TENDER SPECIFICATIONS

PART II

TECHNICAL SPECIFICATIONS

No EEAS/2021/OP/0034

Multiple Framework contract in cascade for the provision of Personal Protective Equipment (PPE)

OPEN PROCEDURE

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1. TECHNICAL SPECIFICATIONS

The subject of this contract is the supply of personal protective equipment and other medical material for the European External Action Service (EEAS) staff, its visitors and medical services.

The requirements of these technical specifications are minimum requirements. During the performance of the contract, the Contractor is responsible for providing any additional elements it has offered in its tender in order to exceed the minimum requirements.

1.1 MAIN PRODUCTS

1.1.1 RESPIRATORY PROTECTION

Medical masks, filtering face piece respirators class 2 (FFP2), Filtering masks FFP3 and face shields shall comply with the following minimum requirements.

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
Medical masks (Item A)	• Single use, disposable • Bicolour to clearly identify the internal and external faces • Consisting of three layers • Three pleats of folds to allow the user to expand the mask so it covers the area from the nose to the chin • Affixed to the head with extendible ear loops to be placed behind the ears • With integrated strong pliable metal strip that can be bent to contour the mask over the bridge of the nose (i.e. the nose bar must be adaptable) • Structured fit that does not collapse on the mouth • Minimum size of the unfolded mask: 17,5 cm X 9,5 cm • Maximum number of masks per pack: 100 pieces • Soft non-woven material, fiberglass free, latex free and hypoallergenic • Storage at t° from + 5° to +40°C • Expiration date of minimum two years from delivery date • Usage and fitting instructions are at least in English	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	EN 14683:2019 + AC:2019 – Type IIR

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
Filtering face piece respirators class 2 (FFP2 NR) (Item B)	• Good breathability with fit that does not collapse on the mouth (e.g. duckbill, cupshaped) • Without exhalation valve • Provided with a metal plate at the top of the nose • Single use, disposable • Affixed to the head with extendible ear loops to be placed behind the ears that enable an easy adjustment of the mask by the wearer (upper band across the crown of the head and the lower band below the ear) • Fiberglass free, hypoallergenic and without natural rubber latex components • Usage and fitting instructions are at least in English • Maximum number of masks per pack: 100 pieces • Expiration date of minimum two years from delivery date • Pouch style mask or/and fish shape • With SO-SOFT lining • Storage requirements from -30°c to +70°C and < 80% relative humidity	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC Category III	"FFP2 NR" according to EN 149:2001 + A1:2009

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
Filtering masks FFP3 NR (Item C)	• Single use, disposable particle filtering mask • Easy to fit to the wearer profile due to the applied adjustable nose piece • Internal and external faces are clearly identified • Affixed to the head with ear loops to be placed behind the ears or elastic headband that enables an easy adjustment of the mask by the wearer • Fiberglass free, latex free and hypoallergenic • The shape of the filtering mask is designed in order to minimize breathing difficulties and speaking discomfort • Provided with exhalation valve which reduces the accumulation of humidity and heat • Maximum number of masks per pack: 50 pieces • Usage and fitting instructions are at least in English • Expiration date of minimum two years from delivery date	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC Category III	"FFP3 NR" according to EN 149:2001 + A1:2009

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
Face shields (Item D)	• Clear plastic lens: with double sided anti fog and scratch resistant treatments • Maximum splash protection: completely covers the sides and lengths of the face (minimum length of face splash: 20 cm) • Fully adjustable and comfortable headband • Area of forehead is filled with foam material that touches the skin to prevent entry of liquids and or droplets • Lightweight • Reusable • Robust material that can be cleaned and disinfected • Fits easily over prescription glasses, medical masks (Item A), FFP2 NR (Item B) and FFP3 NR (Item C) masks	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC Category III	EN 166 : 2001 (field of application to protect the face from drops and splashes of liquid)

1.1.2 HAND PROTECTION

Examination gloves (normal and thicker) shall comply with the following minimum requirements.

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
Examination gloves (Item E)	• Nitrile based, powder-free, latex-free, non-sterile • Long cuffs (minimum 240mm +/- 5mm total length) • Thickness palm 0,07 +/- 0.02mm, fingers 0,09 +/- 0.02mm, cuffs 0,05 +/- 0.01mm • Sizes: S, M, L and XL • Ambidextrous: can be worn on both hands (not pairs of gloves) • Excellent resistance to abrasion and perforation	• Council Directive 93/42/EEC of 14 June 1993 concerning medical devices • Directive 98/79/CE du Parlement européen et du Conseil du 27 octobre 1998	EN 455-1:2000 EN 455-2:2015 EN 455-3:2015 EN 455-4:2009
Examination gloves (thicker ones) (Item F)	• Nitrile based, powder-free, latex-free, non-sterile • Long cuffs (minimum 300mm +/- 5mm total length) • Thickness palm 0,09 +/- 0.02mm, fingers 0,14 +/- 0.02mm, cuffs 0,07 +/- 0.03mm • Sizes: S, M, L and XL • Ambidextrous: can be worn on both hands (not pairs of gloves) • Excellent resistance to abrasion and perforation	• Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC • Council Directive 93/42/EEC of 14 June 1993 concerning medical devices Category II/III	EN ISO 374-5:2016 EN 455-1:2000 EN 455-2:2015 EN 455-3:2015 EN 455-4:2009

1.1.3 BODY PROTECTIONS

Gowns shall comply with the following minimum requirements.

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
Gowns (Item G)	• Single use, disposable • Made from liquid repellent, breathable non-woven material • High resistance to germ transmigration and seepage • Length mid-calf and knitted arm cuffs • Wide overlapping back section, stable tie bands • Sizes: M, L and XL • Ties at neck and waist • Cotton cuffs	• Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 93/42/EEC concerning medical devices	EN 13795-1:2019; EN 13795-2:2019

1.1.4 SANITIZERS

Hand sanitizers shall comply with the following minimum requirements.

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
Hand sanitizer travel size 50ml (Item H) Hand sanitizer size 75ml (Item I) Hand sanitizer size 100 ml (Item J)	• Wide spectrum efficacy: antibacterial (including MRSA), antiviral (including Norovirus/HBV/HIV/HCV), levuricide, antifungal/fungicidal, mycobactericide • Fast acting • Conform to effective range AB (RKI disinfectant list or equivalent) • 70% or more alcohol, phenol or aldehyde based and antiseptic • No artificial dyes or scent • Skin friendly • Dermatologically tested • Texture in form gel • Volume needed as travel size hand sanitisers: 50 ml, 75 ml and 100 ml	• Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	EN 14476:2013+A2:2019 **Groupe 1: désinfectants** TP 1 EN 13727:2012+A2:2015 EN 13624; EN 1500

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
Hand sanitizer (office-size dispenser 500 ml) (Item K)	• Wide spectrum efficacy: antibacterial (including MRSA), antiviral (including Norovirus/HBV/HIV/HCV), levuricide, antifungal/fungicidal, mycobactericide • Fast acting • Conform to effective range AB (RKI disinfectant list or equivalent) • 70% or more alcohol, phenol or aldehyde based and antiseptic • Have pH at +20°C : around 5,5 (close to the skin one), viscosity at +20°C of maximum 1200 to 2500 mPa.s • No artificial dyes or scent • Skin friendly • Dermatologically tested • Texture in form gel • Availability needed as office-size dispensers (500 ml) with pump • Pump bottle	Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	Anti bacterial: EN 1040, 13727, 1500, 1279, or 1276 Anti mycobacteria: EN 14348 Anti fungus: EN 1275,1650 Antivirus: EN 14476+A1

1.1.5 SURFACES PROTECTION

Surface disinfectant and wipes shall comply with the following minimum requirements.

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
Surfaces disinfectant (Item L)	• Need to be biocide for surfaces disinfection in contact with food • To use in one step for disinfection of high surfaces, external structures of non-immersible and non-invasive medical equipment and devices (e.g. tensiometers, reflex hammers, stethoscopes, etc.) • Does not contain CMR, alcohol, perfume, dye • Broad antimicrobial spectrum • Wide compatibility with materials (various polymers (PMMA, PVC, PU...), various metals (stainless steel, aluminium, brass, ...), artificial leather, plastics, Corian • Volume size of 750 ml	• Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products • Council Directive 93/42/EEC concerning medical devices classe IIA	14476:2013+A2:2019 Groupe 1: disinfectants TP2 and TP4 EN 1040, 1327+A1 and EN 13697 antifungi EN 13697; 13624 anti virus
Type	**Minimum requirements**		
	Description/Features	**EU legislation**	**Reference standards**
Surfaces wipes disinfectant (Item M)	• Need to be biocide for surfaces disinfection and detergent in contact with food • To use in one step for disinfection of alcohol-sensitive surfaces, external structures of non-immersible and non-invasive medical equipment and devices • Does not contain CMR, alcohol; perfume, dye • Broad antimicrobial (incl MRSA), antiviral, antifungal (EN 16615) spectrum • Antimicrobial efficiency according to EN 13697 in 2 minutes • Wide compatibility with materials (various polymers (PMMA, PVC, PU,various metals (stainless steel, aluminium, brass, ...), artificial leather, plastics, Corian • Contains hydrogen peroxide minimum	• Groupe 1 – TP 2 et TP 4 – Directive 98/8/CE Medical disposal Classe IIa complies with the provisions of the public health code and the directive 93/42/CEE • Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	14476:2013+A2:2019 EN 16615 EN 13727, EN 13697

Type	Minimum requirements		
	Description/Features	**EU legislation**	**Reference standards**
	• 1g/100g or chlorure didecyldimethylammonium 3mg/gl • Useable at least one month after breaking the seal • 100% biodegradable • Reclosable cap • Minimum size of the wipe: 180x100 mm		

1.2 OTHER PRODUCTS (ITEM N)

During performance of the contract, the contracting authority may decide to buy additional products from the contractor's official catalogue. The catalogue can be on-line or paper-based. These items are not identifiable at the time of the drafting of the technical specifications. The maximum amount of those additional products shall not exceed 10% of the initial contract value. The type of additional products will be in line with the product range described in this document, including e.g.:

- personal protective equipment necessary to combat pandemics,
- safety, medical and para-medical products or equipment,
- etc.

Any item ordered as additional products will be invoiced at the price of the supplier's official catalogue, at the date of the order form is sent by the contracting authority, after deduction of the overall discount according to Annex A. Where the contractors in the cascade are not in a position to supply the additional products, the contracting authority reserves the right to purchase them from other suppliers.

2. DELIVERY

The supplies must be delivered to the EEAS premises – medical service offices located in Brussels under Incoterms DAP1. EEAS will communicate the exact modalities and location of delivery. The contractor must notify the contracting authority of the exact date and time of delivery, which cannot exceed 30 calendar days after the signature of the order form.

3. PACKAGING

Each packaging and labelling should bear the following information in English:

1. Product description
2. Name and/or trademark of the manufacturer
3. Manufacturer's product reference
4. Production lot reference
5. Date and place of production
6. Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol)
7. Number of units per packaging
8. Main product characteristics
9. Information for (particular) storage conditions, as appropriate

[1] Delivered At Place; Incoterms® 2020. These terms are for sale on the website https://iccwbo.org/resources-for-business/incoterms-rules/incoterms-2020/

10. Manufacturer's instructions for use

Medical masks (Item A), Filtering face piece respirators class 2 (FFP2 NR) and filtering masks FFP3 NR (Items B and C):): the contractor shall provide upon request (within five calendar days after the written request by the contracting authority) all certificates and/or declarations of conformity drawn up in English by an European official quality control institute/laboratory or an European agency of recognised competence attesting the conformity of the products clearly identified by references to technical specifications and standards. The certificates and/or declarations of conformity shall cover all production lot references.

The packaging should be made of recycled or plant origin materials.

4. ORDER MANAGEMENT

4.1. PRELIMINARY INQUIRY PRIOR TO PLACEMENT OF ORDERS

This point complements Article I.4.2 of the framework contract.

The contracting authority will place orders on an ad hoc basis, i.e. as needs arise.

Whenever the contracting authority wishes to order supplies, it sends the first contractor in the cascade a preliminary inquiry e-mail with the required supplies, the quantities, as well as the requested delivery time. Within five calendar days from the reception of the e-mail, the contractor replies to the contracting authority whether it can satisfy the request within the requested timeframe or whether it cannot satisfy the request.

If the contractor can entirely satisfy the request of the contracting authority within the requested delivery time, the contracting authority sends the contractor a specific contract or order form according to Article I.4.3 of the framework contract. The specific contract indicates, among other things, the description, quantity and price of supplies.

If the contractor cannot satisfy the request of the contracting authority, the latter contacts the next contractor in the cascade.

5. QUALITY CONTROL AND PRODUCT RECALL

Damaged packaging will be refused and returned to the contractor at its own expenses.

The contracting authority might decide to perform quality checks of the delivered products. Following those quality checks, the contracting authority might decide to recall the products that do not comply with the contract or for any other sound reason, and shall immediately notify the contractor in writing. Upon receipt of such notice, the contractor shall provide the instructions on how to proceed with the return of products and shall replace the defective products within reasonable delays mutually agreed by both parties. The contractor shall bear all the costs related to the return and replacement of the defective products.

All delivered items shall have at least two years expiration date from the delivery date, if applicable.

6. LANGUAGE

For the implementation of the Framework Contract and execution of the Order Forms, all communications shall be made in English.

7. POINTS OF CONTACT

Upon the signature of the contract one or several contact points shall be indicated by all parties, including full contact details, for the timely implementation of the contract. The contact points can be changed at any time by written notification to the.

8. CONTENT OF THE TENDER

The tenderers shall submit via the electronic submission system e-Submission the "Request to participate form" duly completed accompanied by all the information and documents listed in the form.

If any of the documents of the "technical tender" and "financial tender" is missing, the contracting authority shall not request it and will proceed to the evaluation exclusively on the basis of the submitted documents. No further documents or improvement of the content of the tender can be requested by the contracting authority.

In addition, the tenderers are required to submit at no cost to the Contracting Authority the following samples (in the original packaging) accompanied by the packaging and labelling information and the certificates and/or declarations of conformity as described under the section 3. Packaging. **The tenderers shall ensure that the certificates and/or declarations of conformity for the items A, B and C cover the references/lots of the samples/articles supplied.** Samples provided must be identical to those that would be supplied under the contract. Samples will not be sent back to the tenderers for hygienic reasons since the packages will be opened for the purpose of the technical evaluation.

List of samples:

- Six medical masks IIR (Item A);
- Six filtering face piece respirators class 2 (FFP2 NR) (Item B);
- Six filtering masks FFP3 NR (Item C);
- One face shield (Item D);
- Six gloves “normal one” for each size (S, M, L, XL) Items E
- Six gloves “Thicker one” for each size (S, M, L, XL) Items F
- Three gowns for each size (M, L, XL) (Item G);
- Three hand sanitizers travel size 50 ml (Items H)
- Three hand sanitizers travel size 75 ml (Items I)
- Three hand sanitizers travel size 100 ml (Items J)
- One hand sanitizer office-size dispenser (500 ml) (Item K) ;
- Surfaces disinfectant (1 bottle 750 ml) (Item L);
- Surfaces wipes disinfectant (1 box) (Item M).

The deadline for receipt of samples is indicated under Heading IV 2.2 of the contract notice.

You must use one of the following means of submission for the samples:

Means of submission	Time limit	Evidence of dispatch	Address for delivery
Post	**24:00**	Postmark	CALL FOR TENDERS

	(midnight)		**EEAS/2021/OP/0034** European External Action Service Division BA.BS.2, EEAS 05/P246 For the attention of Head of Division Avenue du Bourget 1 B-1140 Brussels (Evere), Belgium
Courier	**24:00 (midnight)**	Deposit slip of courier service	CALL FOR TENDERS **EEAS/2021/OP/0034** European External Action Service Division BA.BS.2, EEAS 05/P246 For the attention of Head of Division Avenue du Bourget 1 B-1140 Brussels (Evere), Belgium
In person (hand delivery)	**17:00 CET**	Proof of receipt, signed and dated by the official in the central mail department who takes delivery	

Mail can be received from 07.30 to 17.00 Mondays to Fridays. The service is closed on Saturdays, Sundays and official holidays of the EEAS in Brussels.

Annex 1 – Statement of compliance with the procurement documents

Statement of compliance with the procurement documents
EEAS/2021/OP/0034

[I] [We], ... , the undersigned, being the authorised legal representative[s] of *[to be completed with the name of the tenderer; for joint tenders, this must include all members]*, hereby declare that we have examined and accept without reserve or restriction all the terms and conditions set out in the invitation to tender, in the tender and technical specifications and in the draft contract for the tender procedure referred to above and, where appropriate, waive the tenderer's own general or specific terms and conditions. We offer to provide the services on the basis of our technical tender and our financial tender which do not diverge in any way from the requirements described in the procurement documents as drafted by the contracting authority. Our tender complies with all the technical requirements indicated in the tender and technical specifications.
We also undertake to respect these requirements scrupulously during the performance of the framework contract in case we become the awardee of the contract.

Name of tenderer:

Name of the legal representative of the tenderer:

Date: **Signature:**

NOTE: For joint tenders, this statement of compliance has to be signed by each member unless the leader is duly authorised to sign on behalf of each member by a power of attorney annexed to the tender.

Name of tenderer
Name of the legal representative of the tenderer:
Date: **Signature:**

Annex 2 – Technical tender

A description of the tender submitted. The tenderer will explain in detail their tender including detailing the tasks which will be performed by each member of a joint tender and each subcontractor whose share of the contract is higher than 10%.

Annex A – Financial tender
Unit price schedule in EUR <u>without VAT</u>

Item	Description	Type of Unit	Unit price in EUR per type of unit or percentage (for N Other Products)
1	**2**	**3**	
A	Medical masks IIR	Per piece	
B	Filtering face piece respirators class 2 (FFP2 NR)	Per piece	
C	Filtering masks FFP3 NR	Per piece	
D	Face shields	Per piece	
E	Examination gloves (S, M, L and XL)	Per piece	
F	Examination gloves (thicker ones) (S, M, L and XL)	Per piece	
G	Gowns (M, L and XL)	Per piece	
H	Hand sanitizers travel size – 50ml	Per piece	
I	Hand sanitizers travel size –75 ml	Per piece	
J	Hand sanitizers travel size –100 ml	Per piece	
K	Hand sanitizers (office-size dispenser 500ml with pump)	Per piece / 500 ml	
L	Surfaces disinfectant	Per bottle / 750 ml	
M	Surfaces wipes disinfectant	Per piece	
N	Other Products	Discount in %	

When filling in this/these table/s, tenderers shall fill in the unit prices for each item and will not modify, add or subtract any item. Failing this, their tender will be eliminated.

<u>Other products</u> (Item N): During the implementation of the contract, the amount for these additional other products cannot be higher than 10% of the estimated total value (230.000 EUR). These products are not identifiable at the moment of establishing the procurement documents. During the implementation of the contract, the contractor will invoice these products at the price of its official catalogue or, if the products are not available in its official catalogue, at the price of the supplier's official catalogue, at the date of the order form is sent by the contracting authority, after deduction of the overall discount according to Annex A.

Annex B – Financial tender
Price scenario over the duration of the contract in EUR <u>without VAT</u>

Item	Description	Estimated number of units over the maximum duration of the contract (4 years)	Unit price in EUR per type of unit	Total price in EUR
1	**2**	**3**	**4**	**5 = 3 x 4**
A	Medical masks IIR	1.500.000		
B	Filtering face piece respirators class 2 (FFP2 NR)	300.000		
C	Filtering masks FFP3 NR	1.000		
D	Face shields	10		
E	Examination gloves (S, M, L and XL)	90.000		
F	Examination gloves (thicker ones) (S, M, L and XL)	23.000		
G	Gowns (M, L and XL)	4.000		
H	Hand sanitizers travel size – 50ml	10.000		
I	Hand sanitizers travel size –75 ml	10.000		
J	Hand sanitizers travel size –100 ml	10.000		
K	Hand sanitizers (office-size dispenser 500ml with pump)	1.000		
L	Surfaces disinfectant	1.000		
M	Surfaces wipes disinfectant	57.000		
N	Other Products			230.000
TOTAL (sum of total prices for all items)				

When filling in this table, tenderers shall fill in in column 3 the same unit prices as tendered for in Annex A – Financial tender. Tenderers will carefully calculate the total in column 5. They will do so for each item, they will not add, suppress or modify any item. Failing this, their tender will be eliminated.

NOTE: For joint tenders, this annex has to be signed by each member unless the leader is duly authorised to sign on behalf of each member by a power of attorney annexed to the tender.

Name of tenderer:

Name of the legal representative of the tenderer:

Date: **Signature:**