CORRIGENDUM No: 2
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

#	DOC	LOT #	ART / ITEM	FORMER TEXT / DOCUMENT(S)	SHALL READ AS NEW TEXT / DOCUMENT(S)
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: 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.	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: c. The average annual turnover of the tenderer in the last three years must be equal or exceed the 25% tenderer's financial offer. d. 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.	For the economic operators, tendering for more than one lot, the average annual turnover of the tenderer in the last three financial years must be equal or exceed the cumulative amount of the 25% 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 25% financial proposal for the years in which they have been operational.
2	**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 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.	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 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. If the product is not covered by any of 93/42/EEC, 98/79/EC and 90/385/EEC regulations, it is out of scope in the Product Tracking System (PTS). Tenderer must be submit a “Out of Scope Declaration”.
3	**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.	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. If the product is not covered by any of 93/42/EEC, 98/79/EC and 90/385/EEC regulations, it is out of scope in the Product Tracking System (PTS). Tenderer must be submit a “Out of Scope Declaration”.

4	**TS GR PC**		3.2.4	New text	The products with temporary license will not be accepted (for only Lot 1).
5	**TS GR PC**		3.2.4	New text	The certificate demonstrating the formula of the product approved by the Ministry of Health should be submitted together with the offer.
6	**TS**	Lot 1	1.1.4	100 g disinfecting solution should contain 42 g Ethyl Alcohol and 0.05 g didecylmethylamoniumchloride.	100 g disinfecting solution should contain 42 g Ethyl Alcohol, 0.05 g didecylmethylamoniumchloride or 40 g Ethyl Alcohol, 10 g isopropyl alcoholand 0.25 g didecylmethylamoniumchloride.
7	**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.	CONTACT PRIOD: In accordance with DGHM/VAH/EN 13727/EN 13624/EN 1276/EN 1650/EN 13697, EN 16615; Surface Disinfection; bactericid, yeasticid 2 min. 5 min. DGHM/VAH, 5 min. Tuberculocid (M. Terrae) (clean conditions as per EN 14348) 1 min. Virucid (Vaccinia, Influenza, BVDV, HBV, HIV, HCV including) 30 sec. Rota 1 min. Noro virus (MNV) (as per EN 14476) 5 min.
8	**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.	The product should has biocidal certificate which is taken from Ministry of Health.
9	**TS**	Lot 1	1.1.22	New text	Stability reports covering the period of shelf life of the proposed products must be included.
10	**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.	100 g ready for use disinfectant should contain; 64.4 g ethanol, 1,3-Butandiol glycerin, perfume, pure water or 70 g ethanol, 0,5 g 2-propanol glycerin, perfume, pure water.
11	**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	Hygenic hand disinfectation (as per EN 1500) 3 ml- 30 sec. Surgical hand disinfectation (as per EN 12791), 3x3 ml- 2

				min.	min.
12	**TS**	Lot 1	1.4.10	It should be clear, liquid and nacrous white.	It should be liquid.
13	**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 manufacturing company must submit the production permit obtained from the Ministry of Health together with its offer.
14	**TS**	Lot 1	1.5.5	The bleach should be clear and viscous.	The bleach should be clear.
15	**TS**	Lot 2	2.1.7	It should include latex.	It should include latex or nitrile.
16	**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 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.
17	**TS**	Lot 6	6.6.5.1	It should be tear resistant, non-flammable and made of 3-layer non-woven material.	It should be disposable.
18	**TS**	Lot 6	6.6.5.2	It should protect against bacteria, viruses and microscopic particles.	It should have rubber ear straps on each side. It should be well suited for 8 hours of continuous use.
19	**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.	It should have an adjustable soft wire support on the edge corresponding to the nose.
20	**TS**	Lot 6	6.6.5.4	It should have a wire support on the edge corresponding to the nose.	It should be made of non-woven polypropylene material.
21	**TS**	Lot 6	6.6.5.5	There should be no gaps between the mask and face. It should completely cover the mouth and nose fitting across the face snugly.	It should be white.
22	**TS**	Lot 6	6.6.5.6	It should allow easy breathing and prevent moisture from building up at a single spot. It should not cause sweating. It also should not have an unpleasant smell and pill (pilling).	It should not contain latex or fiberglass.
23	**TS**	Lot 6	6.6.5.7	It should be hypoallergenic, and should not contain fiberglass, natural rubber latex or dry natural rubber.	It should have 3 layers and a bacteria filter at the centre.
24	**TS**	Lot 6	6.6.5.8	It should have rubber ear straps. It should be worn easily	It should provide liquid barrier protection. It should not

				through strong ear straps which do not come off.	contain fiberglass or latex.
25	**TS**	Lot 6	6.6.5.9	It should be white.	It should allow easy breathing and be used with goggles (safety glasses).
26	**TS**	Lot 6	6.6.5.10	New Text	Boxes should bear date of production and expiration date.
27	**TS**	Lot 6	6.6.5.11	New Text	Shelf life should be adjusted to be at least 2 years from the delivery date of the product.
28	**TS**	Lot 6	6.6.5.12	New Text	It should be delivered in 10-piece packages.
29	**TS**	Lot 6	6.6.5.13	New Text	If any incompatibility is detected after the tender is concluded and the materials are started to be used, the relevant company is responsible for the replacement of the purchased material or definite elimination of the incompatibility.
30	**TS**	Lot 6	6.6.5.14	New Text	It should be of 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.
31	**TS**	Lot 6	6.6.7.1	Dimensions: A5	Dimensions: 15 x 10 cm
32	**TS**	Lot 6	6.6.7.2	Weight and Sort: 80 gr, hard cover	Weight: 90 gr.
33	**TS**	Lot 6	6.6.7.4	New Text	Please see the Appendix 1.

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.