

Procuring organization

Karolinska Universitetssjukhuset
Inger Malmgren

Procurement

Digital health platform
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Legend

 The text is included in the advert	 The text is included in the qualification
 The text will be part of the contract	 The text will be published in the contract catalogue
 The text/question contains requirements to be met	 The text/question contains ESPD requirements
 The question is weighted and included in the evaluation	 The question is weighted and included in the evaluation
 The question is asked for information only	 The question is answered by the buyer
 The question is marked for special follow-up	 Updated section or question

1. Invitation

1.1 Procurement authority

Procurement authority is Karolinska University Hospital (Karolinska) within Region Stockholm (RS), Corporate Identity number: 232100-0016.

Karolinska Universitetssjukhuset is one of Europe's largest hospitals and together with Karolinska Institutet we lead medical development in Sweden. The hospital has approx. 1 340 hospital beds, produces approx. 97,000 care episodes per year, has approx. 1.6 million patient visits per year, turnover approx. 18 billion per year and has approx. 16,000 employees. For us, healthcare research and training are equally important parts in the effort to extend and improve people's lives.

For further information on Karolinska Universitetssjukhuset, see www.karolinska.se

1.2 Coordinated procurement

The procurement is carried out as a coordinated procurement. The procurement authority is Karolinska University Hospital (Karolinska) within Region Stockholm (RS). Corporate Identity Number 232100-0016.

Karolinska makes award decisions and signs framework agreements on behalf of the following authorities, which are entitled to make call-off from the contracted framework agreements:

- Södersjukhuset AB (SÖS), org.nr 556595-7403
- Södertälje sjukhus AB, org.nr 556775-9922
- Danderyd Sjukhus AB (DS, org.nr 556575-6169
- Tiohundra AB, org.nr 556595-7395
- St Eriks Ögonsjukhus, org.nr 556574-3589
- Ambulanssjukvården i Storstockholm AB (AISAB), org.nr 556461-6695
- Region Gotland, org.nr 212000-0803
- Hälso- och sjukvårdsförvaltningen (HSF), org.nr 232100-0016
- Stockholms läns sjukvårdsområde (SLSO, org.nr 232100-0016

The term "Karolinska" thus covers Karolinska University Hospital including the above-mentioned authorities.

1.3 Timetable

Activity	Timing
1. Deadline for submitting a request to participate	Oktober 2023
2. Sending invitations to submit tender to selected tender-candidates.	November 2023
3. Evaluation of tenders	December 2023
4. Sending the Award Decision	January 2024
5. Framework start	February 2024

1.4 Procurement procedure

The procurement is carried out as a restricted procedure in accordance with the Public Procurement Act (2016:1145). A restricted procedure means that all suppliers can apply to participate in the procurement procedure. The candidates who meet the requirements, based on the exclusion grounds and qualification requirements, proceed further to the selection stage. Selection criteria are used to limit the number of candidates invited to submit tenders within each tender area (see section 2.11).

1.5 Framework agreement period

Framework agreement period is 2+1+1 years.

Estimated start of contract is 2024-02-01.

1.6 Questions and response during the application period

Questions regarding the request to participate are sent via www.tendsign.com under the title "Questions and responses" in the current procurement. Questions must clearly state which section, appendix or requirement is referred to.

Responses to received questions and other information regarding the request to participate in the procurement is available to registered companies via TendSign. Tender-Candidates are responsible for all information published in this way within the time limit to submit request to participate in the procurement.

1.7 List of requests to participate

The list of requests to participate in the procurement Digital Health Platform contains the following documents:

- Invitation (this document)
- Qualification requirements

APPENDICES

- Appendix 1 Truth affirmation
- Appendix 2 Area description
- Appendix 3 Reference template
- Appendix 4 Karolinska's IT landscape
- Appendix 5 Consultancy experience matrix

The invitation contains general information about the Procurement, including the requirements stated for tender candidates. In response to this invitation, the Candidates submit Request to participate in the procurement.

1.8 Invitation to request to participate in the procurement

Karolinska search for Suppliers who together with their partners and subcontractors provide open EHR-based technologies and services. Karolinska invites Candidates to submit request to participate for the Digital Health Platform procurement.

The procurement is carried out as a restricted procedure. The request to participate is divided into following areas:

1. Open EHR- based Software

The tender area includes following parts:

- 1a. Software for storage and management of open EHR- based data
- 1b. Software for fine-grained access control
- 1c. Software for fast development, publication and maintenance of open EHR-based applications
- 1d. Software Services

Within area 1, 5-8 Candidates will be invited to submit tender.

2. Software for openEHR content Creation and Transformation

Within area 2, 12-15 Candidates will be invited to submit tender.

3. Consulting Services

Within area 3, 12-15 Candidates will be invited to submit tender.

Tender-Candidates shall state the area(s) offered. Each area (1-3) will be evaluated separately. The request to participate in the procurement can be submitted in one, several or all areas.

For more information regarding respective tender area, *see appendix 2 Area description.*

State the tender areas (1-3) that you are applying to submit a request to participate within.

General requir...



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 Supplier comment allowed

1.9 Requirement for requests to participate



Candidates shall base their request to participate on the conditions and requirements set out in the advertisement and the List of the request to participate (section 1.8).

1.10 Compensation



Compensation is not awarded for submitting a request of participate in the procurement.

1.11 Submission of requests to participate



Requests to participate must be submitted electronically via TendSign. It is not possible to submit requests to participate by other means (e.g. by fax or e-mail) because confidentiality cannot be ensured.

Request to participate in the procurement must reach Karolinska no later than final request date 10/12/2023 11:59 PM. Documents received later than this will not be considered. Candidates are responsible for ensuring that the documents are delivered to Karolinska within the prescribed time.

1.12 Opening the request to participate



Opening of the requests to participate in procurement takes place on the 13th of October 2023 at Karolinska, Solna.

Opening of the request to participate is not public. If Candidates so desire, a representative appointed by the Stockholm Chamber of Commerce may be present at the opening meeting at the expense of the Tender-Candidate.

1.13 Examination (Prequalification)



After opening of the request to participate in the procurement (step 1), prequalification is carried out according to the following steps:

1. Karolinska verifies that the formal requirements are fulfilled.
2. Karolinska verifies that the request to participate fulfills stated requirements regarding exclusion and qualification.
3. Finally, selection is made from the tender-candidates within each tender area. Karolinska will select the candidates invited to submit tenders using selection criteria. For more information (see 2.12).

1.14 Estimated contract value



The total estimated contract value for the procurement is 153 600 000 SEK. The estimated contract value has the following breakdown:

1. OpenEHR -based software: Estimated contract value: 99 980 000 SEK.
2. Software for openEHR content creation and transformation. Estimated contract value: 26 410 000 SEK.
3. Consulting services. Estimated contract value: 27 210 000 SEK

Please note that the above break down is an estimate. The final contract volume may differ from the volume estimated above.

1.15 Definitioner



The following terms have the following meaning in the procurement documents:

- **Candidate(s):** Refers to the supplier(s) submitting a request to participate in the procurement.
- **Category/tender area:** are supposed to be interpreted as synonymous terms
- **List of request to participate:** Refers to this document including the documents listed in section 1.7.
- **Framework agreement:** Refers to an agreement concluded between one or more contracting authorities such as Karolinska University Hospital and one or more suppliers in order to determine the terms and conditions for subsequent award of contracts (in case of call-off or reopening of competition) during a given period of time.
- **LOU:** Refers to Swedish Public Procurement Act
- **Responsible contracting authority:** Karolinska University Hospital
- **Request to participate:** Refers to submitted request to participate in the procurement.
- **Shall/must:** are supposed to be interpreted as synonymous terms

- **Subject-matter of the contract:** Refers to the Digital Health Platform, including software and services
- **Supplier:** Refers to Software and Service Provider.

2. Qualification requirement

2.1 ESPD

Please note that the ESPD-form may not be completed if the questions below are answered.

2.2 Grounds for exclusion



Candidates will be excluded from participation in the procurement if circumstances in Chapter 13, Section 1 LOU, exist.

Candidates will be excluded from the procurement in accordance with Chapter 13, Section 2 LOU, if they have not fulfilled their obligations regarding the payment of taxes or social security contributions in Sweden or in their home country, if the company is registered in another country.

Candidates may be excluded from the Procurement in accordance with Chapter 13, Section 3 LOU, if Karolinska becomes aware of the existence of maladministration in relation to the Tender-candidate activities. Examples of such maladministration may be that the Candidate has breached applicable environmental, social or labor obligations, is the subject of insolvency proceedings, has committed serious professional misconduct or has failed in previous public contracts.

Information regarding the Candidates' performance of their obligations regarding the payment of taxes or social security contributions will be obtained by Karolinska. In the event that it is not possible for Karolinska to obtain such information, the Candidate shall, at Karolinska's request, submit a certificate issued by the competent authority of the State concerned containing current information.

a. Are the above requirements met?

Yes/No. **Yes is required**

General requir...



b. The Candidate shall attach the truth affirmation to the request to participate.

Attachment

General requir...



c. If applicable, please attach a statements showing that there are not grounds for exclusion under Chapter 13, Section 5 of the LOU.

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 Supplier comment allowed

General requir...



2.3 Company registration



Candidates and any Contractors whose capacity the Candidates relies must be registered with Swedish Companies Registration Office or an equivalent authority in the country of origin. The Candidate must be duly registered for VAT and hold an F-tax certificate or equivalent Swedish Tax Agency. For foreign candidates, the corresponding proof must be attached to the request to participate. This proof shall not be older than three months from final request date to participate. Candidates must submit evidence in the form of current and valid certificates, or equivalent documents of company registration and tax registration issued in the country of origin.

a. Are the above requirements met?

Yes/No. Yes is required

General requir...



Yearly

b. Foreign Candidates shall attach the corresponding evidence.

Attachment

General requir...



2.4 Economic and financial position



Candidates must have a stable financial position sufficient to implement the contractual commitment. Candidates must have at least a credit rating: A (Bisnode), 50 (Creditsafe), 3 (UC) or equivalent according to another reputable and commonly known credit rating agency. The above shall be maintained for the entire duration of the Agreement.

In the event that a lower rating is shown, the Candidate shall nevertheless be deemed to meet this requirement if the Candidate provides such a declaration that it can be considered clear that the Candidate possesses equivalent financial stability. It is the responsibility of the Candidate to remain informed as to whether it is necessary to provide an explanation.

Candidates wishing to rely on the financial and economic capacity of others must state this in their request to participate in the procurement.

Candidates shall attach, proof of compliance with the above requirements, certificates from a credit market institution, dated within 3 months before the final request date to participate in the procurement.

a. Is the requirement of financial and economic standing accepted?

Yes/No. Yes is required

General requir...



Yearly

b. Attach a certificate from a credit reference agencies, dated within 3 months before the final request date to participate in the procurement.

Attachment

General requir...



Yearly



c. At a lower rating than: A (Bisnode), 50 (Creditsafe), 3 (UC) or equivalent, an explanation shall be provided regarding how the requirement of financial standing is met by the parent company, guarantor.

General requir...



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2.5 Quality Management System



Tender-candidates must apply procedures to ensure that the company works with continuous improvements to meet customer and legal requirements.

Candidates must attach to the request to participate:

- Certificate of ISO 9001 certification or other equivalent Quality Management System.

Or

A description of its Quality Management System applied by the company, containing the following information:

- Quality policy
- Systematic improvement work
- Routine for documentation, audits and follow-up
- Non-conformity management routine

Certificates or other documentation shall be valid at the final request date.

a. Are the requirements for Quality Management System met?

General requir...



Yearly

Yes/No. Yes is required

Supplier comment allowed

b. Candidate shall as a proof attach Certificates or provide information regarding its own Quality Management System.

General requir...



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2.6 Environmental Management System



Candidates must carry out documented systematic environmental work in their day-to-day operations throughout the contract period. Environmental work shall be carried out with the support of tools and procedures that make it possible to follow up and measure the results achieved against set environmental objectives.

Candidates shall attach:

- Certificate of ISO 14001 certification or other equivalent Environmental Management

System.

Or

A description of its Environmental Management System, containing the following information:

- Environmental policy
- Environmental objectives
- Routine for monitoring environmental work
- Deviation management around sustainability and procedures to correct deviations.

Certificates or other documentation shall be valid at the final request date.

a. Are the requirements met?

Yes/No. **Yes is required**

Digital health p...



b. Candidates shall as a proof attach Certificates or information about its own Environmental Management System.

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General requir...



2.7 Company description



Candidates shall possess and demonstrate that they have documented resources, skills and experience to carry out the requested assignment. Provide a brief description of the company including:

- Business concept and operations
- Organisation and management
- Overview of skills/structure e.g. (technical and professional capacity)

The Candidate shall provide a description of the company.

Attachment

Supplier comment allowed

General requir...



2.8 Systematic Security Work



Candidates must carry out documented Information Security Management System e.g. ISO 27001 for the activities covered by the request to participate.

Candidates must attach:

- Certificate of ISO/IEC 27001 certification or other equivalent Information Security Management System. The certificate shall be valid at the final request date to participate.

Or

A description of its own Information Security Management System containing at least the following information:

- Policies for Information Security, including:
 - Information Security Management
 - Roles and Responsibilities
 - Reporting pathways
 - Process and methodology for measuring and monitoring information security work
 - How information security is integrated with other activities
 - Management and reporting of discrepancies and incidents

Certificates or other documentation shall be valid at the final request date to participate.

a. Are the requirements met?

Yes/No. **Yes is required**

General requir...



b. The Candidate shall attach certificates or provide information regarding its own Security Management System.

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Supplier comment allowed

General requir...



2.9 TECHNICAL AND PROFESSIONAL CAPACITY

As described in “Appendix 2: Area description”, the scope of the procurement is divided into three separate categories. Respond to all questions belonging to the category or categories you intend to offer solutions/services in.

2.9.1 Area 1: OpenEHR- based Software (I)



If Area 1 is applicable, please attach the requested information for Area 1: OpenEHR-based software.

The Candidate (possibly via subcontractors) **must** show that solutions and services in all four sub-categories 1a, 1b, 1c and 1d already have been delivered to existing customers.

Regarding 1c, the following functions **must** be used by some customers:

- form authoring based on openEHR templates
- form rendering
- AQL query execution
- Basic AQL query response viewing
- Basic form of portal.

Regarding 1d the supplier **must** show that they have provided Software services to customers.

The recommendation is that the description does not exceed 2000 characters and is a PDF-

document maximum two A4-pages long (including pictures, if any), use font size 11.

a. Indicate if the requirements for Area 1 are not applicable to your response.

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Supplier comment allowed

b. If section 2.9.1 is applicable, please attach the evidence referred to above.

General requir...



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Supplier comment allowed

2.9.2 Area 1: OpenEHR- based Software (II)



The Solution offered for Category 1a, 1b and 1c **must** be possible to deploy in Karolinska's environment described in the document, see 'Appendix 4 Karolinskas IT-landscape'. The provider **must** be able to deliver the solution in a way that can be hosted and managed in Karolinskas datacenters by Karolinska IT-Staff.

The Candidate **must**:

- Briefly describe the offered Solution and required third party software dependencies.
- Briefly describe how the Solution is delivered and installed/operated.
- Briefly describe how these services will be provided (upgrades, updates, installation, configuration, and implementation services, acceptance and performance testing services, services for operations in our IT-environment)

The recommendation is that the description does not exceed 2000 characters and is a PDF-document maximum two A4-pages long (including pictures, if any), use font size 11.

Please attach the evidence referred to above.

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Supplier comment allowed

2.9.3 Area 1: OpenEHR- based Software (III)



The Candidate or at least the main CDR subcontractor **must** be an openEHR Industry partner listed at https://openehr.org/community/industry_partners/ by the final submission date of this request.

The website listing will be used as evaluation pass/fail criteria. It is thus important that main contractors not yet listed there have declared what main CDR subcontractors they use. Describe what name you and/or your subcontractor is listed by on that web page.

The recommendation is that the description does not exceed 500 characters and is a PDF-

document maximum one A4-pages long (including pictures, if any), use font size 11.

Please attach the evidence referred to above.

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Supplier comment allowed

2.9.4 Area 1: OpenEHR- based Software (IV)



The Candidate **must** have transparent development processes and be able to help Karolinska fulfil CE and relevant MDR or IVDR requirements for solutions that will be developed based on the CDR and associated functions and tools.

Describe your experience of the process to CE label a software as a medical device.

The recommendation is that the description does not exceed 2000 characters and is a PDF-document maximum two A4-pages long (including pictures, if any), use font size 11.

Please attach the evidence referred to above.

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Attachment



Supplier comment allowed

2.9.5 Area 2: Software for openEHR content Creation and Transformation



If Area 2 is applicable, please attach the requested information for Area 2: Software for openEHR content Creation and Transformation.

The Candidate **must** offer tools that can be used to perform tasks related to the core components of the envisaged ecosystem described in the request to participate, see 'Appendix 2 Area description'. This includes tools, SDKs (Software development Kits) and other utilities specifically intended to work with openEHR, SNOMED CT or HL7 FHIR.

The Candidate **must** provide access to support for the supplied software (tools, utilities etc).

- Briefly list and describe the software product(s) that the candidate can offer in the described EHR-ecosystem.

The recommendation is that the description does not exceed 2000 characters and is a PDF-document maximum two A4-pages long (including pictures, if any), use font size 11.

a. Indicate if the requirement for Area 2 are not applicable to your response.

General requir...



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Supplier comment allowed

b. If Area 2 is applicable, please attach the description(s) of software product(s) offered.

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2.9.6 Area 3: Consulting Services



If Area 3 is applicable, please attach the requested information for Category 3: Consulting Services.

The Candidate/Consulting Services Provider **must** show that the Candidate has access to at least one expert that is or have been, actively engaged in the development, maintenance, core community of openEHR and/or SNOMED CT.

This is done by:

1. Filling out and uploading examples of experiences in the "Consultant experience matrix" spreadsheet in 'Appendix 5 Consultancy experience matrix'. (Please note that this file is used twice and that column E and F in the matrix can provide extra points in another requirement regarding research experience, see 2.11.6)
2. Upload a PDF file collecting proof of the things referred to in the spreadsheet 'Appendix 5 Consultancy experience matrix' (where you find further instructions).

Note: It is important that the named example consultants from the spreadsheet can be found in the supplied proof (the PDF) of openEHR or SNOMED CT experiences.

a. Indicate if the requirements for Area 3 are not applicable to your response.

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b. Please attach appendix 5 Consultancy experience matrix,

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Supplier comment allowed

c. Please attach the evidence (PDF with screenshots etc.) referred to above.

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Supplier comment allowed

2.9.7 Requirement/question removed



Requirement/question removed.

Requirement/question removed

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Supplier comment allowed

2.9.8 Candidates reliance on the capacity of other companies.

Candidates/Supplier have the possibility to rely on the capacity of other companies to satisfy requirements relating to economic and financial standing requirements (section 2.3) and technical and professional capacity. The candidate may only rely on the capacity of another company if that company will also perform the services or works for which this capacity is needed.

This presupposes that such an undertaking **must** be included in the request to participate together with an indication of the capacity invoked.

Please attach a list of invoked capacities and their roles for the performance of the framework agreement.

Please note, that if the capacity of another company, including the capacity of another group or associate is invoked the Candidate/Tenderer, in step 2 (next procurement step), **shall** attach a binding agreement, or a written unilateral commitment or other legal commitment (signed by the authorised representative of the invoked entity), demonstrating that the Company **will** have the invoked capacity for the performance of the framework agreement.

A letter of intent or other non-binding declaration of **will** is not sufficient to prove that the Tender-Candidate has the capacity of another.

Please attach the requested information for selected tender area(s) below.

2.9.8.1 Area 1: OpenEHR- based software

If the capacity of another company, including the capacity of another group or associate is invoked, the Candidate **shall** attach a list of invoked capacity and its role.

If applicable, please attach relevant documentation as required above.

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Attachment

Supplier comment allowed

2.9.8.2 Area 2: Software for openEHR content Creation and Transformation

If the capacity of another company, including the capacity of another group or associate is invoked, the Candidate **shall** attach a list of invoked capacity and its role.

If applicable, please attach relevant documentation as required above.

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Attachment



Supplier comment allowed

2.9.8.3 Area 3: Consulting Services

If the capacity of another company, including the capacity of another group or associate is invoked, the Candidate **shall** attach a list of invoked capacity and its role.

If applicable, please attach relevant documentation as required above.

Digital health p...



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Supplier comment allowed

2.10 Experience with similar assignments

In order to ensure that the Candidates/Suppliers have the technical and professional capacity, the Candidate **shall** be able to demonstrate, on the basis of reference assignments, experience of delivering assignments in the selected tender area(s).

- Area 1: openEHR-based Software - Subcategory 1a: Software for storing and managing open EHR-based data
- Area 1: openEHR-based Software - Subcategory 1b: Software for fine-grained access control
- Area 3: Consulting Services

Verification of the reference assignments is to ensure that candidates have the capacity and skills to deliver within selected tender area(s) during the contract period. The reference assignments **shall** include functionalities that are in operation no later than at the final request date to participate.

The information requested regarding subcategories 1a and 1b of Area 1 **shall** be provided in accordance with *Appendix 3, Reference template*. Candidates **must** complete and attach a reference template per reference assignment.

Karolinska intends to contact the Reference person specified in appendix 3 Reference template to check the completed assignment(s).

If candidates perform or have performed assignments for Karolinska in the past, according to the above description, Karolinska may obtain their own reference instead of the candidate's specified reference.

2.10.1 Area 1: OpenEHR-based Software - Subcategory 1a

If "tender area 1: OpenEHR-based Software" is applicable, please attach the below requested information regarding subcategory 1a.

With reference to Subcategory **1a** and the description of using openEHR to manage clinical data, describe relevant reference assignments where you implemented and integrated an openEHR-based CDR together with a Patient Master Index (PMI) or similar functionality.

The Candidate **shall** provide reference assignment in the following perspectives:

- Describe the delivered Solution with regards to tech stack, architecture, technical dependencies etc.
- Describe the delivered Solution with regards to requirements of high availability including e.g. failover, backup and restore routines
- Describe the challenges and the complexity of the project/delivered Solution
- Describe known discrepancies of the Solution with regards to the OpenEHR Specification.
- Describe how the Solution is handled with regards to life cycle management and acceptance testing in the customer environment.

The reference assignment **must** be chosen/relevant according to the following aspects:

- Status: deployed and still in clinical use in a customer installation.
- Size of customer and system: at least one of the reference cases must have at least 100 users of the openEHR CDR containing data for at least 5000 patients.

The recommendation is that the description does not exceed 2000 characters and is a PDF-document maximum two A4-pages long (including pictures, if any), use font size 11.

Candidates **shall** attach at least one (1), maximum two (2) reference assignments within subcategories 1a.

a. If applicable, indicate if the Candidate met the mandatory requirements above.

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Yes/No



Supplier comment allowed

b. The Candidate shall attach "Appendix 3: Reference templates" regarding subcategory 1a.

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Supplier comment allowed

2.10.2 Area 1: OpenEHR-based Software - Subcategory 1b:



If "tender area 1: OpenEHR-based Software - Subcategory 1": Software for fine-grained access control is applicable, please attach requested information:

With reference to subcategory **1b** and the description of the functionality for implementing fine-grained Access Control in the solution. The Candidate **shall** describe relevant reference assignment within the area of identity and access management (IAM) where you have used fine-grained attribute and/or role based access control (ABAC/RBAC) at scale.

The Candidate **shall** provide reference assignment in the following perspectives:

- Briefly describe the technical solution
- Describe the challenges and the complexity of the project/delivered solution
- Explain project/customer according to the aspects below (status, size of org, type of business)
- Explain any partners and/or sub-contractors involved in the project.

The reference assignment **shall** be chosen/relevant according to the following aspects:

- Status: deployed/in use in a customer installation at the final request date to participate.
- Size of organization: at least 1 000 employees and ten organizational sub-units
- Type of business: legally regulated business and/or high demands on the handling of sensitive data and preserving personal privacy. Reference cases in the healthcare business are of great interest but not a requirement.

The recommendation is that the description does not exceed 2000 characters and is a PDF-document maximum two A4-pages long (including pictures, if any), use font size 11.

Candidates **shall** attach at least one (1), maximum two (2) reference assignments within subcategories 1b.

a. If applicable, indicate if the Candidate met the mandatory requirements above.

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Yes/No



Supplier comment allowed

b. The Candidate shall attach appendix 3: Reference templates regarding subcategory 1b.

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Supplier comment allowed

2.10.3 Area 3: Consulting Services



If "Category 3: Consulting Services" is applicable, then please attach requested information:

The Candidate **must**:

-Provide a description, briefly describing some previous assignments that, when added together, prove the consulting experience requested in this procurement.

- Prove that the Candidate or it's subcontractors have performed substantial openEHR and/or SNOMED CT work relevant to the procurement.

- Describe if and how other standards and/or ontologies asked for in this procurement were used in the assignments.

Please note that breadth and depth of proven experience is more interesting than number of described assignments.

The recommendation is that the description does not exceed 2000 characters and is a PDF-document maximum two A4-pages long (including pictures, if any), use font size 11.

a. If applicable, indicate if the Candidate met the mandatory requirements above.

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Yes/No



Supplier comment allowed

b. The Candidate shall attach the above requested assignment description document.

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Attachment



Supplier comment allowed

2.11 Tender selection criteria



In the event that more candidates meet the exclusion and qualification requirements set than the number of candidates invited to submit tenders in each tender area (1-3), Karolinska will select the candidates invited to submit tenders using selection criteria.

Tender selection criteria area 1

If more than eight Request to participate meet the requirements for exclusion and qualification, Karolinska will select eight (8) Candidates to proceed to step 2 Tendering. Decisions are based on the selection criteria below (2.11.1-2.11.3). If there are insufficient number of Candidates that meet the set of qualification requirements, Karolinska can proceed with the procurement with fewer Candidates.

Tender selection criteria area 2

If more than fifteen Request to participate meet the requirements for exclusion and qualification, Karolinska will select fifteen (15) Candidates to proceed to step 2 Tendering. Decisions are based on the selection criteria below (2.11.4). If there are insufficient number of Candidates that meet the set qualification requirements, Karolinska can proceed with the procurement with fewer Candidates.

Tender selection criteria area 3

In the event that more than fifteen Request to participate meet the requirements for exclusion and qualification, Karolinska will select fifteen (15) Candidates to proceed to step 2 Tendering. Decisions are based on the selection criteria below (2.11.5-2.11.7). If there are insufficient number of Candidates that meet the set qualification requirements, Karolinska can proceed with the procurement with fewer Candidates.

2.11.1 Area 1: OpenEHR- based Software (Selection Criteria) I

Karolinska value systems that have been deployed at scale in many places and running for some years. Briefly list some of your largest installations:

- where they are installed and
- how long they have been running and used with real patient data, and
- how many employees, users and patients there are at the described installation sites

Points will be based on the sum of levels on two scales, A and B.

Scale A, based on customers diversity for referenced systems above the minimum size criteria (1 000 employees + 100 users + 5000 patients), is:

3p = 5 references from at least three different countries;

2p = 4 references from at least two different countries or different national subregions;

1p = at least 3 references.

Scale B based on big systems of Region Stockholm's size:

2p = at least two of the referenced deployed systems has handled at least 2 million (real) patient's records during at least two years;

1p = at least one of the referenced deployed systems has handled at least 2 million (real) patient's during at least one year;

(Maximum 5 points total)

The recommendation is that the description does not exceed 2000 characters and is a PDF-document maximum two A4-pages long (including pictures, if any), use font size 11.

If applicable, please attach relevant documentation to the selection criteria above.

Attachment

Digital health p...



2.11.2 Area 1: OpenEHR- based Software (Selection Criteria) II

The Solution offered for Category 1a, 1b and 1c should be possible to deliver as Software as a service (SaaS) with full life cycle management .

Describe briefly how SaaS is delivered and your previous experience of this.

1 point is awarded if the Candidate can deliver the solution as Saas (Software as a Service) within EU/ESS as a future option.

The recommendation is that the description does not exceed 1000 characters and is a PDF-document maximum one A4-pages long (including pictures, if any), use font size 11.

If applicable, please attach relevant documentation to the selection criteria above.

Digital health p...



Attachment

2.11.3 Area 1: OpenEHR- based Software (Selection Criteria) III



The Solution offered for Category 1a, 1b and 1c should be possible to deliver co-hosted in Karolinskas data centers by the Candidate with full life cycle management .

Describe briefly how co-hosting is delivered and your previous experience of this.

1 point is awarded if the provider can, as an alternative, deliver full life cycle management in Karolinskas or other of Region Stockholm's data centers.

The recommendation is that the description does not exceed 1000 characters and is a PDF-document maximum one A4-pages long (including pictures, if any), use font size 11.

If applicable, please attach relevant documentation to the selection criteria above.

Digital health p...



Attachment

2.11.4 Area 2: Software for openEHR content Creation and Transformation



Karolinska value software that has been deployed and used in practice in different contexts.

If the offered products have been used by existing customers of the contractor (or of its subcontractors) for openEHR-, SNOMED CT- or HL7 FHIR-related work, extra points will be rewarded.

Briefly describe the number of customers and exemplify diversity in usage by listing some customers that are using the product(s) in different contexts and regions, include list of customers and specify which products have been used, for what kind of work.

Points will be awarded based on diversity for products that have been used with openEHR, SNOMED CT or HL7 FHIR by different customers:

2p = 3 or more customers and from at least two different countries; or

1p = At least 2 customers

1p= If at least one of the tools/SDKs/utilities is clearly described as having been used for working with openEHR.

1p= If at least one of the tools/SDKs/utilities is clearly described as having been used for working with SNOMED CT.

1p= If at least one of the tools/SDKs/utilities is clearly described as having been used for working with HL7 FHIR.

(Maximum 5 points total)

The recommendation is that the description does not exceed 2500 characters and is a PDF-document maximum three A4-pages long (including pictures, if any), use font size 11.

If applicable, please attach relevant documentation to the selection criteria above.

Attachment

Digital health p...



2.11.5 Area 3: Consulting Services Selection criteria I



The Candidate/Consulting Services Provider should be able to provide access to **integration** (software) development skills regarding other integration standards for healthcare, at least within one of the following areas:

- HL7 FHIR
- Other HL7 or IHE standards
- Laboratory medicine standards and ontologies (preferably including bioinformatics/(gen)omics)
- Imaging or image reporting standards

Based on content in the previously (in 2.10.3) attached assignment description document, points will be awarded:

2p= If experienced consultants available within 2 or more areas or;

1p= If experienced consultants available within 1 area.

1p= If the document clearly describes that any of the above listed areas of integration development was done for data flows going to or from an openEHR system.

(Maximum 3 points total)

2.11.6 Area 3: Consulting Services Selection criteria II



The Candidate/Consulting Services Provider should be able to provide access to some **informatic modeling** skills regarding other integration standards for healthcare, at least within one of the following areas:

- HL7 FHIR
- Other HL7 or IHE standards
- Laboratory medicine standards and ontologies (preferably including bioinformatics/(gen)omics)
- Imaging or image reporting standards

Based on content in the previously (in 2.10.3) attached assignment description document, points will be awarded for:

2p= experienced consultants available within 2 or more areas, or;

1p=experienced consultants available within 1 area

1p= If the document clearly describes that any of the assignments contained substantial

work regarding bioinformatics/(gen)omics,

(Maximum 3 points)

2.11.7 Area 3: Consulting Services Selection criteria III



The Candidate/Consulting Services Provider should be able to have access to research experience regarding openEHR or SNOMED CT or both.

The scientific publications listed in column E & F in 'Appendix 5 Consultancy experience matrix' will be used as criteria to determine if scientific experience relevant to the procurement is available.

Points will be awarded to Candidates that can provide consultants with relevant research experience:

1p regarding openEHR and

1p regarding SNOMED CT.

(Maximum 2p)

2.12 Sanctions against Russia and Belarus



As a contracting authority, Karolinska follows and applies from time to time the EU's decided sanctions against Russia and Belarus.

In accordance with Council Regulation (EU) 2022/576 of 8 April 2022 amending Regulation (EU) no 833/2014 on restrictive measures against the background of Russia's measures that destabilize the situation in Ukraine, Karolinska is prohibited from awarding the contract to which this procurement relates, or in relation to:

- a) Russian and Belarusian citizens or natural or legal persons, entities or bodies established in Russia,
- b) legal persons, entities or bodies whose ownership rights to more than 50 percent directly or indirectly is owned by an entity referred to in point a above, or
- c) natural or legal persons, entities or bodies acting for, or on behalf of, an entity as referred to in point a or b above. What is stated in point c above also includes, provided that they account for more than 10 percent of the value of the contract to which this procurement refers, subcontractors/subcontractors/subconsultants, suppliers/contractors/consultants, or companies or other entities whose capacity is invoked to meet the requirements of economic and financial standing or technical and professional capacity as set forth in this procurement.

If the certification cannot be submitted or is incorrect, the request to participate shall be rejected.

By ticking the relevant box, the Candidate shall certify that Karolinska has the right, taking into account the sanctions decided by the EU, to award a contract to Candidate companies.

General requir...



Yes/No. Yes is required



Supplier comment allowed

3. European Single Procurement Document (ESPD)

Part I: Information concerning the procurement procedure and the contracting authority or contracting entity

Part II: Information concerning the economic operator

Part III: Exclusion grounds

A: Grounds relating to criminal convictions

Article 57(1) of Directive 2014/24/EU sets out the following reasons for exclusion

Participation in a criminal organisation



Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgment for participation in a criminal organisation, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? As defined in Article 2 of Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime (OJ L 300, 11.11.2008, p. 42).

a. Your answer?

Yes/No. No is required

Supplier comment allowed

ESPD templat...



b. Is this information available at no cost to the authorities from an EU Member State database?

Yes/No. No is desired

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a. Date of conviction

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b. Reason

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c. Who has been convicted

Text field

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d. Length of the period of exclusion

Text field

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**e. Have you taken measures to demonstrate your reliability ("Self-Cleaning")**

Yes/No

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**Please describe them**

Text field

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**b. Reference/Code**

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**c. Issuer**

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**Corruption**

Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgment for corruption, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? As defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, OJ C 195, 25.6.1997, p. 1, and in Article 2(1) of Council Framework Decision 2003/568/JHA of 22 July 2003 on combating corruption in the private sector (OJ L 192, 31.7.2003, p. 54). This exclusion ground also includes corruption as defined in the national law of the contracting authority (contracting entity) or the economic operator. "

a. Your answer?

Yes/No. No is required

Supplier comment allowed

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**b. Is this information available at no cost to the authorities from an EU Member State database?**

Yes/No. No is desired

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a. Date of conviction

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**b. Reason**

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**c. Who has been convicted**

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**d. Length of the period of exclusion**

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**e. Have you taken measures to demonstrate your reliability ("Self-Cleaning")**

Yes/No

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**Please describe them**

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**a. URL**

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**b. Reference/Code**

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**c. Issuer**

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**Fraud**

Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgment for fraud, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? Within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests (OJ C 316, 27.11.1995, p. 48).

a. Your answer?Yes/No. **No is required** Supplier comment allowed

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**b. Is this information available at no cost to the authorities from an EU Member State database?**Yes/No. **No is desired**

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**a. Date of conviction**

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**b. Reason**

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**c. Who has been convicted**

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**d. Length of the period of exclusion**

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**e. Have you taken measures to demonstrate your reliability ("Self-Cleaning")**

Yes/No

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**Please describe them**

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***Terrorist offences or offences linked to terrorist activities***

ESPD



Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgment for terrorist offences or offences linked to terrorist activities, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? As defined in Articles 1 and 3 of Council Framework Decision of 13 June 2002 on combating terrorism (OJ L 164, 22.6.2002, p. 3). This exclusion ground also includes inciting or aiding or abetting or attempting to commit an offence, as referred to in Article 4 of that Framework Decision.

a. Your answer?

Yes/No. **No is required**

 Supplier comment allowed

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b. Is this information available at no cost to the authorities from an EU Member State database?

Yes/No. **No is desired**

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a. Date of conviction

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b. Reason

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c. Who has been convicted

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d. Length of the period of exclusion

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e. Have you taken measures to demonstrate your reliability ("Self-Cleaning")

Yes/No

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Please describe them

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**Money laundering or terrorist financing**

Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgment for money laundering or terrorist financing, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? As defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing (OJ L 309, 25.11.2005, p. 15).

a. Your answer?

Yes/No. No is required

Supplier comment allowed

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**b. Is this information available at no cost to the authorities from an EU Member State database?**

Yes/No. No is desired

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**a. Date of conviction**

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**b. Reason**

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**c. Who has been convicted**

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**d. Length of the period of exclusion**

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e. Have you taken measures to demonstrate your reliability ("Self-Cleaning")

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Yes/No

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Child labour and other forms of trafficking in human beings

ESPD



Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction by final judgment for child labour and other forms of trafficking in human beings, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable? As defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims, and replacing Council Framework Decision 2002/629/JHA (OJ L 101, 15.4.2011, p. 1).

a. Your answer?

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Yes/No. *No is required**Supplier comment allowed***b. Is this information available at no cost to the authorities from an EU Member State database?**

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ESPD

Yes/No. *No is desired***a. Date of conviction**

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b. Reason

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**c. Who has been convicted**

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**d. Length of the period of exclusion**

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**e. Have you taken measures to demonstrate your reliability ("Self-Cleaning")**

Yes/No

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**b. Reference/Code**

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***B: Grounds relating to the payment of taxes or social security contributions*****Article 57(2) of Directive 2014/24/EU sets out the following reasons for exclusion*****Payment of taxes***

Has the economic operator breached its obligations relating to the payment of taxes, both in the country in which it is established and in Member State of the contracting authority or contracting entity if other than the country of establishment?

a. Your answer?Yes/No. *No is required* *Supplier comment allowed*

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b. Is this information available at no cost to the authorities from an EU Member State database?

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Yes/No. No is desired

a. Country or Member State concerned

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b. Amount concerned

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c. Has this breach of obligations been established by means other than a judicial or administrative decision?

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Yes/No. No is desired

a. Please describe which means were used

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b. Has the economic operator fulfilled its obligations by paying or entering into a binding arrangement with a view to paying the taxes or social security contributions due, including, where applicable, any interest accrued or fines?

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Yes/No. No is desired

Please describe them

ESPD templat...



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c. If this breach of obligations was established through a judicial or administrative decision, was this decision final and binding?

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Yes/No. No is desired

d. Please indicate the date of conviction or decision

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e. In case of a conviction, insofar as established directly therein, the length of the period of exclusion

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Text field

a. URL

Text field

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**b. Reference/Code**

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**c. Issuer**

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**Payment of social security**

Has the economic operator breached its obligations relating to the payment social security contributions, both in the country in which it is established and in Member State of the contracting authority or contracting entity if other than the country of establishment?

a. Your answer?

Yes/No. No is required

Supplier comment allowed

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**b. Is this information available at no cost to the authorities from an EU Member State database?**

Yes/No. No is desired

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**a. Country or Member State concerned 00**

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**b. Amount concerned**

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**c. Has this breach of obligations been established by means other than a judicial or administrative decision?**

Yes/No. No is desired

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**a. Please describe which means were used**

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b. If this breach of obligations was established through a judicial or administrative decision, was this decision final and binding?

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Yes/No. No is desired

c. Please indicate the date of conviction or decision

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d. In case of a conviction, insofar as established directly therein, the length of the period of exclusion

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e. Has the economic operator fulfilled its obligations by paying or entering into a binding arrangement with a view to paying the taxes or social security contributions due, including, where applicable, any interest accrued or fines?

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Yes/No. No is desired

Please describe them

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a. URL

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b. Reference/Code

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C: Grounds relating to insolvency, conflicts of interests or professional misconduct

Article 57(4) of Directive 2014/24/EU sets out the following reasons for exclusion

Breaching of obligations in the field of environmental law



Has the economic operator, to its knowledge, breached its obligations in the field of environmental law? As referred to for the purposes of this procurement in national law, in the relevant notice or the procurement documents or in Article 18(2) of Directive 2014/24/EU.

Your answer?Yes/No. **No is required** Supplier comment allowed

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**a. Please describe them**

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**b. Have you taken measures to demonstrate your reliability ("Self-Cleaning")**Yes/No. **No is desired**

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**Please describe them**

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**Breaching of obligations in the field of social law**

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Has the economic operator, to its knowledge, breached its obligations in the field of social law? As referred to for the purposes of this procurement in national law, in the relevant notice or the procurement documents or in Article 18(2) of Directive 2014/24/EU.

Your answer?Yes/No. **No is required** Supplier comment allowed

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**Please describe them**

Text field

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**a. Have you taken measures to demonstrate your reliability ("Self-Cleaning")**Yes/No. **No is desired**

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**b. Please describe them**

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**Breaching of obligations in the fields of labour law**

ESPD



Has the economic operator, to its knowledge, breached its obligations in the field of labour law? As referred to for the purposes of this procurement in national law, in the relevant notice or the procurement documents or in Article 18(2) of Directive 2014/24/EU.

Your answer?Yes/No. **No is required** Supplier comment allowed

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**Please describe them**

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**a. Have you taken measures to demonstrate your reliability ("Self-Cleaning")**Yes/No. **No is desired**

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**b. Please describe them**

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**Bankruptcy**

ESPD



Is the economic operator bankrupt? This information needs not be given if exclusion of economic operators in this case has been made mandatory under the applicable national law without any possibility of derogation where the economic operator is nevertheless able to perform the contract.

a. Your answer?Yes/No. **No is required** Supplier comment allowed

ESPD templat...

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**b. Is this information available at no cost to the authorities from an EU Member State database?**Yes/No. **No is desired**

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**a. Please describe them**

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**b. Indicate reasons for being able nevertheless to perform the contract**

Text field

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**a. URL**

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b. Reference/Code

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**c. Issuer**

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**Insolvency**

Is the economic operator the subject of insolvency or winding-up? This information needs not be given if exclusion of economic operators in this case has been made mandatory under the applicable national law without any possibility of derogation where the economic operator is nevertheless able to perform the contract.

a. Your answer?

Yes/No. No is required

Supplier comment allowed

ESPD templat...

**b. Is this information available at no cost to the authorities from an EU Member State database?**

Yes/No. No is desired

ESPD templat...

**a. Please describe them**

Text field

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**b. Indicate reasons for being able nevertheless to perform the contract**

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**a. URL**

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**b. Reference/Code**

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**c. Issuer**

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**Arrangement with creditors**

Is the economic operator in arrangement with creditors? This information needs not be

given if exclusion of economic operators in this case has been made mandatory under the applicable national law without any possibility of derogation where the economic operator is nevertheless able to perform the contract.

a. Your answer?

Yes/No. **No is required**

 Supplier comment allowed

ESPD templat...

ESPD



b. Is this information available at no cost to the authorities from an EU Member State database?

Yes/No. **No is desired**

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a. Please describe them

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b. Indicate reasons for being able nevertheless to perform the contract

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b. Reference/Code

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c. Issuer

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ESPD



Analogous situation like bankruptcy under national law

ESPD



Is the economic operator in in any analogous situation like bankruptcy arising from a similar procedure under national laws and regulations? This information needs not be given if exclusion of economic operators in this case has been made mandatory under the applicable national law without any possibility of derogation where the economic operator is nevertheless able to perform the contract.

a. Your answer?

Yes/No. **No is required**

 Supplier comment allowed

ESPD templat...

ESPD



b. Is this information available at no cost to the authorities from an EU Member State database?

ESPD templat...



Yes/No. No is desired

a. Please describe them

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b. Indicate reasons for being able nevertheless to perform the contract

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a. URL

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b. Reference/Code

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c. Issuer

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Assets being administered by liquidator



Are the assets of the economic operator being administered by a liquidator or by the court? This information needs not be given if exclusion of economic operators in this case has been made mandatory under the applicable national law without any possibility of derogation where the economic operator is nevertheless able to perform the contract.

a. Your answer?

Yes/No. No is required

Supplier comment allowed

ESPD templat...



b. Is this information available at no cost to the authorities from an EU Member State database?

Yes/No. No is desired

ESPD templat...



a. Please describe them

Text field

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b. Indicate reasons for being able nevertheless to perform the contract ESPD templat... ESPD i

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a. URL ESPD templat... ESPD i

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b. Reference/Code ESPD templat... ESPD i

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c. Issuer ESPD templat... ESPD i

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Business activities are suspended ESPD !

Are the business activities of the economic operator suspended? This information needs not be given if exclusion of economic operators in this case has been made mandatory under the applicable national law without any possibility of derogation where the economic operator is nevertheless able to perform the contract.

a. Your answer? ESPD templat... ESPD !

Yes/No. *No is required*

 *Supplier comment allowed*

b. Is this information available at no cost to the authorities from an EU Member State database? ESPD templat... ESPD i

Yes/No. *No is desired*

a. Please describe them ESPD templat... ESPD i

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b. Indicate reasons for being able nevertheless to perform the contract ESPD templat... ESPD i

Text field

a. URL ESPD templat... ESPD i

Text field

b. Reference/Code ESPD templat... ESPD i
Text field

c. Issuer ESPD templat... ESPD i
Text field

Agreements with other economic operators aimed at distorting competition ESPD !

Has the economic operator entered into agreements with other economic operators aimed at distorting competition?

Your answer? ESPD templat... ESPD !
Yes/No. *No is required*
 *Supplier comment allowed*

a. Please describe them ESPD templat... ESPD i
Text field

b. Have you taken measures to demonstrate your reliability ("Self-Cleaning") ESPD templat... ESPD i
Yes/No

Please describe them ESPD templat... ESPD i
Text field

Guilty of grave professional misconduct ESPD !

Is the economic operator guilty of grave professional misconduct? Where applicable, see definitions in national law, the relevant notice or the procurement documents.

Your answer? ESPD templat... ESPD !
Yes/No. *No is required*
 *Supplier comment allowed*

a. Please describe them ESPD templat... ESPD i
Text field

b. Have you taken measures to demonstrate your reliability ("Self-Cleaning")

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ESPD



Yes/No

Please describe them

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Text field

Conflict of interest due to its participation in the procurement procedure

ESPD



Is the economic operator aware of any conflict of interest, as indicated in national law, the relevant notice or the procurement documents due to its participation in the procurement procedure?

Your answer?

Yes/No. No is required

Supplier comment allowed

ESPD templat...

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**Please describe them**

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Early termination, damages or other comparable sanctions

ESPD



Has the economic operator experienced that a prior public contract, a prior contract with a contracting entity or a prior concession contract was terminated early, or that damages or other comparable sanctions were imposed in connection with that prior contract?

Your answer?

Yes/No. No is required

Supplier comment allowed

ESPD templat...

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**a. Please describe them**

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b. Have you taken measures to demonstrate your reliability ("Self-Cleaning")

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Yes/No

Please describe them

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Guilty of misinterpretation, withheld information, unable to provide required documents and obtained confidential information of this procedure



Can the economic operator confirm that:

- a) It has been guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria,
- b) It has withheld such information,
- c) It has not been able, without delay, to submit the supporting documents required by a contracting authority or contracting entity, and
- d) It has undertaken to unduly influence the decision making process of the contracting authority or contracting entity, to obtain confidential information that may confer upon it undue advantages in the procurement procedure or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award?

Your answer?

Yes/No. **No is required**

Supplier comment allowed

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Direct or indirect involvement in the preparation of this procurement procedure



Has the economic operator or an undertaking related to it advised the contracting authority or contracting entity or otherwise been involved in the preparation of the procurement procedure?

Your answer?

Yes/No. **No is required**

Supplier comment allowed

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Please describe them

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D: Purely national exclusion grounds

Do the purely national grounds of exclusion, which are specified in the relevant notice or in the procurement documents, apply?

Purely national exclusion grounds



Other exclusion grounds that may be foreseen in the national legislation of the contracting

authority's or contracting entity's Member State. Has the economic operator breached its obligations relating to the purely national grounds of exclusion, which are specified in the relevant notice or in the procurement documents?

a. Your answer?

Yes/No. **No is required**

 Supplier comment allowed

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b. Is this information available at no cost to the authorities from an EU Member State database?

Yes/No. **No is desired**

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a. Please describe them

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b. Have you taken measures to demonstrate your reliability ("Self-Cleaning")

Yes/No. **No is desired**

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Part IV: Selection criteria

a: Global indication for all selection criteria

Concerning the selection criteria the economic operator declares that

It satisfies all the required selection criteria

ESPD

It satisfies all the required selection criteria indicated in the relevant notice or in the procurement documents referred to in the notice.

Your answer?Yes/No. **Yes is desired** Supplier comment allowed

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**A: Suitability****Article 58(2) of Directive 2014/24/EU sets out the following selection criteria****Enrolment in a relevant professional register**

ESPD

It is enrolled in relevant professional registers kept in the Member State of its establishment as described in Annex XI of Directive 2014/24/EU; economic operators from certain Member States may have to comply with other requirements set out in that Annex.

a. Your answer?Yes/No. **Yes is desired** Supplier comment allowed

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**b. Is this information available at no cost to the authorities from an EU Member State database?**Yes/No. **No is desired**

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**Enrolment in a trade register**

ESPD

It is enrolled in trade registers kept in the Member State of its establishment as described in Annex XI of Directive 2014/24/EU; economic operators from certain Member States may have to comply with other requirements set out in that Annex.

a. Your answer?Yes/No. **Yes is desired** Supplier comment allowed

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b. Is this information available at no cost to the authorities from an EU Member State database?

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Yes/No. No is desired

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For service contracts: authorisation of particular organisation needed

Is a particular authorisation of a particular organisation needed in order to be able to perform the service in question in the country of establishment of the economic operator?

a. Your answer?

Yes/No. Yes is desired



Supplier comment allowed

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b. Is this information available at no cost to the authorities from an EU Member State database?

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Yes/No. No is desired

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For service contracts: membership of particular organisation needed ESPD

Is a particular membership of a particular organisation needed in order to be able to perform the service in question in the country of establishment of the economic operator?

a. Your answer?Yes/No. *Yes is desired* *Supplier comment allowed*

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ESPD**b. Is this information available at no cost to the authorities from an EU Member State database?**Yes/No. *No is desired*

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ESPD**Please describe them**

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ESPD**B: Economic and financial standing**

Article 58(3) of Directive 2014/24/EU sets out the following selection criteria

General yearly turnover

Its general yearly turnover for the number of financial years required in the relevant notice, the procurement documents or the ESPD is as follows:

Average yearly turnover

Its average yearly turnover for the number of years required in the relevant notice, the procurement documents or the ESPD is as follows:

Specific yearly turnover

Its specific yearly turnover in the business area covered by the contract for the number of financial years required in the relevant notice, the procurement documents or the ESPD is as follows:

Specific average turnover

Its specific average yearly turnover in the business area covered by the contract for the number of years required in the relevant notice, the procurement documents or the ESPD is as follows:

Set up of economic operator

In case the information concerning turnover (general or specific) is not available for the entire period required, please state the date on which the economic operator was set up or started trading:

Financial ratio

Concerning the financial ratios specified in the relevant notice, the procurement documents or the ESPD, the economic operator declares that the actual values for the required ratios are as follows:

Professional risk indemnity insurance

The insured amount in its professional risk indemnity insurance is the following:

Other economic or financial requirements

Concerning the other economic or financial requirements, if any, that may have been specified in the relevant notice or the procurement documents, the economic operator declares that:

C: Technical and professional ability

Article 58(4) of Directive 2014/24/EU sets out the following selection criteria

For works contracts: performance of works of the specified type

For public works contracts only: During the reference period, the economic operator has performed the following works of the specified type. Contracting authorities may require up to five years and allow experience dating from more than five years.

For supply contracts: performance of deliveries of the specified type

For public supply contracts only: During the reference period, the economic operator has delivered the following principal deliveries of the type specified. Contracting authorities may require up to three years and allow experience dating from more than three years.

For service contracts: performance of services of the specified type

For public service contracts only: During the reference period, the economic operator has provided the following main services of the type specified. Contracting authorities may require up to three years and allow experience dating from more than three years.

Technicians or technical bodies for quality control

It can call upon the following technicians or technical bodies, especially those responsible for quality control. For technicians or technical bodies not belonging directly to the economic operator's undertaking but on whose capacities the economic operator relies as set out under Part II, Section C, separate ESPD forms must be filled in.

For works contracts: technicians or technical bodies to carry out the work

In the case of public works contracts, the economic operator will be able to call on the following technicians or technical bodies to carry out the work:

Technical facilities and measures for ensuring quality

It uses the following technical facilities and measures for ensuring quality and its study and research facilities are as follows:

Study and research facilities

It uses the following study and research facilities:

Supply chain management

It will be able to apply the following supply chain management and tracking systems when performing the contract:

Allowance of checks

ESPD

For complex products or services to be supplied or, exceptionally, for products or services which are required for a special purpose: The economic operator will allow checks to be conducted on the production capacities or the technical capacity of the economic operator and, where necessary, on the means of study and research which are available to it and on the quality control measures? The check is to be performed by the contracting authority or, in case the latter consents to this, on its behalf by a competent official body of the country in which the supplier or service provider is established.

Do you allow checks?

Yes/No. Yes is desired



Supplier comment allowed

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Educational and professional qualifications

The following educational and professional qualifications are held by the service provider or the contractor itself, and/or (depending on the requirements set out in the relevant notice or the procurement documents) by its managerial staff.

Environmental management measures

The economic operator will be able to apply the following environmental management measures when performing the contract:

Number of managerial staff

The economic operator's number of managerial staff for the last three years were as follows:

Average annual manpower

The economic operator's average annual manpower and the number of managerial staff for the last three years were as follows:

Tools, plant or technical equipment

The following tools, plant or technical equipment will be available to it for performing the contract:

Subcontracting proportion

The economic operator intends possibly to subcontract the following proportion (i.e. percentage) of the contract. Please note that if the economic operator has decided to subcontract a part of the contract and relies on the subcontractor's capacities to perform that part, then please fill in a separate ESPD for such subcontractors, see Part II, Section C above.

For supply contracts: samples, descriptions or photographs without certification of authenticity



For public supply contracts: The economic operator will supply the required samples, descriptions or photographs of the products to be supplied, which do not need to be accompanied by certifications of authenticity.

a. Your answer?

Yes/No. **Yes is desired**



Supplier comment allowed

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b. Is this information available at no cost to the authorities from an EU Member State database?

Yes/No. **No is desired**

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**For supply contracts: samples, descriptions or photographs with certification of authenticity**

ESPD

For public supply contracts: The economic operator will supply the required samples, descriptions or photographs of the products to be supplied and will provide certifications of authenticity where applicable.

a. Your answer?Yes/No. **Yes is desired**

Supplier comment allowed

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**b. Is this information available at no cost to the authorities from an EU Member State database?**Yes/No. **No is desired**

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**For supply contracts: certificates by quality control institutes**

ESPD

Can the economic operator provide the required certificates drawn up by official quality control institutes or agencies of recognised competence attesting the conformity of products clearly identified by references to the technical specifications or standards, which are set out in the relevant notice or the procurement documents?

a. Your answer?Yes/No. **Yes is desired**

Supplier comment allowed

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**b. Is this information available at no cost to the authorities from an EU Member State database?**Yes/No. **No is desired**

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If not, please explain why and state which other means of proof can be provided:

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D: Quality assurance schemes and environmental management standards

Article 62(2) of Directive 2014/24/EU sets out the following selection criteria

Certificates by independent bodies about quality assurance standards

ESPD

Will the economic operator be able to produce certificates drawn up by independent bodies attesting that the economic operator complies with the required quality assurance standards, including accessibility for disabled persons?

a. Your answer?

Yes/No. **Yes is desired**

Supplier comment allowed

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b. Is this information available at no cost to the authorities from an EU Member State database?

Yes/No. **No is desired**

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If not, please explain why and specify which other means of proof concerning the quality assurance scheme can be provided:

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**Certificates by independent bodies about environmental management systems or standards** ESPD

Will the economic operator be able to produce certificates drawn up by independent bodies attesting that the economic operator complies with the required environmental management systems or standards?

a. Your answer?Yes/No. *Yes is desired* *Supplier comment allowed*

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**b. Is this information available at no cost to the authorities from an EU Member State database?**Yes/No. *No is desired*

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**If not, please explain why and specify which other means of proof concerning the environmental management systems or standards can be provided:**

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**Finish****Part V: Reduction of the number of qualified candidates**

The economic operator declares that:

It meets the objective and non discriminatory criteria or rules to be applied in order to limit the number of candidates in the following way: In case certain certificates or other forms of documentary evidence are required, please indicate for each whether the economic operator has the required documents:

ESPD

If some of these certificates or forms of documentary evidence are available electronically, please indicate for each:

a. Your answer?

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Yes/No. **Yes is desired**

Supplier comment allowed

b. Is this information available at no cost to the authorities from an EU Member State database?

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Yes/No. **No is desired**

Please describe them

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Part VI: Concluding statements

Concluding statements

The undersigned formally declare that the information stated under Parts II - V above is accurate and correct and that it has been set out in full awareness of the consequences of serious misrepresentation.

The undersigned formally declare to be able, upon request and without delay, to provide the certificates and other forms of documentary evidence referred to, except where:

a) The contracting authority or contracting entity has the possibility of obtaining the supporting documentation concerned directly by accessing a national database in any

Member State that is available free of charge (on condition that the economic operator has provided the necessary information (web address, issuing authority or body, precise reference of the documentation) allowing the contracting authority or contracting entity to do so. Where required, this must be accompanied by the relevant consent to such access),
or

b) As of 18 October 2018 at the latest (depending on the national implementation of the second subparagraph of Article 59(5) of Directive 2014/24/EU), the contracting authority or contracting entity already possesses the documentation concerned.

The undersigned formally consent to [identify the contracting authority or contracting entity as set out in Part I, Section A], gaining access to documents supporting the information, which has been provided in [identify the Part/Section/Point(s) concerned] of this European Single Procurement Document for the purposes of [identify the procurement procedure: (summary description, reference of publication in the Official Journal of the European Union, reference number)].

Date, place and, where required or necessary, signature(s):