CLARIFICATIONS No: 1
to the
TENDER DOSSIER

Publication Reference **:** SIHHAT/2020/SUP/INT/01
Subject **:** Supply of Hygiene and Cleaning Materials in the Scope of COVID-19 Pandemic
Location **:** Turkey/EU

CN: Contract Notice
TD: Tender Dossier
DOC: Document
ART: Article
TS: c4f_annexiitechspeciiitechoffer_en [Annex II + III: Technical Specifications + Technical Offer]*
GR: General Requirements
PC: Particular Conditions
** In-parenthesis parts show the title inside the documents.*
Further to the requests received from the tenderers, the following clarifications are provided

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#	DOC	LOT/ ART / ITEM	CLAUSE	QUESTION	ANSWER
1	CN	16.1	Economic and financial capacity of tenderer (based on i.a. item 3 of the tender form for a supply contract). In case of tenderer being a public body, equivalent information should be provided. The reference period which will be taken into account will be the last three financial years for which accounts have been closed. The selection criteria for each tenderer are as follows:	In Section 16 of Contract Notice (Selection Criteria) it is written that "For the economic operators, tendering for more than one lot, the average annual turnover of the tenderer in the last three financial years must exceed the cumulative amount of the financial offers of all the lots for which the tenderer submitted tenders." Does it mean that in case we would like to attend more than one lot, 25% average	Please see the Corrigendum No: 2 to the Tender Dossier.

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			a. The average annual turnover of the tenderer in the last three years must be equal or exceed the 25% tenderer's financial offer. b. Current ratio (current assets / current liabilities) in the last three financial years accounts of which have been closed must be at least 1. In case of a consortium, this criterion must be fulfilled by each member. For the economic operators, tendering for more than one lot, the average annual turnover of the tenderer in the last three financial years must exceed the cumulative amount of the financial offers of all the lots for which the tenderer submitted tenders. All supporting documents must be approved by Revenue Administration or certified accountants. Economic operators that have been operational for less than three years will have to demonstrate an operational cash flow, which must exceed their financial proposal for the years in which they have been operational.	turnover rule (Selection Criteria 16.1)b. will not be applied and Tenderer must have annual turnover average of three years equal to total amount of Financial Offer presented for the lots tendered? These two criteria seem contradictory.	
2	CN	16.3	Technical capacity of tenderer (based on i.a. items 5 and 6 of the tender form for a supply contract). The reference period which will be taken into account will be the last five years from submission deadline.	Should the experience required in the technical capacity specified in paragraph 3 of Article 16 of the Contract Notice document be the same product as the lot we	Considering the volume of the tender and the risk assessment of the Contracting Authority, the

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			a. For Lot 1, Lot 2, Lot 3, Lot 4, Lot 6 The tenderer has delivered supplies under at most three contracts with a budget of at least one-fourth (¼) of the financial offer of the lot being tendered in supply of medical consumable(s). b. For Lot 5 The tenderer has delivered supplies under at most three contracts with a budget of at least one-fourth (¼) of the financial offer of the lot being tendered in supply of medical equipment(s) and/or medical device(s).	offer or is it acceptable to have any disposable medical device experience?	existing requirement assessed to be sufficient.
3	CN	19	… All tenders must be received at the address of the Contracting Authority stated in the Article 18 above by **17:00** (local time) on **22.06.2020**. …	In Contract Notice it is written that submission deadline of the tender procedure will be 22.06.2020 – 17:00. We would like to highlight that material supply process of manufacturers have been disrupted due to pandemic disease issue and this is why timely completion time of the project is at risk. In this regard, we kindly request deadline of the tender submission to be postponed.	Please see the Corrigendum No: 1 to the Tender Dossier.
4	TD			When we examine the tender documents, there is no sample request, can you confirm? If there is a sample request, which part of the documents should we apply?	There is no need to provide samples when the tender dossier submission or during the evaluation process.
5	TS GR PC	3.2.1	It is mandatory that the products offered are registered in the National Information Bank of Medicine and Medical Device as of the date of the tender in accordance with	Please be informed, most of the products that are in this tender have biocidal certificates which are taken from Ministry of Healty MOH. According to our research, biocidal	Please see the Corrigendum No: 2 to the Tender Dossier.

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			the provisions dated 02.06.2017 and numbered E.1967 from Republic of Turkey Ministry of Health Treatment Services General Directorate; and the products to be purchased must be approved by Republic of Turkey Ministry of Health in PTS. A document showing that the products are approved (NDB printout) shall be added in to the tender file or it shall be asked before contract signature.	certified products are out of the scope of UTS. So it's not possible to register products with Biocidal certificate to UTS. We kindly request you to remove the obligation of the registration of UTS. We kindly request you to remove the obligation of the registration of UTS from the "PARTICULAR CONDITIONS 3.2.1".	
6	TS GR PC	3.2.2	The tenderer companies shall give documents certifying company identification number indicating that they are registered with the PTS if they are manufacturers and / or importers of the products offered in this scope; the dealer identification numbers if they are dealers together with the offer or it shall be asked before contract signature.	Is PTS Registration required for these products and if it is required can the registration be obtained before signing the contract?	Please see the Corrigendum No: 2 to the Tender Dossier.
7	TS	Lot 1 / 1.1.4	100 g disinfecting solution should contain 42 g Ethyl Alcohol and 0.05 g didecylmethylamoniumchloride.	We kindly request the following modification in the article: 100 g disinfecting solution should contain 40g Ethyl Alcohol, 10 g isopropyl alcoholand 0,25 g didecylmethylamoniumchloride.	Please see the Corrigendum No: 2 to the Tender Dossier.
8	TS	Lot 1 / 1.1.6	Disinfectant should be used for disinfection of alcohol-resistant non-invasive medical device surfaces (patient beds, operating tables, stretchers, operating lamp systems, surgical scrubs etc.) where rapid disinfection is required.	*As Disinfectant For Equipment - Equipment Disinfecting Spray* define the specifications for products used in the health sector and the products corresponding to these specifications. Therefore, we kindly request amendment about the article for the name of	Disinfectant should be used not only for disinfection of alcohol-resistant non-invasive medical device surfaces but also used on the surfaces where rapid disinfection is required.

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				product as *"As Disinfectant For Equipment - Equipment Disinfecting Spray or Quick Surface Disinfectant". In addition, in the article 1.1.6 of the specification, we request the modification to be made since the product is not only an equipment disinfectant but can also be used on the surfaces.*	
9	TS	Lot 1 / 1.1.9	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.	Are the specified certifications' verification documents needed (DGHM/VAH/EN 13727/EN 13624/EN 1276/EN 1650/EN 13697, EN 16615) or is it enough to be produce products in accordance with the specified certifications?	The item remains unchanged considering the needs of the Contracting Authority.
10	TS	Lot 1 / 1.1.9	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.	We kindly request the following modification in the article: CONTACT PRIOD in accordance to EN 13727/EN 13624/EN 1276/EN 1650, EN 16615. bactericid, yeasticid 2 min. 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) 5min.	Please see the Corrigendum No: 2 to the Tender Dossier.

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			Rota 1 min. Noro virus (MNV) (as per EN 14476) 5 min.		
11	TS	Lot 1 / 1.1.14	Ph should be 7 ± 1.	We kindly request the following modification in the article: Ph should be 7 ± 1.5	The item remains unchanged considering the needs of the Contracting Authority.
12	TS	Lot 1 / 1.1.17	The product should be registered to product Monitoring System (PMS) in accordance with Medical Device Regulation; and the products should be approved by Ministry of Health.	Please be informed, this product has biocidal certificate which is taken from Ministry of Healty MOH. According to our research, biocidal certified products are out of the scope of UTS. So it's not possible to register products with Biocidal certificate to UTS. We kindly request you to remove the obligation of the registration of UTS.	Please also see the Corrigendum No: 2 to the Tender Dossier.
13	TS	Lot 1 / 1.1.21	The original analysis certificate of manufacturing batch (lot number) of the product to be delivered should be provided during product delivery.	As it is known, pandemic was declared regarding the Covid-19 outbreak in the world and many companies were given temporary licenses, biocidal licenses and production permits in order to meet the needs. Therefore, we kindly request from you to add an article that “the products with temporary license will not be accepted” in the specification, since many of the products requested in your specification will not be presented with reports that prove the test, report and activity times.	The item remains unchanged considering the needs of the Contracting Authority.
14	TS	Lot 1 / 1.1.22	---	We kindly request from you to add an article that "Stability reports covering the period of	Please also see the Corrigendum No: 2 to the Tender Dossier.

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				shelf life of the proposed products must be included" in the specification.	
15	TS	Lot 1 / 1.2.4	100 g ready for use disinfectant should contain; 64.4 g ethanol, 1,3-Butandiol, glycerin, perfume and pure water.	We kindly request the following modification in the article:100 g ready for use disinfectant should contain; 70 g ethanol, 0,5 2-propanol,glycerin, perfume and pure water.	Please also see the Corrigendum No: 2 to the Tender Dossier.
16	TS	Lot 1 / 1.2.11	Bacteria: S.aureus ATCC 6538, P.aeruginosa ATCC 15442, E.coli K12 NCTC 10538, E.hirae ATCC 10541 1 min. Fungus: C.Albicans ATCC 10231 1 min. Virus: Poliovirus Type 1, LSc-2ab, Adeno virus Type 5 Strain Adenoid 75 ATCCVR-5 Murinenorovirus,Strain S99 Berlin 1 min. Mycobacteria: M.terrea ATCC 15755, M.avium ATCC 15769 5 min	Are the specified certifications' verification documents needed (ATCC 6538, ATCC 15442,NCTC 10538, ATCC 10541, ATCC 10231, ATCCVR-5) or is it enough to be produce products in accordance with the specified certifications?	The item remains unchanged considering the needs of the Contracting Authority.
17	TS	Lot 1 / 1.2.12	Hygenic hand disinfectation (as per EN 1500) 3 ml- 30 sec. Surgical hand disinfectation (as per EN 12791), 3x3 ml- 1.5 min.	We request the following changes to be made due to revisions to the EN 1500 and EN 12791 standards. HYGIENIC HAND DISINFECTION (in accordance to EN 1500) 3 ML- 15 SEC " SURGICAL HAND DISINFECTION (in accordance to EN 12791), 3 ML - 2 MINUTES "	Please also see the Corrigendum No: 2 to the Tender Dossier.
18	TS	Lot 1 / 1.2.19		As it is known, pandemic was declared regarding the Covid-19 outbreak in the world and many companies were given	Please also see the Corrigendum No: 2 to the Tender Dossier.

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				temporary licenses, biocidal licenses and production permits in order to meet the needs. Therefore, we kindly request from you to add an article that "the products with temporary license will not be accepted" in the specification, since many of the products requested in your specification will not be presented with reports that prove the test, report and activity times.	
19	TS	Lot 1 / 1.3.7	The product should be diluted by tap water, should not cause allergic reaction, the odor should not be disturbing and it should be provided in 5-liter packages. 1 (one) dosage pump should be provided for each 2 packages.	The product should be diluted by tap water, should not cause allergic reaction, the odor should not be disturbing and it should be provided in 5-liter packages. 1 (one) dosage pump should be provided for each 10 packages. Due to the pandemic, we kindly request amendment of the article in order not to have problems with the pump supply. Because, in the Supply of Medical Equipment, Devices and Consumables tender made by your institution, we think that 1 pump will meet the needs of 10 packages, since the pump has been delivered to each institution before the ground surface disinfectant purchase.	The item remains unchanged considering the needs of the Contracting Authority.
20	TS	Lot 1 / 1.3.10	• Bactericide as per EN 13727 standard (Pseudomanas aeruginosa, Staphylococcus aureus, Enterococcus hirae),	Are the specified certifications' verification documents needed (EN 13727, EN 14348, ATCC 10231, ATCC 16404) or is it enough to be produce products in accordance with the specified certifications?	The item remains unchanged considering the needs of the Contracting Authority.

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21	TS	Lot 1 / 1.3.11	• Mycobactericide as per EN 14348 standard (M. terrae, M. avium)	Are the specified certifications' verification documents needed (EN 13727, EN 14348, ATCC 10231, ATCC 16404) or is it enough to be produce products in accordance with the specified certifications?	The item remains unchanged considering the needs of the Contracting Authority.
22	TS	Lot 1 / 1.3.12	• Fungucide as per EN13624 standard (Candida albicans ATCC 10231, Aspergillus brasiliensis, Aspergillus niger ATCC 16404)	Are the specified certifications' verification documents needed (EN 13727, EN 14348, ATCC 10231, ATCC 16404) or is it enough to be produce products in accordance with the specified certifications?	The item remains unchanged considering the needs of the Contracting Authority.
23	TS	Lot 1 / 1.4.10	It should be clear, liquid and nacrous white.	We demand that the article be changed to be "fluid and liquid". Because, in previous the tender of Supply of Medical Equipment, Devices and Consumables made by your institution, the tender was made in liquid soap product as "fluid and liquid".	Please also see the Corrigendum No: 2 to the Tender Dossier.
24	TS	Lot 1 / 1.4.17	The original analysis certificate of manufacturing batch (lot number) of the product to be delivered should be provided during product delivery.	The original analysis certificate of the 3 samples which were selected according to the production batch (lot no.) of the product to be provided at random should be given during the delivery of the product. Your institution shall purchase 25.920 plastic cans of liquid soap. The statement in the technical specification as "The production batch (lot number) and original analysis certificate of the product to be delivered must be presented during product delivery." refers to the analyses to be carried out for each lot. Each device (production machine) can approximately produce 5.000	The item remains unchanged considering the needs of the Contracting Authority.

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				tons of goods in each batch (lot). Therefore, this figure refers to 26 series. The analysis of these 26 series will both exceed the deadline and create a great cost. We request this item to be changed because we think that it would be more suitable to analyze 3 batches to be selected by the officials that will determined by your institution after the delivery has been made.	
25	TS	Lot 1 / 1.4.17	The original analysis certificate of manufacturing batch (lot number) of the product to be delivered should be provided during product delivery.	Since the product to be purchased does not fall into the disinfectant class, an analysis certificate should not be requested. Because analysis certificates examine whether disinfectant or antibacterial soap products are effective against viruses and bacteria, or their duration of activity. Therefore, we kindly request the removal of this article.	Please also see the Corrigendum No: 2 to the Tender Dossier.
26	TS	Lot 1 / 1.5.5	The bleach should be clear and viscous.	We demand that the article be changed to be "bleach should be clear". Because, in previous the tender of Supply of Medical Equipment, Devices and Consumables made by your institution, the tender was made in the bleach product as "bleach should be clear"	Please also see the Corrigendum No: 2 to the Tender Dossier.
27	TS	Lot 1 / 1.5.10	If required by the Examination Commitee, for each series sufficient samples shall be taken and sent to Turkish Public Health Organization in particular and other institutions for analysis at the company's own expense (microbial efficacy, toxicology, chemical content, corosive	Since the product to be purchased does not fall into the disinfectant class, an analysis certificate should not be requested. Because analysis certificates examine disinfectant products are effective against viruses and bacteria, or their duration of activity.	The item remains unchanged considering the needs of the Contracting Authority.

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			effect etc.). Deficient stocks due to analysis shall be replenished by the company.	Therefore, we kindly request the removal of this article.	
28	TS	Lot 1 / 1.5.11	The original analysis certificate of manufacturing batch (lot number) of the product to be delivered should be provided during product delivery.	The original analysis certificate of the 3 samples which were selected according to the production batch (lot no.) of the product to be provided at random should be given during the delivery of the product. Your institution shall purchase 25.920 plastic cans of bleach. The statement in the technical specification as "The production batch (lot number) and original analysis certificate of the product to be delivered shall be presented during product delivery." refers to the analyses to be carried out for each lot. Each device (production machine) can approximately produce 5.000 tons of goods in each batch (lot). Therefore, this figure refers to 26 series. The analysis of these 26 series will both exceed the deadline and create a great cost. We request this item to be changed because we think that it would be more suitable to analyze 3 batches to be selected by the officials that will determined by your institution after the delivery has been made.	The item remains unchanged considering the needs of the Contracting Authority.
29	TS	Lot 2 / 2.1.5	It should be powder-free.	Please be informed, It is nearly impossible these days to find this amount as powder free examination gloves, because of COVID-19 pandemic stock availability of market	The item remains unchanged considering the needs of the Contracting Authority.

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				always changing due to the that is it possible to provide some amount as powdered gloves?	
30	TS	Lot 2 / 2.1.7	It should include latex.	It should include latex or nitrile COVID-19 disease caused by Coronavirus was declared as a pandemic by World Health Organization as of March 11. Therefore, the product use worldwide has significantly increased and it has reached to a point where the needs cannot be met. In the event that this change has been made, there will be no damage as the price is not different between the latex examination glove that your institution will purchase and the nitrile glove. Nitrile and latex examination gloves are non-sterile and we request this item to be changed since they both serve the same purpose.	Please also see the Corrigendum No: 2 to the Tender Dossier.
31	TS	Lot 3 / 3.1.10	It should have 3 layers and a bacteria filter at the centre.	It should have 3 layers.	The item remains unchanged considering the needs of the Contracting Authority.
32	TS	Lot 3 / 3.1.17	It should be of N) EU MDD Directive 93/42/EEC Category III or its equivalent; EN 14683 Type II, IR, IIR; or ASTM F2100 minimum Level 1 or its equivalent standards.	It should be of N) EU MDD Directive 93/42/EEC or its equivalent; EN 14683 or ASTM F2100 minimum Level 1 or its equivalent standards	Please also see the Corrigendum No: 2 to the Tender Dossier.
33	TS	Lot 6 / 6.6.5.3	It should have a liquid barrier protecting the user from infections that are transmitted through blood and liquid splashes.	We request the removal of this item.	Please also see the Corrigendum No: 2 to the Tender Dossier.

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34	TS	Lot 6 / 6.6.7.2	Weight and Sort: 80 gr, hard cover	Weight and Sort: 80 gr, hard cover Hard cover is requested in this item and it is not clear what is meant with the hard cover. Does the product mentioned refer to a double-sided printed hand brochure or a short booklet? We request clarification on this item.	Please also see the Corrigendum No: 2 to the Tender Dossier.
35	TS	Lot 6 / 6.6.7	Brochure (280.000 pieces)	The paper quality is not mentioned in the technical specification. Shall the brochure to be prepared be printed on high grade glossy paper or bristol board? We request an explanation regarding this clause.	Please also see the Corrigendum No: 2 to the Tender Dossier.
36	TS	Lot 6 / 6.6.7	Brochure (280.000 pieces)	We kindly request visual and more detailed information for this product to avoid any misunderstanding.	Please also see the Corrigendum No: 2 to the Tender Dossier.
37	TS	Lot 6 / 6.6.7	Brochure (280.000 pieces)	No information was provided about the text that should be included in the brochure. Can you enlighten us about this?	Please also see the Corrigendum No: 2 to the Tender Dossier.
38	TS	Lot 6 / 6.6.8	Cloth Bag (280.000 pieces)	There is no information regarding if the bag in the technical specifications shall be printed or not, or if the both sides shall be printed or not. We request an explanation regarding this clause.	In accordance with the visibility rules (General Requirment Item 4) the bags will have printing on. Details about printing will be given to the company after the contract is signed.
39	TS	Lot 6 / 6.6.8	Cloth Bag (280.000 pieces)	Is the bag required with zipper or will be open ?	The Cloth Bag should be open.

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40	TS	Lot 6 / 6.6.8	Cloth Bag (280.000 pieces)	Is the logo of "SIHHAT PROJECT" required to be printed on the bag?	In accordance with the visibility rules (General Requirment Item 4) the bags will have printing on. Details about printing will be given to the company after the contract is signed.