CHANGES No: 1 to TENDER DOSSIER

Contract Title **:** Supply of Medical Equipment, Devices and Consumables

Publication Reference **:** SIHHAT/2019/SUP/INT/15

CN: Contract Notice
TD: Tender Dossier
DOC: Document
ART: Article
ITT: c4b_itt_en [Instructions to Tenderers]*
TS: c4f_annexiitechspeciiitechoffer_en [Annex II + III: Technical Specifications + Technical Offer]*
DC: Draft Contract
SC: c4d_specialconditions_en [Special Conditions]*
App B: Appendix B to Annex II - Training Proposal [Appendix B to Annex II+III Training Proposal]*
Ann V: Annex V - Warranty Proposal [Annex V - Warranty Obligations Form]*
Ann IV: Annex IV - Budget breakdown (Model financial offer)
** In-parenthesis parts show the title inside the documents.*

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
1	SC	32.6	… • All equipment must have at least 5 years of commercial warranty (for Lot 3 and Lot 4). …	… • All equipment must have at least 2 years of commercial warranty (for Lot 3 and Lot 4). …
2	Annex V	6	… • All equipment must have at least 5 years of commercial warranty (for Lot 3 and Lot 4). …	… • All equipment must have at least 2 years of commercial warranty (for Lot 3 and Lot 4). …

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3	TS	1.6.4	The mask should be in pediatric sizes, transparent and disposable; it should fit on the face and should not stink. The mask should cover the mouth and nose.	The mask should be in adult sizes, transparent and disposable; it should fit on the face and should not stink. The mask should cover the mouth and nose.
4	TS	1.23.6	1 roll should be 15 meters at least.	1 roll should be 15 meters (±2 m) at least.
5	TS	1.23.7	The roll weight should be 400 grams at least.	The roll weight should be 400 grams (±5 gr) at least.
6	TS	1.23.8	The width of a leaf should be 10 cm.	The width of a leaf should be 10 cm (±2 cm).
7	TS	1.23.9	Breaking strength should be N/m 30 at least.	Breaking strength should be N/m 30 (±2 N/m) at least.
8	TS	1.23.10	Extension rate % should be 10-35 cm at least.	Extension rate % should be 10-35 cm (±2 cm) at least.
9	TS	1.25.5	The fiber dimensions should be 21.5x24 cm.	The fiber dimensions should be 21.5 x 24 cm (±2 cm).
10	TS	1.25.6	The pack should include 12 packages and package weight should be 400 grams at least.	The pack should include 12 packages and package weight should be 400 grams (±40 gr) at least.
11	TS	2.4.4	No should be 3/0 25±3 mm 3/8, sharp, 45 cm.	No should be 3/0 25±3 mm 3/8, sharp, at least 45 cm.
12	TS	2.8.4	No should be 5/0 16±3 mm 3/8, sharp, 75 cm.	No should be 5/0 16±5 mm 3/8, sharp, 75 cm.
13	TS	2.9.4	No should be 6/0 13±3 mm 3/8, sharp, 75 cm.	No should be 6/0 13±5 mm 3/8, sharp, at least 45 cm.
14	TS	2.20.7	It should be sterilized by gamma beams and sterilization method should be specified on the packages.	It should be sterilized by gamma beams or ethylene oxide and sterilization method should be specified on the packages.
15	TS	2.24.8	Adhesive should be polymeric acrylate. Back side should be made of non-woven polyester fabric.	Adhesive should be polymeric acrylate. Back side should be made of non-woven polyester fabric. The dimensions should be 10 cm x 10 m.

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16	TS	2.F.8	The manufacturer company should have ISO 9001 or ISO 9002 and EN 46001 quality certificates.	The manufacturer company should have ISO 9001 or ISO 9002 or EN 46001 quality certificates.
17	TS	2.27.10	Dimensions should be 7 x9 cm.	Dimensions should be 7 x 9 cm (±1 cm).
18	TS	2.40.12	The manufacturing company should have CE certificate, ISO 13485:2003 Quality Management System certificates.	The manufacturing company should have CE certificate, ISO 13485:2003 Quality Management System certificates or ISO 13485:2016 Quality Management System certificates.
19	TS	2.41.4	IV infusion filter set should have 1 bacteria trapping filter and this filter should be 0.2 micron.	Manufactured from medical grade PVC.
20	TS	2.41.5	The filter set should have a hydrophobic air discharge membrane.	Shall be packed single and sterile.
21	TS	2.41.6	Inner diameter of the filter set tube should be 3 to 4.1 mm.	Shall have a air inlet puncture hole.
22	TS	2.41.7	A latex-free injection port aqnd luer lock connector should exist on the set for additional dose administrations.	The drop adjuster shall be large enough to be easily gripped by finger and to facilitate movement of the roller in the desired direction.
23	TS	2.41.8	The manufacturer company should have ISO 9001 or ISO 9002 and EN 46001 quality certificates.	Shall have an injection port.
24	TS	2.41.9	New	Tube length shall be at least 1,5 m and shall not king.
25	TS	2.41.10	New	Shall have 20 drops = 1 ml
26	TS	2.41.11	New	The tank shall be soft and easily filled and must be at least 12 ± 2 cc in volume.
27	TS	2.41.12	New	The tank shall have a fixed 15 micron liquid filter at its base.

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28	TS	2.41.13	New	The tank shall have a fixed 15 micron liquid filter at its base.
29	TS	2.41.14	New	Shall be designed to be opened without contaminating its sterileness.
30	TS	2.45.6	It should be provided in 5-liter cans and the cans should have a gasket and a locked cap to prevent leak.	It should be provided in 5-liter plastic barrels and the barrels should have a gasket and a locked cap to prevent leak.
31	TS	2.47.4	100 g disinfecting solution should contain 42 g Ethyl Alcohol and 0.05 g didecylmethylamoniumchloride.	100 g disinfecting solution should contain minimum 42 g Ethyl Alcohol and minimum 0.05 g didecylmethylamoniumchloride.
32	TS	2.47.9	CONTACT PRIOD: In accordnace with DGHM/VAH/EN 13727/EN 13624/EN 1276/EN 1650/EN 13697, EN 16615; Surface Disinfection; bactericid, yeasticid 2 min. DGHM/VAH, 5 min. Tuberculocid (M. Terrae) (clean conditions as per EN 14348) 1 min. Virucid (Vaccinia, Influenza, BVDV, HBV, HIV, HCV dahil) 30 sec. Rota 1 min. Noro virus (MNV) (as per EN 14476) 5 min.	CONTACT PRIOD: In accordance with EN 13727/EN 13624/EN 1276/EN 1650/EN 13697, EN 16615; Surface Disinfection; bactericid, yeasticid 2 min. DGHM/VAH, 5 min. Tuberculocid (M. Terrae) (clean conditions as per EN 14348) 1 min. Virucid (Vaccinia, Influenza) 30 sec. Rota 1 min. Noro virus (MNV) (as per EN 14476) 5 min.
33	TS	2.47.10	It should be dermatologically tested.	Deleted
34	TS	2.48.4	100 g ready for use disinfectant should contain; 64.4 g ethanol, 1,3-Butandiol, glycerin, perfume and pure water.	100 g ready for use disinfectant should contain; minimum 63 g ethanol, maximum 1,3-Butandiol, glycerin, perfume and pure water
35	TS	2.48.12	Hygenic hand disinfectation (as per EN 1500) 3 ml- 30 sec. Surgical hand disinfectation (as per EN 12791), 3x3 ml- 1.5	Hygenic hand disinfectation (as per EN 1500) 3 ml - 30 sec. Surgical hand disinfectation (as per EN 12791) 3 ml - 3 min.

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			min.	
36	TS	2.49.5	The product should include quarterner ammonium compounds (Alkyldimethylbenzyl ammonium chloride, Alkyldimethylbenzyl ammonium chloride, alkyl didesil dimethyl ammmonium chloride, dialkyl dimetil ammonium chloride etc.), non-ionic surfactant and anti-corosive agents.	The product should include quarterner ammonium compounds (Alkyldimethylbenzyl ammonium chloride, alkyl didesil dimethyl ammmonium chloride, dialkyl dimetil ammonium chloride etc.), non-ionic surfactant and anti-corosive agents.
37	TS	2.49.9	In accordance with Biocidal Product regulation dated on 22.6.2015; the product should be effective against the following; • Bactericide as per EN 13727 standard (Pseudomanas aeruginosa, Staphylococcus aureus, Enterococcus hirae), • Mycobactericide as per EN 14348 standard (M. terrae, M. avium) • Fungucide as per EN13624 standard (Candida albicans ATCC 10231, Aspergillus brasiliensis, Aspergillus niger ATCC 16404) • Virucide as per EN14476 standard (Human Adenovirus Type 5 Strain ,Poliovirus Type 1- LSc-2ab, • Adenoid 75, HBV, HCV, HIV, Polio, Papova, Adeno, Vaccina Parvovirüs). • Reports obtained from accredited organizations referred by Ministry of Health as a prrof of such effect.	In accordance with Biocidal Product regulation dated on 22.6.2015, the product should have the Biocidal Licence of MOH in Turkey.
38	TS	2.49.10	The product should be licensed by Turkish Public Health Organization of TR Ministry of Health and included in Biocidal Inventory List. The manufacturer company should have TSE and ISO quality certificates.	The product should be licensed by Republic of Turkey Ministry of Health, Directorate General of Public Health and included in Biocidal Inventory List.
39	TS	2.50.5	The bleacher should be clear and viscous.	The bleacher should be clear.

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40	TS	2.51.10	It should be clear, liquid and nacrous white.	It should be viscous and liquid.
41	TS	3.1.7	The device to be given with the strips shall be able to produce results at 10 to 40 degrees.	The device to be given with the strips shall be able to produce results at least between 10 to 32 degrees.
42	TS	3.1.8	At least 20 devices shall be given with the strips.	At least 1000 strips shall be given with each device.
43	TS	3.1.11	The company shall do a demo and receive approval before the tender.	Deleted
44	TS	3.1.12	The Directorate is authorized to procure 20% less than the specified amount.	Deleted
45	TS	3.1.13	The measurement strip shall be able to measure at the 20-70% hematocrit range.	The measurement strip shall be able to measure at the 20-60% hematocrit range.
46	TS	3.1.14	Each strip shall be covered in aluminum foil and shall not be affected from moisture, heat and light.	Strips shall be in a box and shall not be affected from moisture, heat and light.
47	TS	3.1.15	The system shall use biosensor technology or amperometric, capillary sensor technology.	The system shall use; biosensor technology or amperometric, capillary sensor technology or photometric sensor technology or GDH - FAD enzyme.
48	TS	3.1.17	The company shall provide batteries for the devices, shall supply the control serum till the end of the year free of charge.	The company shall provide at least 2 (two) pieces of batteries and at least 2 (two) pieces 2 ml Control Serum with per devices.
49	TS	3.1.18	The company shall bring samples to our laboratories for approval (at least 20 illnesses).	Deleted
50	TS	3.2.6	The tape shall show both cm and inches.	The tape shall show centimeter.
51	TS	3.2.8	Inspection and acceptance shall be done after our Department carries out trials by taking into consideration the rights and	Deleted

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			responsibilities of the company and its partners in the routine working conditions of the system and its annexes by our personnel.	
52	TS	3.3.6	Electrical characteristics of the device: 220V/50Hz - not more than 0.4 Amp/70Watt.	Electrical characteristics of the device: 220V/50 Hz (± 10%) - not more than 0.4 Amp / 70 Watt or maximum 170 VA.
53	TS	3.3.7	The devices compressor air flow in a minute shall be at least 6.5 liters and the outlet pressure must be at least 3.0 bar.	The devices compressor air flow in a minute shall be at least 6 liters and the outlet pressure must be at least 2.4 bar.
54	TS	3.3.10	The noise level of the device shall not exceed 56 decibels.	The noise level of the device shall not exceed 60 decibels.
55	TS	3.3.11	The aerosol particles formed by the device shall have a diameter (MMAD) of 0.30 micron to 6 microns. Atomizer capacity shall be 6 ml.	The aerosol particles formed by the device shall have a diameter (MMAD) of 0.30 micron to 6 microns.
56	TS	3.4.5	The device shall have a sensitivity of 5 gr up to 10 kg and 15 gr over 10 kg.	The device shall have a maximum sensitivity of 5 gr up to 10 kg and a maximum sensitivity of 15 gr for above 10 kg.
57	TS	3.4.10	Shall be able to weigh gross weight, gross weighing shall be possible automatically done by pressing a button.	Shall be able to weigh gross weight, gross weighing shall be possible automatically done with/without pressing a button.
58	TS	3.5.5	It shall be able to work with storage battery or cell battery.	It shall be able to work with storage battery or cell battery or built-in rechargeable battery.
59	TS	3.5.6	It shall have a digital (LCD) indicator and shall be waterproof.	It shall have a digital (LCD or LED) indicator and shall be waterproof.
60	TS	3.5.8	Batteries shall be supplied with the scale.	Batteries or built-in rechargeable batteries shall be supplied with the scale.
61	TS	3.7.6	The device should work with 16 bit Q-Chip technology to minimize artefacts caused by motion.	Deleted

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62	TS	3.7.7	The measuring range of the device shall be 20-300 bpm and the measurement accuracy shall be ± 1.	The measuring range of the device shall be 30 – 250 bpm and the measurement accuracy shall be ± 2.
63	TS	3.7.8	The saturation measurement range of the device shall be between 0-100% and the measurement accuracy shall be ± 2 between 70% - 100%.	The saturation measurement range of the device shall be between at least 35-100% and the measurement accuracy shall be ± %3 between 70% - 99%.
64	TS	3.7.9	The device shall be able to operate continuously for at least 50 hours with 2 AAA alkaline batteries.	The device shall be able to operate continuously for at least 15 hours with 2 AAA alkaline batteries.
65	TS	3.7.10	The dimensions of the device shall be 57 mm x 35 mm x 27 mm.	The dimensions of the device shall be 57 mm x 35 mm x 27 mm (±5 mm).
66	TS	3.7.11	The weight of the device shall not exceed 50 grams including the battery.	The weight of the device shall not exceed 60 grams including the battery.
67	TS	3.7.17	The device shall be able to operate at -20-50 °C.	The device shall be able to operate at 10-40 °C.
68	TS	3.7.19	If required, the charging unit and the vehicle charge shall be provided in exchange for a fee.	Deleted
69	TS	3.7.22	The importer or seller company shall have a TSE Service Location Qualification Certificate and the name and brand of this document should be indicated.	Deleted
70	TS	3.8.12	Microscope’s standard Abbé nA 1.20 shall be standard condenser.	Microscope’s standard Abbé nA 1.20 or 1.25 shall be standard condenser.
71	TS	3.8.14	Microscope shall have a revolver with infinite rotation of at least 4 lenses.	Deleted
72	TS	3.8.17	Microscope’s lighting shall be provided with 3W LED lighting system.	Microscope’s lighting shall be provided with at least 3W LED lighting system.

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73	TS	3.9.6	The device ultrasonic density should be below 9 mW / cm. The heart rate shall be within the range of 60-240 bpm.	The device ultrasonic density should be below or equal 10 mW / cm^2. The heart rate shall be within the range of 60-240 bpm or 50-210 bpm.
74	TS	3.9.7	Clips shall be provided on the device to fit into a pocket or attached to a belt.	Clips shall be provided on the device to fit into a pocket or attached to a belt or the device shall have a soft carrying case.
75	TS	3.9.9	The device shall have a tape or external speaker connection and an alternate audio output that can be used in the recording.	The device shall have a tape or external speaker connection or internal speaker and an alternate audio output that can be used in the recording or for earphones.
76	TS	3.9.15	The device shall be able to produce results even in the case of sufficient IFS.	Deleted
77	TS	4.3.35	In the proposed device, it shall be possible to add volume probes and Real Time 3D (4D) imaging function as software and hardware against a fee. As an option, it shall be possible to connect 4D probes to the device. In 4D applications, Tomographic Ultrasound Imaging, Thick Slice Imaging, Multi Slice Display and similar functions shall be present to be used in post process actions. The 4D frame rate value of the device shall go up to at least 30 volume / second. The price of this optional function cannot exceed 10% of the unit price acquired by updating the tender unit price cost over the Turkish Statistical Institute's Price Index on the date of tender.	In the proposed device, it shall be possible to add volume linear and vaginal probes or Real Time 3D (4D) imaging function as software and hardware against a fee. As an option, it shall be possible to connect 3D probes to the device. In 3D applications, Tomographic Ultrasound Imaging, Thick Slice Imaging, Multi Slice Display and similar functions shall be present to be used in post process actions. The 4D frame rate value of the device shall go up to at least 30 volume / second or it should be possible for Linear volume transducers to support Intuitive 3D navigation and save as 3D volume loops that can support review package with advanced 3D realtime post-processing in 3D B-mode and sharwave Eastography volume measurements. The price of this optional function cannot exceed 10% of the unit price acquired by updating the tender unit price cost over the Turkish Statistical Institute's Price Index on the date of tender.

All other terms and conditions of the tender dossier remain unchanged. The above alterations and /or corrections to the tender dossier are integral part of the tender dossier.