Classification
DEF-9000A/B/C/D DEF-8000A/B/C/D AED-7000/7000+ DEF-7000	Defibrillator	11129	Class III

And declare that:

- **The product meets the essential requirements set out in MDD93/42/EEC Annex VII**

The manufacturing site for the above products comply with EN ISO13485:2016 Quality Management System Requirements for Medical Devices.

ARI Medical Technology Co., Ltd.
Roy Wang
Sales Director

For and on behalf of
ARI Medical Technology Co., Limited
合肥奥立瑞医疗科技有限公司

.....
Authorized Signature(s)

Date: July 31, 2019

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 016389 0025 Rev. 00

Holder of Certificate: **VBM Medizintechnik GmbH**
Einsteinstr. 1
72172 Sulz a. N.
GERMANY

Facility(ies): VBM Medizintechnik GmbH
Einsteinstr. 1, 72172 Sulz a. N., GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production and distribution of medical products for Airway Management, Emergency, Accessories for Anesthesia and Intensive Care as well as Tourniquets**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713117338

Valid from: 2018-11-19
Valid until: 2021-11-18

Date, 2018-11-19

Stefan Preiß

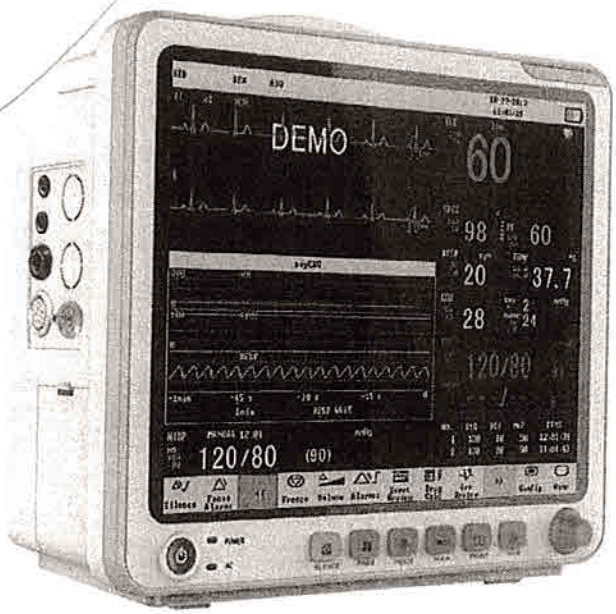
TÜV SÜD ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

LOT 2 item 9

ARI MEDICAL

ARI Medical Technology Co., Ltd.

AM-12 Patient Monitor (12.1 inch)



Feature

1. 12.1-inch Six Standard parameters: ECG, RESP, NIBP, SPO2, 2_TEMP, PR/HR
2. 13 Type Arrhythmic Analysis, Multi_Lead ECG Waveforms Display in Phase, Real time S_T segment analysis, pacemaker detection Drug calculation and titratiotable;
3. Efficient resistance to interference of defibrillator and electrosurgical cautery;
4. SPO2 can testing for 0.1% Weak;
5. RA-LL impedance Respiration;
6. Trend Coexist Display;
7. OxyCRG DyNamic View Display;
8. Bed to Bed view Display;
9. Networking capacity and nurse calling system;
10. Options: Central Monitoring System, IBP, EtCO2, Recorder, 12-Channel ECG, Touch Screen, VGA;
11. Built-in rechargeable battery 4400mAh;
12. 12.1" high resolution color TFT LCD display;
13. Large volume of tabular and graphic trends information storage and easy to recall;
14. Anti-ESU, anti- defibrillator;
15. Capture dynamic waveforms.

Technical Specification

ECG

Lead Mode: 5 Leads (R, L, F, N, C or RA, LA, LL, RL, V)

Lead selection: I, II, III, avR, avL, avF, V,
Waveform: 2 ch
Lead mode: 3 Leads (R, L, F or RA, LA, LL)
Lead selection: I, II, III,
Waveform: 1 ch
Gain: '2.5mm/mV, '5.0mm/mV, '10mm/mV, '20mm/mV, auto

Heart Rate and Alarm

Range
Adult: 15 ~ 300 bpm
Neo/Ped: 15 ~ 350 bpm
Accuracy: ± 1% or ± 1bpm, which great
Resolution: 1 bpm
Sensitivity: > 200 (uV P-P)
Differential Input Impedance: > 5 MΩ
CMRR
-Monitor: > 105 dB
-Operation: > 105 dB
-Diagnosis: > 85 dB
Electrode offset potential: ±300mV
Leakage Current: < 10 uA
Baseline Recovery: < 3 S after Defi.
ECG Signal Range: ±8 m V (Vp-p)
Bandwidth
-Surgery: 1 ~ 15 Hz
-Monitor: 0.5 ~ 35 Hz
-Diagnostic: 0.05 ~ 100 Hz
Calibration Signal: 1 (mV p-p), Accuracy: ±5%
ST Segment Monitoring Range: Measure and Alarm -2.0 ~ +2.0 mV
ARR Detecting
Type: ASYSTOLE, VFIB/VTAC, COUPLET, BIGEMINY, TRIGEMINY, R ON T, VT>2, PVC, TACHY, BRADY, MISSED BEATS, PNP, PNC
Alarm: Available
Review: Available

Respiration

Method: Impedance between R-F (RA-LL)
Differential Input Impedance: >2.5 MΩ
Measuring Impedance Range: 0.3~5.0Ω
Base line Impedance Range: 0 – 2.5 KΩ
Bandwidth: 0.3 ~ 2.5 Hz
Resp. Rate
Measuring and Alarm Range
-Adult: 0 ~ 120 rpm

-Neo/Ped: 0 ~ 150 rpm
Resolution: 1 rpm
Accuracy: ±2 rpm
Apnea Alarm: 10 ~ 40 S

NIBP

Method: Oscillometric
Mode: Manual, Auto, STAT
Measuring Interval in AUTO Mode: 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240,480 (Min)
Measuring Period in STAT Mode: 5 Min
Pulse Rate Range: 40 ~ 240 bpm
Alarm Type: SYS, DIA, MEAN
Measuring and alarm range
Adult Mode
-SYS: 40 ~ 270 mmHg
-DIA: 10 ~ 215 mmHg
-MEAN: 20 ~ 235 mmHg
Pediatric Mode
-SYS: 40 ~ 200 mmHg
-DIA: 10 ~ 150 mmHg
-MEAN: 20 ~ 165 mmHg
Neonatal Mode
-SYS: 40 ~ 135 mmHg
-DIA: 10 ~ 100 mmHg
-MEAN: 20 ~ 110 mmHg
Resolution Pressure: 1mmHg
Accuracy Pressure Maximum Mean error: ±5mmHg
Maximum Standard deviation: ±8mmHg
Overpressure Protection
-Adult Mode: 297±3 mmHg
-Pediatric Mode: 240±3 mmHg
-Neonatal Mode: 147±3 mmHg

SpO2

Measuring Range: 0 ~ 100 %
Alarm Range: 0 ~ 100 %
Resolution: 1 %
Accuracy: 70% ~ 100% ±2 %; 0% ~ 69% unspecified
Actualization interval: about 1 Sec.
Alarm Delay: 10 Sec.
Pulse Rate
Measuring and Alarm Range: 20~300bpm
Resolution: 1bpm

Accuracy: ±2bpm

Temperature

Channel: 2
Measuring and Alarm Range: 0 ~ 50 °C
Resolution: 0.1°C
Accuracy: ±0.1°C
Actualization interval: about 1 Sec.
Average Time Constant:<10 Sec.

IBP(optional)

Label: ART, PA, CVP, RAP, LAP, ICP, P1, P2
Measuring and alarm range
-ART: 0 ~ 300 mmHg
-PA: -6 ~ 120 mmHg
-CVP/RAP/LAP/ICP: -10 ~ 40 mmHg
-P1/P2: -10 ~ 300 mmHg
Press Sensor
Sensitivity: 5 uV/V/mmHg
Impedance: 300-3000Ω
Resolution: 1 mmHg
Accuracy: ±2% or ±1mmHg, which great
Actualization interval: about 1 Sec

Standard Packing List

5-lead ECG cable (including RESP)
Adult finger SpO2 sensor
Adult NIBP cuff
NIBP extension tube
TEMP sensor
AC power adaptor
ECG electrodes
Operation instruction

Optional Function

Central Monitoring System, IBP, EtCO2, Recorder, 12-Channel ECG, Touch Screen, VGA

Mobile Access
Add: Block B, CC Park, No.728 Lanzhou Road, Baohe Industrial Zone, Hefei, China.
Tel: 0086-551-63802963 Fax: 0086-551-63802920
Web: www.ari-cn.com Email: sales@ari-cn.com

ARI MEDICAL

ARI Medical Technology Co., Ltd.

CE EC Declaration of Conformity CE

Manufacturer:

ARI Medical Technology Co., Ltd

Block A, Lotus Industrial Park, Economic Development Zone, Hefei City, Anhui, China

According to EC Declaration of Conformity set out in Annex VII of the Council Directive 93/42/EEC (MDD93/42/EEC) concerning medical devices for the following products Series:

Item No	Products Name	UMDNS Code	Classification
Space Blankets Spine board Scoop stretcher Cervical collars Self-loader Stretchers Traction Splints First-aid Bag Resuscitator	First-Aid Apparatus	16630	Class I

And declare that:

- **The product meets the essential requirements set out in MDD93/42/EEC Annex VII**

The manufacturing site for the above products comply with EN ISO13485:2016 Quality Management System Requirements for Medical Devices.

ARI Medical Technology Co., Ltd
Roy Wang
Sales Director

For and on behalf of
ARI Medical Technology Co., Limited
合肥奥立瑞医疗科技有限公司

.....
Authorized Signature(s)

Date: August 29, 2019

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 016389 0017 Rev. 01

Manufacturer:

VBM Medizintechnik GmbH
Einsteinstr. 1
72172 Sulz a. N.
GERMANY

Facility(ies):

VBM Medizintechnik GmbH
Einsteinstr. 1, 72172 Sulz a. N., GERMANY

Product Category(ies): **Tourniquet Systems and Pressure Infusors with cuffs, Medical Devices for Trans Tracheal Ventilations, Laryngeal Tubes, Respiration Sets, Respiration accessories (except class I), Rectal Tampon by Roche (RTR)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713137731_1

Valid from: 2018-10-21
Valid until: 2023-10-20

Date, 2018-10-18

Stefan Preiß

TÜV SÜD ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

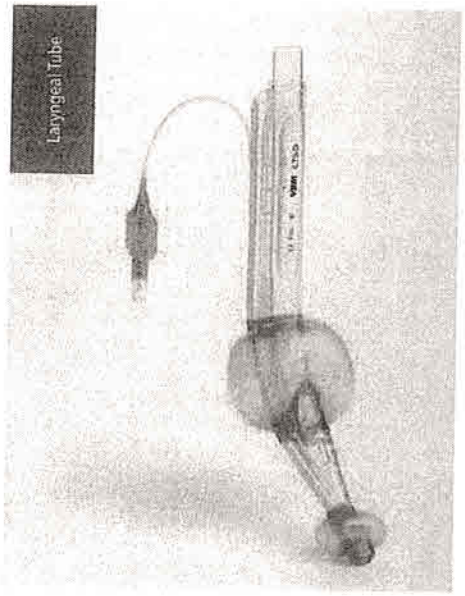
Lot item 8

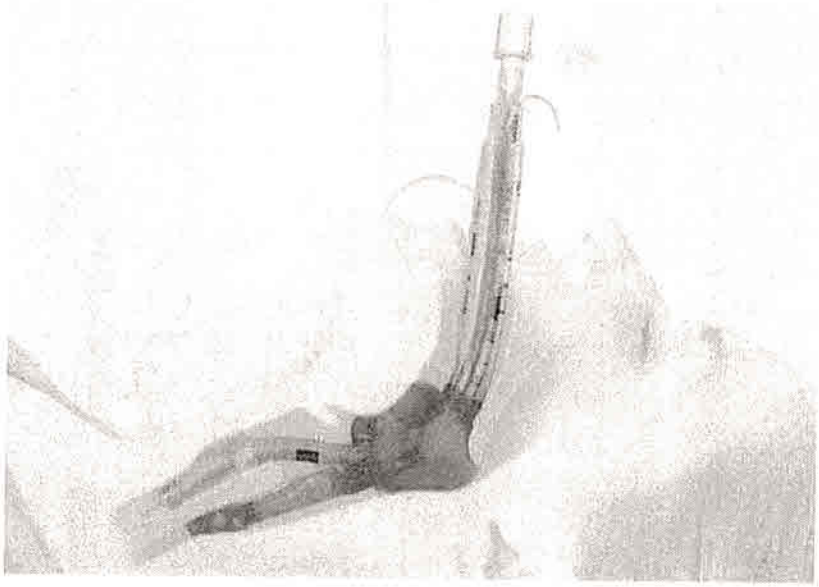
Laryngeal Tube

intubating Laryngeal Tube iLTS-D

VBM's 3rd generation supraglottic airway device

Laryngeal Tube





Up to 20% of all emergency intubations are estimated to be difficult to manage.[1] Having the right system available is the cornerstone of effective airway management in an emergency. Airway algorithms recommend the usage of supraglottic airway devices (SAD) as options to overcome difficult scenario.

In order to prevent aspiration, the NAP4 report prescribes the use of devices with gastric access.
SAD with intubating capability provide a way to reach a definitive airway (ET Tube placement).

As VBM's 3rd generation SAD the iLTS-D compiles all essential features required to achieve and protect an airway:

Ventilation – wide airway section to optimise gas flow and low pressure cuffs to maximise sealing performance (< 60 cmH_2O)

Drain Tube – allows the insertion of a gastric tube or suction catheter

Intubation – special design of ventilation lumen to enable fiberoptic insertion of an ET Tube

[1] Walls, Ron MD et al. "Manual of Emergency Airway Management" (2012): 4th edition, chapter 2, p. 9.

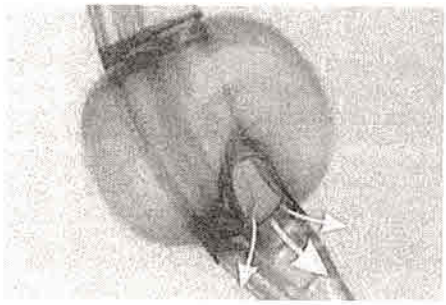
Features

Efficient sizing

The iLTS-D is the ideal solution to save space in emergency bags and crash carts.
Only two sizes match all patients ≥ 125 cm.

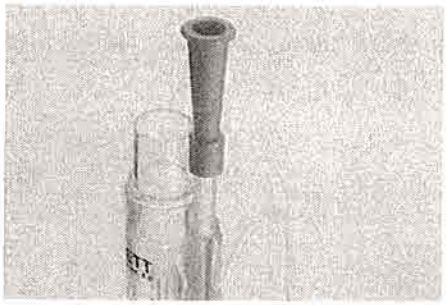
#2.5/3:	125–155 cm
#4/5:	≥ 155 cm

Laryngeal Tube



Ventilation

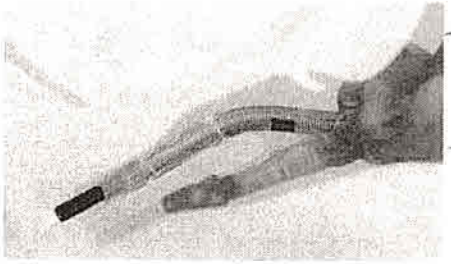
The design of the ventilation section optimises gas flow and prevents airway obstruction from a downfolded epiglottis.
Thin walled cuffs guarantee a maximum airway leak pressure at low cuff pressure (< 60 cmH_2O).



Drain Tube

The drain tube can accommodate a large gastric tube or suction catheter:

# 2.5/3:	max. 16 Fr
# 4/5:	max. 18 Fr



Intubation

The iLTS-D secures the airway in emergency and enables fiberoptic placement of an ET Tube without compromising patency of supraglottic ventilation.

# 2.5/3:	ET Tube max. 6.5 mm I.D.
# 4/5:	ET Tube max. 8.0 mm I.D.

Order information

Intubating Laryngeal Tube iLTS-D

For single use, sterile

Size	Patient	Single Set 1x iLTS-D 1x Syringe	Set of 10 10x iLTS-D	Intubation Set 1x iLTS-D 1x ET Tube with Stabilizer 1x Syringe
2.5/3	125–155 cm	**REF 32-08-123-1**	**REF 32-08-023-1**	**REF 32-08-309-1**
4/5	≥ 155 cm	**REF 32-08-145-1**	**REF 32-08-045-1**	**REF 32-08-209-1**

ET Tube with Stabilizer

Armored, for single use, sterile

Size	For iLTS-D Size	REF	Box
5.5 mm I.D.	2.5/3	**31-40-055-1**	10
7.5 mm I.D.	4/5	**31-40-075-1**	10

Application video: iLTS-D

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
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Report No.: 713137731_1

Valid from: 2018-10-21
Valid until: 2023-10-20

Date, 2018-10-18

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body (identification number 0123)