CLARIFICATIONS No. 1 to the TENDER DOSSIER

Contract Title: Supply of Electrical and Medical Equipment, Furniture and Consumables
Publication Reference: SIHHAT/2025/SUP/INT/03

Doc: Document
ITT: Instructions to Tenderers
TS: Annex II + III: Technical Specifications + Technical Offer / c4f_annexiitechspeciiitechoffer_en

Further to the requests received from the tenderers, the following clarifications are provided.

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
1	ITT	11.3.b)	The "Tender form for a supply contract", together with Annex 1 "Declaration on honour on exclusion criteria and selection criteria", both duly completed, which includes the tenderer's declaration, point 7, (from each member if a consortium, (if any)). Signed originals of the Declaration on honour shall be submitted.	Could you please share Annex 1 decleration on honour document?	Please see page 11 of the Tender Form for a Supply Contract (**c4l_tenderform_en**) in the Tender Dossier. Additionally, you can find the form a14a, available at the following link: https://wikis.ec.europa.eu/display/ExactExternalWiki/Annexes#Annexes-AnnexesA(Ch.2):General
2	TS	Lot 3/ 3.2.3.	Seat must be upholstered with artificial leather or fabric on 5 cm thick 35HR sponge material.	The seat should be 5cm thick 35DNS HR sponge material with artificial leather or fabric upholstery.	**Please see Changes to the Tender Dossier**.
3	TS	Lot3/ 3.3.2.	Upper and lower tables must be manufactured from 30 mm chipboard and the edges must have 1 mm PVC edge band. Elevation table must be manufactured from 8 mm satin glass.	Upper and lower tables must be manufactured from 30 mm chipboard and the edges must have 1 mm PVC edge band. Elevation table must be manufactured from 8 mm satin glass **or 18 mm suntalam**	**Please see Changes to the Tender Dossier.**
4	TS	Lot 3/ 3.5.7.	Foot and wheels shall be 15 x 30 x 1.5 (± 2) mm in size and made of oval pipe.	The metal leg should be manufactured by drawing DKP sheet metal in sizes of Q25x1.5mm. The metal profiles should be manufactured by CNC bending in special molds.	**Please see Changes to the Tender Dossier.**

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5	TS	Lot 3/ 3.5.9.	Artificial leather shall be 2% polyurethane, 80% polyester, 80% PVC and its weight shall be 450 g/m2. Polyester fabric and polyolefin shall be minimum 200 g/m2 and shall also be resistant to abrasion.	Artificial leather **or fabric upholstery** shall be 2% polyurethane, 80% polyester, 80% PVC and its weight shall be 450 g/m2. Polyester fabric and polyolefin shall be minimum 200 g/m2 and shall also be resistant to abrasion.	**This item will remain as it was stated in TS.**
6	TS	Lot 3/ 3.5.10.	The profile pipe shall be made of 15 x 30 x 1.5 mm oval pipe (for the foot).	The profile pipe shall be made of 25 x 1.5 mm oval pipe (for the foot).	**Please see Changes to the Tender Dossier.**
7	TS	Lot 3/ 3.5.15.	Four-legged metal frame, seat and support part must be made of plastic material. Seat surface and backrest shall be made of cast sponge, plastic shoe shall be covered with artificial leather or fabric.	The metal leg; should be manufactured by drawing DKP sheet metal in sizes of Q25x1.5mm. The metal profiles should be manufactured by CNC bending in special molds. The leg surface; should be coated with 90 micron thick (textured) electrostatic powder oven paint should be used	**Please see Changes to the Tender Dossier.**
8	TS	Lot 3 / 3.8.2.	The upper table must be manufactured from 1 piece of 30 mm MDF; edges must be manufactured with 2 mm PVC edge bands; the front panel must be made of 18 mm MDF and the edges must be manufactured with 0.40 mm PVC edge bands.	The upper table must be manufactured from 1 piece of 30 mm MDF; edges must be manufactured with 2 mm PVC edge bands; the front panel must be made of 18 mm **MDF or Suntalam** and the edges must be manufactured with 0.40 mm PVC edge bands.	**This item will remain as it was stated in TS.**
9	TS	Lot 3/ 3.8.4.	For the connection of the table leg and crossbar, the electrostatic powder paint connection sheet made of 5 mm HRP sheet material must be welded to the legs and must be manufactured as ready-to-assemble in a way that it can be mounted to the holes in the crossbars with M8 screws. The assembly must be made with plastic shoes between the table top and the legs and there must be a 25 mm gap.	For the connection of the table leg and crossbar, the electrostatic powder paint connection sheet made of **4 mm** HRP sheet material must be welded to the legs and must be manufactured as ready-to-assemble in a way that it can be mounted to the holes in the crossbars with M8 screws. The assembly must be made with plastic shoes between the table top and the legs and there must be a 25 mm gap.	**Please see Changes to the Tender Dossier.**
10	TS	Lot3/ 3.10.1.	Upper table thickness must be 30 mm MDF.	Upper table thickness must be 30 mm **MDF or suntalam**.	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
11	TS	Lot 3/ 3.10.4.	For table leg and connection, connection must be made of 5 mm HRP sheet material with electrostatic powder paint and must be manufactured as ready-to-assemble so that they can be assembled to each other with M8 screws.	For table leg and connection, connection must be made of **4 mm** HRP sheet material with electrostatic powder paint and must be manufactured as ready-to-assemble so that they can be assembled to each other with M8 screws.	**Please see Changes to the Tender Dossier.**
12	TS	Lot 3/ 3.14.6.	The material can be wood, MDF or 40-micron electrostatic painted metal.	The material can be wood, MDF **or suntalam** or 40-micron electrostatic painted metal.	**This item will remain as it was stated in TS.**
13	TS	Lot 3/ 3.19.1	Artificial leather must be used. 32 kg/m^3 gray cast sponge must be used.	In the technical specification, it is stated that there should be 32 m^3 cast sponge, but in the market, cast sponge is not produced less than 45 m^3. Do you mean 32 m^3 DNS cutting sponge?	**Please see Changes to the Tender Dossier.**
14	TS	Lot 3/ 3.19.5	It must have a backrest adjustable in 3 stages.	In the technical specification stated that it must have a backrest adjustable in 3 stages. Will this feature be motorized or mechanical?	**Please see Changes to the Tender Dossier.**
15	TS	Lot 3/ 3.19.6	The fabric must be non-flammable, stain-proof and wipeable.	The technical specification states that the fabric must be fireproof, stainproof and wipeable. Can you provide more specific information about the fireproof feature? For example, how many seconds should the fabric fireproof?	**Please see Changes to the Tender Dossier.**
16	TS	Lot 4/ 4.4.17.	The product must be registered in the PTS/ÜTS (Product Tracking System).	Only UTS is requested for the Gynecological Examination Table. Is there a UTS requirement for other products?	**There is a PTS/UTS (Product Tracking System) obligation for the specified products in the TS.** **Please see Changes to the Tender Dossier.**
17	TS	Lot 4/ 4.4.18.	The manufacturer must have FDA, CE, ISO certificates.	Is there an FDA document requirement for the Gynecological Examination Table? Because FDA documents are generally not obtained in Turkish production.	**Please see Changes to the Tender Dossier.**
18	TS	Lot 5/ 5.13.1.3.	**Oxygen Mask (Adult-Pediatric)**	While the title of the specification refers to an "Oxygen Mask (Adult-Pediatric)", the content includes technical specifications for both a Reservoir Oxygen Mask and a Manual Resuscitator (Ambu	**Please see Changes to the Tender Dossier.**

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				Bag). We would like to emphasize that the Oxygen Mask, Reservoir Oxygen Mask, and Manual Resuscitator (Ambu) are three distinct products. Therefore, we kindly request clarification on which specific item is required.	
19	TS	Lot 5/ 5.13.1.7.b.	Each emergency kit must contain 2 packages of gloves in total, 1 package powdered and 1 package powder-free.	The American Food and Drug Administration (FDA) has banned powdered gloves used in medical procedures on the grounds that they harm human health. It is thought that this situation will cause problems in the process of obtaining the Medical Device Regulation MDR Certificate related to the products. For this reason, all "Powdered Gloves" required in the current specification: • "Powdered or Powder Free Gloves" or • We request that "Powdered Gloves" be removed from the specification or changed to "Powder Free Gloves"	**Please see Changes to the Tender Dossier.**
20	TS	Lot 5/ 5.6.16.	Tenderer must have a TSI Service Place Qualification Certificate and the name and brand of the device for the offer must be included in the TSI Service Qualification Certificate.	The TSE Service Qualification Certificate can only be obtained by the manufacturer/producer or the importer of the product, and therefore it is not always possible for the bidding (reseller) company to provide this certificate for all offered products.For this reason, we kindly request that the related clause be revised as follows: “A TSE Service Qualification Certificate must be submitted by the manufacturer, importer, or seller of the offered products, and the brand of the product must be clearly stated on the certificate."	**Please see Changes to the Tender Dossier.**
21	TS	Lot 5/ 5.15.18.	The tenderer must have a TSI Service Place Qualification Certificate and the name and brand of the device for the offer must be included in the TSI Service Qualification Certificate.	The TSE Service Qualification Certificate can only be obtained by the manufacturer/producer or the importer of the product, and therefore it is not always possible for the bidding (reseller) company to provide this certificate for all offered products.For this reason, we kindly request that the related clause	**Please see Changes to the Tender Dossier.**

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				be revised as follows: “A TSE Service Qualification Certificate must be submitted by the manufacturer, importer, or seller of the offered products, and the brand of the product must be clearly stated on the certificate."	
22	TS	Lot 5/ 5.16.18.	The tenderer must have a TSI Service Place Qualification Certificate and the name and brand of the device for the offer must be included in the TSI Service Qualification Certificate.	The TSE Service Qualification Certificate can only be obtained by the manufacturer/producer or the importer of the product, and therefore it is not always possible for the bidding (reseller) company to provide this certificate for all offered products.For this reason, we kindly request that the related clause be revised as follows: “A TSE Service Qualification Certificate must be submitted by the manufacturer, importer, or seller of the offered products, and the brand of the product must be clearly stated on the certificate."	**Please see Changes to the Tender Dossier.**
23	TS	Lot 5/ 5.17.17.	The tenderer must have a TSI Service Place Qualification Certificate and the name and brand of the device for the offer must be included in the TSI Service Qualification Certificate.	The TSE Service Qualification Certificate can only be obtained by the manufacturer/producer or the importer of the product, and therefore it is not always possible for the bidding (reseller) company to provide this certificate for all offered products.For this reason, we kindly request that the related clause be revised as follows: “A TSE Service Qualification Certificate must be submitted by the manufacturer, importer, or seller of the offered products, and the brand of the product must be clearly stated on the certificate."	**Please see Changes to the Tender Dossier.**
24	TS	Lot 5/ 5.18.17.	The tenderer must have a TSI Service Place Qualification Certificate and the name and brand of the device for the offer must be included in the TSI Service Qualification Certificate.	The TSE Service Qualification Certificate can only be obtained by the manufacturer/producer or the importer of the product, and therefore it is not always possible for the bidding (reseller) company to provide this certificate for all offered products.For this reason, we kindly request that the related clause be revised as follows: “A TSE Service Qualification Certificate must be submitted by the manufacturer, importer, or seller of the offered products, and the brand of the product must be clearly stated on the certificate."	**Please see Changes to the Tender Dossier.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
25	TS	Lot 5/ 5.17.11.	The outer fabric of the cuff must be 10 x 47 cm (± 0.5 cm) and there must be a mark indicating the stethoscope entry point.	The cuff outer fabric dimensions are stated as 10 x 47 cm ± 0.5 cm, and there must be a mark indicating the stethoscope entry point. However, the dimensions specified in the technical specification are incorrect. The correct dimensions, as outlined in the adult sphygmomanometer specification, should be 38.5 × 11 cm (± 1 cm). We kindly request that the specification be reviewed and revised accordingly.	**This item will remain as it was stated in TS.**
26	TS	Lot 5/ 5.18.10.	The outer fabric of the cuff must be 38.5×11 cm (+/- 1 cm) and there must be a mark indicating the stethoscope entry point.	The cuff outer fabric dimensions should be 38.5 × 11 cm (± 1 cm), and there must be a marking indicating the stethoscope entry point. However, the dimensions currently stated in the specification are incorrect. They should be corrected to 13 × 47 cm (± 2.0 cm). We kindly request that the specification be reviewed and revised accordingly.	**This item will remain as it was stated in TS.**
27	TS	Lot 6/ 6.11.	The filter settings on the device must meet minimum 3 of the 20 Hz, 25 Hz, 35 Hz, 40 Hz, 45 Hz and 300 Hz options.	It is not clear which filter is being mentioned, which filter is the requested feature for?	**Please see Changes to the Tender Dossier.**
28	TS	Lot 6/ 6.12.	There must be a connection indicator filter to detect the disconnection of the electrode.	A connection indicator is requested to detect the disconnection of the electrode. Instead of an indicator there is a solid line or a visual alarm. Is this suitable?	**This item will remain as it was stated in TS.**
29	TS	Lot 6/ 6.15.	The accuracy of the device must be ± 5% less.	What is the accuracy sensitivity mentioned required for? What will be the basis for accuracy?	**It is used to increase the sensitivity of the value taken from the patient.**
30	TS	Lot 6/ 6.21.	The filter value of the device shall be adjustable to minimum 3 (three) values.	It is not clear which filter is being mentioned, which filter is the requested feature for?	**Please see Changes to the Tender Dossier.**
31	TS	Lot 6/ 6.22.	The printer sensitivity of the device shall be adjustable to minimum 3 (three) steps as 5 (five) mm/mV, 10 (ten) mm/mV or 12.5 (twelve and a half) and 20 (twenty) mm/mV.	Is it appropriate for the printer sensitivity to be 5, 12.5, 25, 50, 100 mm/sec increments?	**Please see Changes to the Tender Dossier.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
32	TS	Lot 6/ 6.26.5.	Vacuum Pipette Filler set (two sets)	Is the desired set of chest electrodes?	**It is the requested vacuum puar set. Please see Changes to the Tender Dossier.**
33	TS	Lot 8/ 8.1.8.	There must be CE mark and number on the product and its packaging.	There must be CE mark **or** number on the product and its packaging.	**Please see Changes to the Tender Dossier.**
34	TS	Lot 8/ 8.3.5.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications marked on the catalog **or** by marking the original product code and product image in the catalog, in their bid documents.	**Please see Changes to the Tender Dossier.**
35	TS	Lot 8/ 8.3.7.	It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
36	TS	Lot 8/ 8.4.1.	It must be suitable for dental use. It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	It must be suitable for dental use. It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
37	TS	Lot 8/ 8.4.9.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue **or** by marking the original product code and product image in the catalog.	**Please see Changes to the Tender Dossier.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
38	TS	Lot 8/ 8.5.5.	The handle part must be ergonomic. It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	The handle part must be ergonomic. It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
39	TS	Lot 8/ 8.5.8.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue **or** by marking the original product code and product image in the catalogue.	**Please see Changes to the Tender Dossier.**
40	TS	Lot 8/ 8.6.4.	The outer part must not be coated. It must be made of stainless steel. It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	The outer part must not be coated. It must be made of stainless steel. It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
41	TS	Lot 8/ 8.6.6.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue **or** by marking the original product code and product image in the catalog.	**Please see Changes to the Tender Dossier.**
42	TS	Lot 8/ 8.7.2.	The handle part must be ergonomic. It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	The handle part must be ergonomic. It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
43	TS	Lot 8/ 8.7.5.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue **or** by marking the original product code and product image in the catalog.	**Please see Changes to the Tender Dossier.**

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44	TS	Lot 8/ 8.8.2.	It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
45	TS	Lot 8/ 8.8.6.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue **or** by marking the original product code and product image in the catalog.	**Please see Changes to the Tender Dossier.**
46	TS	Lot 8/ 8.9.2.	Two different sizes shall be provided. The tip sizes of 150 amalgam pluggers must be between 1.4 and 1.9 mm and of 150 amalgam pluggers must be between 2.5 and 3.0 mm, making a total of 300 pieces.	It is seen that 100 packages are requested in the Offer Schedule and a total of 300 packages of 2 different types are requested in the Specification. We request clarification on this issue.	**The requested number of that item is totally 300 (Piece). That is same as written in the ITT and Appendix I- Delivery Point (Distribution) list. This item will remain as it was stated in TS.**
47	TS	Lot 8/ 8.9.6.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue **or** by marking the original product code and product image in the catalog.	**Please see Changes to the Tender Dossier.**
48	TS	Lot 8/ 8.10.6.	The outer part must not be coated. It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	The outer part must not be coated. It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
49	TS	Lot 8/ 8.10.8.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on	**Please see Changes to the Tender Dossier.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				the catalogue **or** by marking the original product code and product image in the catalog.	
50	TS	Lot 8/ 8.11.6.	The outer part must not be coated. It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	The outer part must not be coated. It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
51	TS	Lot 8/ 8.11.8.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue.	Tenderers must submit the original product catalogue/brochure etc. of the material proposed (Brochures obtained by photocopying or other duplication methods and the offers based on these shall not be accepted) in the tender dossier, with all technical specifications of the material marked on the catalogue **or** by marking the original product code and product image in the catalog.	**Please see Changes to the Tender Dossier.**
52	TS	Lot 8/ 8.15.12.	The product must not be required to be stored in the refrigerator and must be produced with a technology that can be stored at minimum 25 degrees room temperature. This feature must be stated on the product packaging and in the original prospectus.	We request that this article be removed.	**Please see Changes to the Tender Dossier.**
53	TS	Lot 8/ 8.20.1.	Each package must contain 30 diamond rounds. The size of 15 burs must be 014 and the size of other 15 burs must be 021.	In the unit price offer, 150 packages were requested as a package, we request clarification on this issue.	**The requested number of that item is totally 100 (Package). Each package must contain 30 diamond rounds. That is same as written in the ITT and Appendix I- Delivery Point (Distribution) list. This item will remain as it was stated in TS.**
54	TS	Lot 8/ 8.22.5.	It must be manufactured from one-piece tungsten-carbide alloy.	It must be manufactured from tungsten-carbide alloy.	**This item will remain as it was stated in TS.**
55	TS	Lot 8/ 8.23.5.	It must be manufactured from one-piece tungsten-carbide alloy.	It must be manufactured from tungsten-carbide alloy.	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
56	TS	Lot 8/ 8.24.5.	There must be 50 pieces in the package. 25 pieces must be in size 018 and 25 pieces must be in size 025.	There must be 50 pieces in the package. 25 pieces must be in size 018 and 25 pieces must be in size 025 **or** 023.	**Please see Changes to the Tender Dossier.**
57	TS	Lot 8/ 8.27.	**Matrix Strip Flat (5 mm)**	In the unit bid sheet, the name of the product should be Automatrix Strip Flat (5mm).	**This item will remain as it was stated in TS.**
58	TS	Lot 8/ 8.28.	**Matrix Strip Flat (6.3 mm)**	In the unit bid sheet, the name of the product should be Automatrix Strip Flat (6.3 mm).	**This item will remain as it was stated in TS.**
59	TS	Lot 8/ 8.31.	**Matrix Tool Flat**	In the unit bid sheet, the name of the product must be Automatrix gun.	**This item will remain as it was stated in TS.**
60	TS	Lot 8/ 8.32.10.	Matrix tool must have FDA and CE certificates and these must be submitted in the tender dossier.	Matrix tool must have FDA **or** CE **or** ÜTS certificates and these must be submitted in the tender dossier.	**Please see Changes to the Tender Dossier.**
61	TS	Lot 8/ 8.42.1.	It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	The outer part must not be coated. It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
62	TS	Lot 8/ 8.43.1.	It must be compatible with the scalpel handle and in boxes of 100. It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	It must be compatible with the scalpel handle and in boxes of 100. It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
63	TS	Lot 8/ 8.44.4.	The length of the bone file rasp tips must be long. It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	The length of the bone file rasp tips must be long. It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
64	TS	Lot 8/ 8.45.1.	It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
65	TS	Lot 8/ 8.46.3.	It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**

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66	TS	Lot 8/ 8.48.10.	It must be in individual sterile and transparent packages that allow the product to be visible from the outside and the packages must be made of a material that does not tear, does not absorb liquid and does not trap moisture, so that the back side maintains its integrity throughout its shelf life.	We request that this article be removed.	**This item will remain as it was stated in TS.**
67	TS	Lot 8/ 8.48.11.	It shall be 10 mm x 10 mm x 10 mm in size.	It shall be 10 mm x 10 mm x 10 mm **or** 14x7x7 size	**Please see Changes to the Tender Dossier.**
68	TS	Lot 8/ 8.52.5.	Sheet quantity must be minimum 280Pcs/Roll.	Sheet quantity must be minimum **250Pcs/Roll.**	**Please see Changes to the Tender Dossier.**
69	TS	Lot 8/ 8.57.3.	It must be easily applied to the interface of the teeth without deformation. It must be 9 mm wide.	It must be easily applied to the interface of the teeth without deformation. It must be **at least** 9 mm wide.	**Please see Changes to the Tender Dossier.**
70	TS	Lot 8/ 8.60.1.	Cavitron tips must be compatible with the devices used in our institutions,	It should be reported which brand devices are used in the institutions.	**Please see Changes to the Tender Dossier.**
71	TS	Lot 8/ 8.61.5.	Brush bristles must be resistant to sterilization and disinfection conditions and must not burn or melt with heat.	We request that this article be removed.	**This item will remain as it was stated in TS.**
72	TS	Lot 8/ 8.63.8.	It must be autoclavable together with the bur stand.	As there is no such stand for disks, we request that this article be removed.	**Please see Changes to the Tender Dossier.**
73	TS	Lot 8/ 8.65.1.	It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden. Its polishing must be smooth and even.	It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden. Its polishing must be smooth and even.	**Please see Changes to the Tender Dossier.**
74	TS	Lot 8/ 8.65.4.	Bein must be 2.5 mm and 3.5 mm and 4 mm wide.	Bein must be **at least** 2-3mm and 4 mm wide.	**Please see Changes to the Tender Dossier.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
75	TS	Lot 8/ 8.66.11.	It must be 420 (1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	It must be 420 (1.4021 **or** 1.4034) grade stainless steel and must be of a quality that can be heat treated and can harden.	**Please see Changes to the Tender Dossier.**
76	TS	Lot 8/ 8.68.8.	They must be made of 56 g/m2 laminated fabric. The manufacturer must submit a letter of undertaking and approved test documents from accredited organizations to ensure that the product in question has the required features.	It must be made of at least 40 g/m2 laminated fabric.	**Please see Changes to the Tender Dossier.**
77	TS	Lot 9/ All Items	…	Is there a UTS registration requirement for all products in the lot?	**The relevant document is required for all products subject to the PTS/UTS.**
78	TS	Lot 9/ 9.1.15.	Synthetic absorbable multifilament suture must not be disconnected from the needle connection and must not break easily, the Nickel Ratio in the needle must be 7-11% and the Chromium Ratio must be 16-18% so that the needles do not bend or break easily while passing through the tissue. These features must be documented by the company with original documents.	Is a nickel ratio of 0-11% and a chromium ratio of 12-18% acceptable?	**This item will remain as it was stated in TS.**
79	TS	Lot 9/ 9.1.16.	Requirements regarding suture: Suture length may vary by 10% from the size specified in the tender list, +/- 10% tolerance shall be granted. Requirements regarding needle: +/- 10% tolerance shall be granted for needle lengths over 10mm.	Can suture length tolerance be accepted as 20% instead of 10%?	**This item will remain as it was stated in TS.**
80	TS	Lot 9/ 9.4.1.	The scalpel must be made of steel.	The product is available in the market as carbon steel. Is it accepted as such?	**Please see Changes to the Tender Dossier.**
81	TS	Lot 9/ 9.4.1.	The scalpel must be made of steel.	The scalpel must be made of steel *or* carbon steel.	**Please see Changes to the Tender Dossier.**
82	TS	Lot 9/ 9.5.	**Surgical Glove Sterile**	Is the product desired to be powdered or powder-free?	**The requested material must be powder-free.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
83	TS	Lot 9/ 9.6.	**Surgical Powdered Glove Sterile**	The American Food and Drug Administration (FDA) has banned powdered gloves used in medical procedures on the grounds that they harm human health. It is thought that this situation will cause problems in the process of obtaining the Medical Device Regulation MDR Certificate related to the products. For this reason, all "Powdered Gloves" required in the current specification: • "Powdered or Powder Free Gloves" or • We request that "Powdered Gloves" be removed from the specification or changed to "Powder Free Gloves"	**Please see Changes to the Tender Dossier.**
84	TS	Lot 9/ 9.7.	**Examination Glove**	The size distribution of product quantities is not clear. Can you provide information on this?	**Although it can be changed at the contracting stage, approximately 20% S, 30% M, 40% L, 10% XL will be specified at the that stage.**
85	TS	Lot 9/ 9.9.5.	The special grade silicone in the body shall facilitate the movement capacity of the pisto.	Due to incomplete information, an evaluation could not be made regarding the technical sufficiency and its counterpart in practice regarding the expression "special grade" in the relevant specification article. Could you please provide more information?	**Please see Changes to the Tender Dossier.**
86	TS	Lot 9/ 9.9.6.	The needle tip must be made of AISI 316 quality stainless steel.	Can we offer AISI 304 quality instead of AISI 316 for the requested product?	**Please see Changes to the Tender Dossier.**
87	TS	Lot 9/ 9.9.6.	The needle tip must be made of AISI 316 quality stainless steel.	Technical feedback received from manufacturing companies regarding the use of "AISI 316 quality stainless steel" specified in the relevant specification was evaluated. The evaluations carried out showed that AISI 316 stainless steel has too soft and flexible a structure in some applications, which can lead to difficulties in	**Please see Changes to the Tender Dossier.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				the manufacturing process and undesirable results in the functionality of the final product. It is therefore proposed that, instead of being limited to AISI 316 quality only, the relevant specification clause should be more comprehensive and include other AISI grades to allow the use of alternative stainless steel grades that meet technical and functional requirements. For example, AISI 304 etc.	
88	TS	Lot 9/ 9.9.12.	Injector needles shall comply with TS 4002 EN ISO 7864 or ISO 7864. This document shall be submitted to the committee when the committee deems it necessary.	Would it be enough for you if we added a declaration producer for the mentioned standards?	**Any Decleration document could not be accepted. Please see Changes to the Tender Dossier.**
89	TS	Lot 9/ 9.9.12.	Injector needles shall comply with TS 4002 EN ISO 7864 or ISO 7864. This document shall be submitted to the committee when the committee deems it necessary.	TS 4002 EN ISO 7864 standard was cancelled on 9.12.2016. ISO 7864:2016 is a product standard and its certification can be performed through analytical assessment. The statement proposed to amend as: "Single-use sterile hypodermic needles shall comply with the requirements of TS EN ISO 7864:2016. When the Commission deems it necessary, a certificate of analysis complying with ISO 7864:2016 will be provided."	**Please see Changes to the Tender Dossier.**
90	TS	Lot 9/ 9.11.8.	The manufacturer must have CE and ISO 13485 Quality Management System certificates and submit these in the tender dossier.	The manufacturer must have CE *or* ISO 13485 Quality Management System certificates and submit these in the tender dossier.	**This item will remain as it was stated in TS.**
91	TS	Lot 9/ 9.16.5.	The manufacturer's information, the barcode number of the bandage approved by the Ministry of Health and the production and expiry dates must be written on the packaging.	The manufacturer's information, the barcode number of the bandage approved by the Ministry of Health and the production *or* expiry dates must be written on the packaging.	**This item will remain as it was stated in TS.**
92	TS	Lot 9/ 9.18.1.	Dimensions must be 19x18x18 cm (± 2 cm).	Mouth diameter must be 22 cm, height 18 cm (± 2 cm).	**Please see Changes to the Tender Dossier.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
93	TS	Lot 9/ 9.19.4.	The needle label must include the product name, sterilization method, lot number, expiry date, CE mark and the logo of the manufacturer.	Would it be okay for you to have an importer logo instead of the manufacturer's logo on the product and its packaging?	**Please see Changes to the Tender Dossier.**
94	TS	Lot 9/ 9.20.3.	Scalp vein set must include a transparent protective cover integrated to prevent injuries that may occur when withdrawing the needle from the vein or discarding it after blood-letting.	There is a necessity for clearer, more precise and technically explanatory information about the requested product.	**This item will remain as it was stated in TS.**
95	TS	Lot 9/ 9.20.6.	Color-coded wings according to needle size must be 21G green. Tube length must be 18cm – 20cm.	The statement proposed to amend as: "Tube length should be at least 18cm -20cm"	**This item will remain as it was stated in TS.**
96	TS	Lot 9/ 9.21.12.	There must be a fixed 15-micron liquid filter at the bottom of the chamber.	ISO 8536-4:2020 includes the information "Should be provided with a liquid filter. The latex particle retention of the filter should not be less than 80%" and does not include information on micron permeability. The statement proposed to amend as: "Should be provided with a liquid filter. The latex particle retention of the filter should not be less than 80%".	**Please see Changes to the Tender Dossier.**
97	TS	Lot 9/ 9.21.14.	It must be possible to use light-protected types without the need to wrap anything.	In order to conduct correct cost analysis, there is a necessity for clearer and more precise information about the quantity of light protected serum sets.	**A light-protected product is not obligatory, but if the product to be provided is light-protected, this item applies. This item will remain as it was stated in TS.**
98	TS	Lot 9/ 9.21.14.	It must be possible to use light-protected types without the need to wrap anything.	Is a light-protected serum set required or a standard serum set required? Could you please inform us?	**A light-protected product is not obligatory, but if the product to be provided is light-protected, this item applies. This item will remain as it was stated in TS.**
99	TS	Lot 9/ 9.25.1	Disinfectant must be 100 g solution and must contain 63.14 g Propan-2-ol (70% v/v), 2.256 g (2%) Chlorhexidine digluconate (CHG).	**The statement "Disinfectant must be 100 g solution and must contain 63.14 g Propan-2-ol (70% v/v), 2.256 g (2%) Chlorhexidine digluconate (CHG)." should be amended to: "The product must be in liquid form, must contain**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				isopropanol as the active substance, and the total alcohol content must not be less than 70%." **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	
100	TS	Lot 9/ 9.25.3	The pH of the product must be between 6.9-8.0.	**The statement "The pH of the product must be between 6.9-8.0." should be amended to: "The pH of the product must be between 5.0-8.0."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	**Please see Changes to the Tender Dossier.**
101	TS	Lot 9/ 9.25.6	It must have a permanent effect for 3 hours after application and the report must be submitted in the tender dossier.	**The statement "It must have a permanent effect for 3 hours after application and the report must be submitted in the tender dossier." Should be completely removed.** **Reason:The clause, in its current form, restricts competition. Moreover, it is not a requirement necessary for the functionality of the product.**	**This item will remain as it was stated in TS.**
102	TS	Lot 9/ 9.25.7	There must be analysis reports from nationally authorized laboratories and submitted as an attachment to the dossier. • Bactericidal under clean conditions according to EN 13727 1 min • Bactericidal under clean conditions according to EN 1276 15 sec • Yeasticidal under clean conditions according to EN 13624 1 min • Yeasticidal under clean conditions according to EN 1650 15 sec	**The following statements should be removed:** **"There must be analysis reports from nationally authorized laboratories and submitted as an attachment to the dossier.** • **Bactericidal under clean conditions according to EN 13727 1 min** • **Bactericidal under clean conditions according to EN 1276 15 sec** • **Yeasticidal under clean conditions according to EN 13624 1 min**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
			• Effective against enveloped viruses under clean conditions according to EN 14476 15 sec • (including HBV, HIV, HCV) • Mycobactericidal under clean conditions according to EN 14348 1 min • (including M. Avium, M. terrae) • Tuberculocidal under clean conditions according to EN 14348 30 sec • (including M.terrae) Surgical hand disinfection according to EN 12791 3ml X 3 min	• **Yeasticidal under clean conditions according to EN 1650 15 sec** • **Effective against enveloped viruses under clean conditions according to EN 14476 15 sec** • **(including HBV, HIV, HCV)** • **Mycobactericidal under clean conditions according to EN 14348 1 min** • **(including M. Avium, M. terrae)** • **Tuberculocidal under clean conditions according to EN 14348 30 sec** • **(including M.terrae)** **Surgical hand disinfection according to EN 12791 3ml X 3 min"** **and replaced with the following:** **"It must demonstrate bactericidal (including VRE, Acinetobacter, and MRSA), fungicidal, virucidal, and tuberculocidal effects within 30 seconds. Test reports verifying these effects must be obtained from internationally accredited laboratories or laboratories authorized by the Ministry of Health of the Republic of Türkiye and submitted accordingly."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	
103	TS	Lot 9/ 9.25.8	Analysis reports from international laboratories must be received and submitted as an attachment to the dossier.	**The following statements should be removed:**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
			• Tuberculocidal under clean conditions according to EN 14348 5 min • Mycobactericidal under clean conditions according to EN 14348 5 min • Bactericidal under clean conditions according to EN 13727 30 sec • Yeasticidal according to EN 13624 30 sec • Virucidal according to EN 14476 30 sec	**"Analysis reports from international laboratories must be received and submitted as an attachment to the dossier.** • **Tuberculocidal under clean conditions according to EN 14348 5 min** • **Mycobactericidal under clean conditions according to EN 14348 5 min** • **Bactericidal under clean conditions according to EN 13727 30 sec** • **Yeasticidal according to EN 13624 30 sec** • **Virucidal according to EN 14476 30 sec"** **and replaced with the following:** **"It must demonstrate bactericidal (including VRE, Acinetobacter, and MRSA), fungicidal, virucidal, and tuberculocidal effects within 30 seconds. Test reports verifying these effects must be obtained from internationally accredited laboratories or laboratories authorized by the Ministry of Health of the Republic of Türkiye and submitted accordingly."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	
104	TS	Lot 9/ 9.26.2	The product must contain minimum 45% ethyl alcohol, 5% isopropyl alcohol and quaternary ammonium compound. The disinfection inactive ingredient ratio, excluding alcohol, must not exceed 0.1%.	**From the statement "The product must contain minimum 45% ethyl alcohol, 5% isopropyl alcohol and quaternary ammonium compound. The disinfection inactive ingredient ratio, excluding alcohol, must not exceed 0.1%.", the phrase "The disinfection inactive ingredient**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				ratio, excluding alcohol, must not exceed 0.1%." should be removed. **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	
105	TS	Lot 9/ 9.26.5	The microbiological activity of the product must be for: • Bacteria (Pseudomonas aeruginosa, Staphylococcus aureus, according to EN 13727 standard, • Enterococcus hirae, Escherichia coli, Acinetobacter baumannii, MRSA, VRE) on 5 log 1 min • According to EN 14348 standard, Mycobacteria (Mycobacterium terrae, Mycobacterium avium) on 4 log 1 min • According to EN13624 standard, Fungi (Candida albicans, Aspergillus brasiliensis) on 4 log 1 min • According to EN14476 standard, Viruses (Adenovirus, Poliovirus, Murine Norovirus, Vaccinia virus, Rotavirus) under clean and dirty conditions on 4 log 1 min.	**The following statement:** **"The microbiological activity of the product must be for:** • **Bacteria (Pseudomonas aeruginosa, Staphylococcus aureus, according to EN 13727 standard,** • **Enterococcus hirae, Escherichia coli, Acinetobacter baumannii, MRSA, VRE) on 5 log 1 min** • **According to EN 14348 standard, Mycobacteria (Mycobacterium terrae, Mycobacterium avium) on 4 log 1 min** • **According to EN13624 standard, Fungi (Candida albicans, Aspergillus brasiliensis) on 4 log 1 min** • **According to EN14476 standard, Viruses (Adenovirus, Poliovirus, Murine Norovirus, Vaccinia virus, Rotavirus) under clean and dirty conditions on 4 log 1 min."** **should be supplemented with the following alternative statement:** **"or** • **Bacteria (Pseudomonas aeruginosa, Staphylococcus aureus, according to EN 13727 standard,**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				• **Enterococcus hirae, Escherichia coli, Acinetobacter baumannii, MRSA, VRE) 1 min** • **According to EN 14348 standard, Mycobacteria (Mycobacterium terrae, Mycobacterium avium) 1-5 min** • **According to EN13624 standard, Fungi (Candida albicans, Aspergillus brasiliensis) 1 min** • **According to EN14476 standard, Viruses (Adenovirus, Poliovirus, Murine Norovirus, Vaccinia virus, Rotavirus) under clean and dirty conditions 1 min."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	
106	TS	Lot 9/ 9.26.12	The product must have a biocidal license from the Ministry of Health of the Republic of Türkiye.	**The statement "The product must have a biocidal license from the Ministry of Health of the Republic of Türkiye." should be supplemented with "or the product must be registered in the Ministry of Health of the Republic of Türkiye's UTS (Product Tracking System)."** **Reason:In accordance with the regulations established by the Ministry of Health of the Republic of Türkiye, a biocidal license is not mandatory for this product.**	**This item will remain as it was stated in TS.**
107	TS	Lot 9/ 9.27.1	Disinfectant must contain minimum 88% ethyl alcohol by volume (v/v) in 100 g of ready-to-use solution.	**The statement "Disinfectant must contain minimum 88% ethyl alcohol by volume (v/v) in 100 g of ready-to-use solution." should be amended to "Disinfectant must contain minimum 70% ethyl alcohol by volume (v/v) in 100 g of ready-to-use solution."**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.	
108	TS	Lot 9/ 9.27.3	Product shelf life must be 3 years.	**The statement "Product shelf life must be 3 years." should be amended to "Product shelf life must be at least 2 years."** **Reason:The clause, in its current form, restricts competition. In general, products of this type have a shelf life of two years.**	**This item will remain as it was stated in TS.**
109	TS	Lot 9/ 9.27.5	Disinfectant must be dermatologically tested in vivo (on living beings) and must be submitted in the tender dossier.	**The statement "Disinfectant must be dermatologically tested in vivo (on living beings) and must be submitted in the tender dossier." should be amended to "Disinfectant must have undergone dermatological/skin irritation testing and must be submitted in the tender dossier."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	**This item will remain as it was stated in TS.**
110	TS	Lot 9/ 9.27.6	It must contain vitamin E or Lanette for more sensitive skin compatibility.	**The statement "It must contain vitamin E or Lanette for more sensitive skin compatibility." should be amended to "It must contain vitamin E, Lanette or glycerin for more sensitive skin compatibility.** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	**Please see Changes to the Tender Dossier.**
111	TS	Lot 9/ 9.27.12	There must be analysis reports from nationally authorized laboratories and submitted as an attachment to the dossier. • Bactericidal EN 1276 clean condition 1 min	**The following statements:** **"There must be analysis reports from nationally authorized laboratories and submitted as an attachment to the dossier.** • **Bactericidal EN 1276 clean condition 1 min**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
			EN 13727 clean condition 30 sec • Yeasticidal EN 1650 clean condition 30 sec EN 13624 clean condition 30 sec • Tuberculocidal EN 14348 clean condition 5 min (M. terrae) • Mycobactericidal EN 14348 clean condition 5 min • Virucidal EN 14476 clean condition 30 sec	**EN 13727 clean condition 30 sec** • **Yeasticidal EN 1650 clean condition 30 sec** **EN 13624 clean condition 30 sec** • **Tuberculocidal EN 14348 clean condition 5 min (M. terrae)** • **Mycobactericidal EN 14348 clean condition 5 min** **Virucidal EN 14476 clean condition 30 sec"** **should be supplemented with:** **"or test reports based on EN 13727, EN 1276, EN 13624, EN 1650, EN 14348, and EN 14476 standards conducted by laboratories authorized by the Ministry of Health of the Republic of Türkiye must be submitted."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	
112	TS	Lot 9/ 9.27.13	Analysis reports from international laboratories must be received and submitted as an attachment to the dossier. • Hygienic hand disinfection EN 1500/VAH App. recommendation for 30 sec. • Surgical hand disinfection EN 12791/VAH App. recommendation for 1.5 min. • Yeasticidal EN 13624 clean condition 30 sec • Candida albicans dirty condition 30 sec • Bactericidal EN 13727 clean condition 30 sec	**The following statements:** **"Analysis reports from international laboratories must be received and submitted as an attachment to the dossier.** • **Hygienic hand disinfection EN 1500/VAH App. recommendation for 30 sec.** • **Surgical hand disinfection EN 12791/VAH App. recommendation for 1.5 min.** • **Yeasticidal EN 13624 clean condition 30 sec**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
			dirty condition 30 sec • Fungicidal EN 13624 clean condition 1.5 min (A. Brasiliensis) dirty condition 2 min • Tuberculocidal EN 14348 clean condition 30 sec (M. Terrae) • Mycobactericidal EN 14348 clean condition 30 sec (M. avium and M. Terrae) • Virucidal EN 14476 clean condition 30 sec • Noroviruses (MNV) EN 14476 clean condition 30 sec • Adenovirus EN 14476 clean condition 30 sec • Poliovirus EN 14476 clean condition 30 sec	• **Candida albicans dirty condition 30 sec** • **Bactericidal EN 13727 clean condition 30 sec** **dirty condition 30 sec** • **Fungicidal EN 13624 clean condition 1.5 min** **(A. Brasiliensis) dirty condition 2 min** • **Tuberculocidal EN 14348 clean condition 30 sec** **(M. Terrae)** • **Mycobactericidal EN 14348 clean condition 30 sec** **(M. avium and M. Terrae)** • **Virucidal EN 14476 clean condition 30 sec** • **Noroviruses (MNV) EN 14476 clean condition 30 sec** • **Adenovirus EN 14476 clean condition 30 sec** • **Poliovirus EN 14476 clean condition 30 sec"** **should be supplemented with:** **"or the product must demonstrate bactericidal activity within 30 seconds (including Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae, Acinetobacter baumannii, VRE, and MRSA), fungicidal activity**	

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				within 30 seconds, virucidal activity within 1 minute (including Adenovirus, Poliovirus, Norovirus, and Vaccinia virus), and mycobactericidal activity within 5 minutes (including Mycobacterium terrae and Mycobacterium avium). Test reports demonstrating these effects must be obtained from laboratories authorized by the Ministry of Health of the Republic of Türkiye" **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	
113	TS	Lot 9/ 9.27.17	It must have DGHM/VAH certificate and submit it in the tender dossier.	**The statement "It must have DGHM/VAH certificate and submit it in the tender dossier." should be amended to "It must have DGHM/VAH or FDA certificate and submit it in the tender dossier."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	**This item will remain as it was stated in TS.**
114	TS	Lot 9/ 9.28.4	The product must contain sodium Iaureth ether sulfate or sodium Iaureth sulfate 2-10%, glycerin or cocoamide DEA 0.5-5%, cocamidopropyl betaine 2-10%, sodium chloride, citric acid, preservative and perfume.	**The statement "The product must contain sodium Iaureth ether sulfate or sodium Iaureth sulfate 2-10%, glycerin or cocoamide DEA 0.5-5%, cocamidopropyl betaine 2-10%, sodium chloride, citric acid, preservative and perfume." should be supplemented with "or sodium Iaureth sulfate, cocamidopropyl betaine, glycerin, coloring agent and perfume."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
115	TS	Lot 9/ 9.28.5	Its density must be between 1.01-1.05 g/mL at 20 °C.	**The statement "Its density must be between 1.01-1.05 g/mL at 20 °C." should be amended to "Its density must be between 0.98-1.05 g/mL at 20 °C."** **Reason:The clause, in its current form, restricts competition. Moreover, there is no difference in terms of the product's functionality.**	**Please see Changes to the Tender Dossier.**
116	TS	Lot 9/ 9.28.6	Its direct pH must be between 5.5-6.5.	**The statement "Its direct pH must be between 5.5-6.5." should be amended to "Its direct pH must be between 5.5-7.0."** **Reason:The clause, in its current form, restricts competition. Moreover, there is no difference in terms of the product's functionality.**	**Please see Changes to the Tender Dossier.**
117	TS	Lot 9/ 9.28.8	The manufacturer must undertake that the perfume used complies with the "IFRA CONFORMITY CERTIFICATE" and submit its undertaking in the tender dossier.	**The statement "The manufacturer must undertake that the perfume used complies with the "IFRA CONFORMITY CERTIFICATE" and submit its undertaking in the tender dossier." should be completely removed.** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Moreover, it is not a requirement necessary for the quality or functionality of the product.**	**This item will remain as it was stated in TS.**
118	TS	Lot 9/ 9.28.12	The product must be suitable for use with liquid soap dispensers.	**The statement "The product must be suitable for use with liquid soap dispensers." should be completely removed.** **Reason:It is not appropriate for this clause to remain without specifying the types of dispensers with which it is to be used.**	**This item will remain as it was stated in TS.**
119	TS	Lot 9/ 9.28.14.	The product must be in 5 Lt (± 100 ml) original packaging.	There are products that are packaged and produced in the range of 3500 ml - 4000 ml. We can offer the total amount of 176,000 liters required. Would this be acceptable to you?	**Please see Changes to the Tender Dossier.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
120	TS	Lot 9/ 9.28.17	The manufacturer must have a GMP (Good Manufacturing Practices) certificate approved by the TSI (TSI EN ISO 22716) and submit this certificate in the tender dossier.	**The following statement:** **"The manufacturer must have a GMP (Good Manufacturing Practices) certificate approved by the TSI (TSI EN ISO 22716) and submit this certificate in the tender dossier."** **should be supplemented with:** **"or the manufacturer must have a GMP (Good Manufacturing Practices) certificate (EN ISO 22716) and submit this certificate in the tender dossier** **Reason:The clause, in its current form, restricts competition. Possession of a GMP certificate issued by the competent authority is sufficient.**	**Please see Changes to the Tender Dossier.**
121	TS	Lot 9/ 9.28.20	The product must have a TS 11885 Type 1 certificate and it must be submitted in the tender dossier.	**The statement "The product must have a TS 11885 Type 1 certificate and it must be submitted in the tender dossier." should be completely removed.** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Moreover, it is not a requirement necessary for the quality or functionality of the product.**	**This item will remain as it was stated in TS.**
122	TS	Lot 9/ 9.31.	***Nebulizer Diffuser Mask Adult***	The technical specifications provided for these products match exactly and exclusively with a patented product of a single brand and model -- **OXYMASK.** The specified products are manufactured by the **OXYMASK** brand, which is imported and distributed in Türkiye solely by **Yigit Saglik Arac Gerecleri Ith. ihr. Paz. Ltd. Sti.** Within **LOT 9** of the tender, there are 50 different product types, and any participating bidder is required to provide pricing for all 50 items. We would like to emphasize that the inclusion of the two specified items makes it practically	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				impossible to submit an offer for the entire LOT, due to the exclusive and patented nature of the OXYMASK brand. Therefore, we respectfully inform you that the current technical specifications favor a single brand, which prevents fair competition. In light of the above, we kindly request that item **9.31 — Adult Nebulizer Diffuser Mask** be removed from LOT 9 and instead be procured separately by the institution if needed.	
123	TS	Lot 9/ 9.32.	**Nebulizer Diffuser Mask Pediatric**	The technical specifications provided for these products match exactly and exclusively with a patented product of a single brand and model -- **OXYMASK.** The specified products are manufactured by the **OXYMASK** brand, which is imported and distributed in Türkiye solely by **Yigit Saglik Arac Gerecleri Ith. ihr. Paz. Ltd. Sti.** Within **LOT 9** of the tender, there are 50 different product types, and any participating bidder is required to provide pricing for all 50 items. We would like to emphasize that the inclusion of the two specified items makes it practically impossible to submit an offer for the entire LOT, due to the exclusive and patented nature of the OXYMASK brand. Therefore, we respectfully inform you that the current technical specifications favor a single brand, which prevents fair competition. In light of the above, we kindly request that item 931 — **Adult Nebulizer Diffuser Mask** be removed from LOT 9 and instead be procured separately by the institution if needed.	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
124	TS	Lot 9/ 9.33.2.	The push handle must be made of metal.	The push handle *and* pres handle must be made of metal.	**This item will remain as it was stated in TS.**
125	TS	Lot 9/ 9.37.1	The product must be made of 100% bleached chemical cellulose. There must be an analysis report from an accredited laboratory and it must be submitted in the tender dossier.	**The statement "The product must be made of 100% bleached chemical cellulose. There must be an analysis report from an accredited laboratory and it must be submitted in the tender dossier." should be completely removed.** **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this clause is neither functionally necessary for the product nor legally mandated.**	**This item will remain as it was stated in TS.**
126	TS	Lot 9/ 9.37.2	The manufacturer must have a letter of undertaking stating that the product is made of 100% cellulose and submit this document in the tender dossier.	**The statement "The manufacturer must have a letter of undertaking stating that the product is made of 100% cellulose and submit this document in the tender dossier." should be completely removed.** **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this clause is neither functionally necessary for the product nor legally mandated.**	**This item will remain as it was stated in TS.**
127	TS	Lot 9/ 9.37.3	The manufacturer must have an FSC certificate and submit this certificate in the tender dossier. As proof that the product has FSC, the FSC logo must be on the packaging according to the specified standards and the submitted document must be verifiable from the original FSC website.	**The statement "The manufacturer must have an FSC certificate and submit this certificate in the tender dossier. As proof that the product has FSC, the FSC logo must be on the packaging according to the specified standards and the submitted document must be verifiable from the original FSC website." should be completely removed.** **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				clause is neither functionally necessary for the product nor legally mandated.	
128	TS	Lot 9/ 9.37.8	There shall be 150 (± 2) sheets in a roll. The product must have TSI 12385 Class-1, Category-3, Type-1, Variety-1, Sort-1, Shape-1 certificate and this certificate must be submitted in the tender dossier.	**The statement "There shall be 150 (± 2) sheets in a roll. The product must have TSI 12385 Class-1, Category-3, Type-1, Variety-1, Sort-1, Shape-1 certificate and this certificate must be submitted in the tender dossier." should be completely removed.** **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this clause is neither functionally necessary for the product nor legally mandated.**	**This item will remain as it was stated in TS.**
129	TS	Lot 9/ 9.37.11	There must be a product identity certificate from the manufacturer's authorized official showing the physical test results of the product and the certificate must be submitted in the tender dossier.	**The statement "There must be a product identity certificate from the manufacturer's authorized official showing the physical test results of the product and the certificate must be submitted in the tender dossier." should be amended to "Quality certificates related to the product must be submitted."** **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this clause is neither functionally necessary for the product nor legally mandated.**	**This item will remain as it was stated in TS.**
130	TS	Lot 9/ 9.39.1	The product must be made of 100% bleached chemical cellulose. There must be an analysis report from an accredited laboratory and it must be submitted in the tender dossier.	**The statement "The product must be made of 100% bleached chemical cellulose. There must be an analysis report from an accredited laboratory and it must be submitted in the tender dossier." should be completely removed.** **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this clause is neither functionally necessary for the product nor legally mandated.**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
131	TS	Lot 9/ 9.39.2	The manufacturer must have a letter of undertaking stating that the product is made of 100% cellulose and submit this document in the tender dossier.	**The statement "The manufacturer must have a letter of undertaking stating that the product is made of 100% cellulose and submit this document in the tender dossier." should be completely removed.** **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this clause is neither functionally necessary for the product nor legally mandated.**	**This item will remain as it was stated in TS.**
132	TS	Lot 9/ 9.39.3	The manufacturer must have an FSC certificate and submit this certificate in the tender dossier.	**The statement "The manufacturer must have an FSC certificate and submit this certificate in the tender dossier." should be completely removed.** **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this clause is neither functionally necessary for the product nor legally mandated.**	**This item will remain as it was stated in TS.**
133	TS	Lot 9/ 9.39.4	It must be two-ply and water-resistant. As proof that the product has FSC, the FSC logo must be on the packaging according to the specified standards and the submitted document must be verifiable from the original FSC website.	**The second sentence of the statement "It must be two-ply and water-resistant. As proof that the product has FSC, the FSC logo must be on the packaging according to the specified standards and the submitted document must be verifiable from the original FSC website." should be completely removed.** **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this clause is neither functionally necessary for the product nor legally mandated.**	**This item will remain as it was stated in TS.**
134	TS	Lot 9/ 9.39.14	There must be a product identity certificate from the manufacturer's authorized official showing the physical test results of the product and the certificate must be submitted in the tender dossier.	**The statement "There must be a product identity certificate from the manufacturer's authorized official showing the physical test results of the product and the certificate must be submitted in the tender dossier." should be amended to**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				"Quality certificates related to the product must be submitted." **Reason:The current version of the clause points to a single brand and restricts competition. Furthermore, the requirement stated in this clause is neither functionally necessary for the product nor legally mandated.**	
135 136	TS	Lot 9/ 9.45.2. and 9.45.3.	The width of the sheet must be 45 cm. The length of the sheet must be 25 cm.	Are you sure about the dimensions of requested item?	**This item will remain as it was stated in TS.**
137	TS	Lot 9/ 9.47.2	The product chemical content must have didecyldimethylammonium chloride, N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine, non-ionic detergent for cleaning properties and chelating agent for reducing metal ions in water.	**The following statement:** **"The product chemical content must have didecyldimethylammonium chloride, N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine, non-ionic detergent for cleaning properties and chelating agent for reducing metal ions in water."** **should be supplemented with:** **"or the disinfectant must contain active ingredients such as <3% Bis(3-aminopropyl) dodecylamine, <6% Didecyl dimethyl ammonium chloride, and <8% Benzalkonium chloride, along with auxiliary substances. It must not contain aldehyde, phenol, or chlorine derivatives."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	**This item will remain as it was stated in TS.**
138	TS	Lot 9/ 9.47.6	The microbiological activity of the product must be for: - Bacteria (Pseudomonas aeruginosa, Staphylococcus aureus, according to EN 13727 standard, - Enterococcus hirae, Escherichia coli, Acinetobacter baumannii, MRSA, VRE) 5 min	**The following statement:** **"The microbiological activity of the product must be for:** **- Bacteria (Pseudomonas aeruginosa, Staphylococcus aureus, according to EN 13727 standard,**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
			- Fungi (Candida albicans, Aspergillus brasiliensis) according to EN 13624 standard 5 min - Mycobacteria (Mycobacterium terrae, Mycobacterium avium) according to EN 14348 standard 5 min - Viruses (Poliovirus, Adenovirus, Murine Norovirus, Vaccinia virus, Rotavirus) according to EN 14476 standard 5 min The company must submit studies conducted by accredited laboratories that demonstrate that it meets these specifications.	**- Enterococcus hirae, Escherichia coli, Acinetobacter baumannii, MRSA, VRE) 5 min** **- Fungi (Candida albicans, Aspergillus brasiliensis) according to EN 13624 standard 5 min** **- Mycobacteria (Mycobacterium terrae, Mycobacterium avium) according to EN 14348 standard 5 min** **- Viruses (Poliovirus, Adenovirus, Murine Norovirus, Vaccinia virus, Rotavirus) according to EN 14476 standard 5 min** **The company must submit studies conducted by accredited laboratories that demonstrate that it meets these specifications."** **should be supplemented with:** **"or the disinfectant must be broad-spectrum; demonstrating virucidal activity (including Adenovirus, Poliovirus, Norovirus, HBV, HCV, and HIV), as well as bactericidal and fungicidal effects. Upon request, clinical microbiological analysis reports obtained from laboratories authorized by the Ministry of Health must be made available to verify these properties."** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Furthermore, there is no functional difference in terms of the product.**	
139	TS	Lot 9/ 9.48.2	The manufacturer must have an "EIA is not required" certificate and must submit it in the tender dossier.	**The statement "The manufacturer must have an "EIA is not required" certificate and must submit it in the tender dossier." should be completely removed.** **Reason:The clause, in its current form, refers to a single brand and restricts competition.**	**Please see Changes to the Tender Dossier.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				Additionally, the requirement stated in this clause is not a legal obligation.	
140	TS	Lot 9/ 9.48.3	The manufacturer must have a Good Manufacturing Practices (GMP) Certificate issued by the Turkish Medicines and Medical Devices Agency and must submit it in the tender dossier.	**The statement "The manufacturer must have a Good Manufacturing Practices (GMP) Certificate issued by the Turkish Medicines and Medical Devices Agency and must submit it in the tender dossier." should be completely removed.** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Additionally, the requirement stated in this clause is not a legal obligation.**	**Please see Changes to the Tender Dossier.**
141	TS	Lot 9/ 9.48.4	A 16-item Product Safety Data Sheet and a safety data sheet preparer certificate from TSI or TURKAK approved accredited institutions must be available for the preparer, the MSDS report must be stamped and signed by the certificate holder, the certificate holder must have a notarized signature declaration and must submit it in the tender dossier.	**The following statement:** **"A 16-item Product Safety Data Sheet and a safety data sheet preparer certificate from TSI or TURKAK approved accredited institutions must be available for the preparer, the MSDS report must be stamped and signed by the certificate holder, the certificate holder must have a notarized signature declaration and must submit it in the tender dossier."** **should be completely removed.** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Additionally, the requirement stated in this clause is not a legal obligation.**	**This item will remain as it was stated in TS.**
142	TS	Lot 9/ 9.48.7	It must be clear, very slightly yellowish, homogeneously viscous and the product viscosity must be minimum 400 mPas at 20°C.	**The statement "It must be clear, very slightly yellowish, homogeneously viscous and the product viscosity must be minimum 400 mPas at 20°C." should be completely removed.** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Additionally, the requirement stated in this clause is not a legal obligation.**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
143	TS	Lot 9/ 9.48.12	The product must have a biocidal certificate and it must be submitted in the tender dossier.	**The statement "The product must have a biocidal certificate and it must be submitted in the tender dossier." should be completely removed.** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Additionally, the requirement stated in this clause is not a legal obligation.**	**This item will remain as it was stated in TS.**
144	TS	Lot 9/ 9.49.1.	The 16-item Product Safety Data Sheet must be prepared by taking into account the "Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals" published in the official gazette dated July 23, 2017 and numbered 30105, and the product safety data sheet preparer must have a "Chemical Evaluation Expert" certificate and a notarized signature circular and these must be submitted in the tender dossier.	**The following statement:** **"The 16-item Product Safety Data Sheet must be prepared by taking into account the "Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals" published in the official gazette dated July 23, 2017 and numbered 30105, and the product safety data sheet preparer must have a "Chemical Evaluation Expert" certificate and a notarized signature circular and these must be submitted in the tender dossier."** **should be completely removed.** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Additionally, the requirement stated in this clause is not a legal obligation.**	**This item will remain as it was stated in TS.**
145	TS	Lot 9/ 9.49.3	The manufacturer must have an EIA or "EIA is not required" certificate and must submit it in the tender dossier.	**The statement "The manufacturer must have an EIA or "EIA is not required" certificate and must submit it in the tender dossier." should be completely removed.** **Reason:The clause, in its current form, refers to a single brand and restricts competition. Additionally, the requirement stated in this clause is not a legal obligation.**	**Please see Changes to the Tender Dossier.**
146	TS	Lot 9/ 9.49.6	The perfume must be scented. The manufacturer must have an "IFRA" conformity certificate for the perfume and must submit it in the tender dossier.	**The statement "The perfume must be scented. The manufacturer must have an "IFRA" conformity certificate for the perfume and must**	**This item will remain as it was stated in TS.**

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
				submit it in the tender dossier." should be completely removed. **Reason:The clause, in its current form, indicates a single brand and hinders competition. Moreover, the requirement specified in this clause is not necessary for the functionality of the product.**	
147	TS	Lot 9/ 9.49.7	The perfume must have an allergen certificate obtained from the manufacturer and the certificate must be submitted in the tender dossier.	**The statement "The perfume must have an allergen certificate obtained from the manufacturer and the certificate must be submitted in the tender dossier." should be completely removed.** **Reason:The clause, in its current form, indicates a single brand and hinders competition. Moreover, the requirement specified in this clause is not necessary for the functionality of the product.**	**Please see Changes to the Tender Dossier.**