



TENDER SPECIFICATIONS BXL 14628

Dynamic Purchasing System

Public supply contract
for the acquisition, installation and maintenance of medical
equipment in the Democratic Republic of the Congo

RESTRICTED PROCEDURE

This call for tenders concerns a restricted procedure, i.e. a two-stage procedure. This document concerns the first stage of the call for applications.

The **first stage**, known as the **selection stage**, consists of the evaluation of applications for participation based on the exclusion and selection criteria of these Tender Specifications.

Please note that certain terms of the Tender Specifications are confidential and will only be accessible to selected candidates.

For the **second stage**, known as the **award stage**, only the selected candidates will be invited to submit a tender and will receive unrestricted access to the Tender Specifications. That stage consists of awarding the public contract after evaluating the tenders on the basis of the award criteria

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1 Preamble

Award procedure	Restricted Procedure
Dynamic Purchasing System Contracting authority	Enabel, public-law company with social purposes, represented by Inge Janssens, Manager Global Procurement Services and Danny Verspreet, Director of Finance and IT.
Managing official	Stefaan Van Bastelaere, Health, Human Rights & Social Protection expert
Deadline date and time for submitting requests to participate	All applications must be received before 10/01/2025 at 10:00 a.m.

2 Explanation of the Dynamic Purchasing System

A dynamic purchasing system (DPS) is an entirely electronic public procurement technique that enables suppliers to be referenced on an ongoing basis and then put out to tender at specific times.

It is conducted according to the rules of the restricted procedure, i.e. an award procedure in which any interested economic operator may request to participate in response to a contract notice and in which only selected candidates may submit a tender.

The DPS is an entirely electronic process which is open, throughout the period of validity of the purchasing system, to all economic operators fulfilling the selection criteria.

I. Qualification of economic operators during the process of setting up the DPS and during the DPS management phase

A DPS is a system open to competition. In practical terms, this means that interested economic operators can submit (or withdraw) their applications at any time during the period when a DPS is being set up, as well as during its lifetime, i.e. the period when the DPS is being managed.

The call for tenders is published at European level and is visible throughout the life of the DPS.

The contracting authority analyses the applications, checking that the candidates comply with the selection criteria and that they are not in a situation of exclusion, as provided for in public procurement legislation (Articles 67 and 68 of the Law of 17 June 2016).

For each application received, the contracting authority will draw up a reasoned decision on selection or non-selection. This decision may be appealed before the competent administrative courts, namely the Council of State, rue de la Science 33, 1040 Brussels.

II. Managing calls for tender using a DPS

Once the DPS has been set up, admitted participants will be given access to the DPS, where specific public contracts will be awarded and where they will be invited to submit a tender.

The DPS begins on the date on which the first need is expressed.

When a requirement is expressed, all participants admitted are invited to submit a tender for a subsequent 'specific public contract' and the specific public contract will be awarded to the selected candidate with the most economically advantageous tender in the light of the award criteria defined for each of the specific public contracts.

The minimum time limit for the receipt of tenders is at least ten days starting on the date of dispatch of the invitation to tender.

This invitation to tender will include a detailed description of the public contract and the award criteria. These may differ from one public contract to another.

A standstill period (15 calendar days) must also be observed between the award and notification of a specific public contract with a value above the European threshold.

3 Applicable regulations ¹

3.1 Derogations from the General Implementing Rules

Section 4. 'Specific contractual and administrative conditions' section of these Tender Specifications (CSC/Cahier Spécial des Charges) holds the specific administrative and contractual provisions that apply to this public contract by way of derogation from the Royal Decree of 14 January 2013 or as a complement or an elaboration thereof.

3.2 Contracting authority

The contracting authority of this public contract is Enabel, the Belgian development agency, public-law company with social purposes, with its registered office at Rue Haute 147, 1000 Brussels in Belgium (enterprise number 0264.814.354, RPM/RPR Brussels).

Enabel has the exclusive competence for the execution, in Belgium and abroad, of public service tasks of direct bilateral cooperation with partner countries. Moreover, it may also perform other development cooperation tasks at the request of public interest organisations, and it can develop its own activities to contribute towards realisation of its objectives.

For setting up the DPS Enabel is represented by Inge Janssens, Manager Global Procurement Services and Danny Verspreet, Director of Finances & IT.

For specific public contracts, Enabel is validly represented by Léa LECOMTE, Contract Support Manager DRC and Fabien LOCHT, Country Portfolio Manager.

Rules governing the DPS and specific public contracts

The applicable regulation for awarding and performing the DPS and specific public contract, i.e.:

- The Law of 17 June 2016 on public contracts and its subsequent changes, hereinafter referred to as "the Law";
- The Law of 17 June 2013 on justifications, notification and legal remedies for public contracts and certain contracts for works, supplies and services, and its subsequent changes;
- Royal Decree of 18 April 2017 on the awarding of public contracts in the classic sectors, and its subsequent changes, hereinafter referred to as "the RDAwarding";
- Circulars of the Prime Minister with regards to public procurement;
- Enabel's Policy regarding sexual exploitation and abuse – June 2019;
- Enabel's Policy regarding fraud and corruption risk management – June 2019;
- Local legislation with regards to sexual harassment at the workplace or equivalent;
- General Regulation (EU) 2016/679 of 27 April 2016 on data protection (GDPR);
- The provisions relating to the GDPR apply if, and only if, the performance of the public contract involves the management, by the contractor (= subcontractor within the meaning of the GDPR), on a principal basis (the very subject-matter of procurement) or

¹ All Belgian regulations on public contracts can be consulted on www.publicprocurement.be

as an accessory basis (a mere consequence of the performance of the public contract), of one or more processing operations on personal data, on behalf of and in accordance with the instructions of the contracting authority (= controller within the meaning of the GDPR);

- Enabel's Code of Conduct and the policies mentioned above can be consulted on Enabel's website or via [Integrity - Enabel - Belgian Development Agency |](#)

All Belgian regulations on public contracts can be consulted on [Public procurement | BOSA \(belgium.be\)](#).

3.3 Documents applicable to the DPS

The documents applicable to the DPS and its specific public contracts are:

- This call for tenders or call to participate in the DPS
- Notices and corrective notices concerning this call to participate, published in the Official Journal of the European Union or in the Belgian Public Tender bulletin.
- The questions and answers minutes.
- The call to participate form.
- The European Single Procurement Document
- The notification of the selection decision.

The Tender Specifications for specific public contracts take precedence over the tenderer's clauses of calls for tenders.

In the event of a contradiction between the tenderer's general and special conditions and the technical provisions of the Tender Specifications, the latter shall take precedence, including any amendments to these technical provisions communicated in writing to the tenderers during the negotiation, in accordance with Article 38, §5, of the Law of 17 June 2016.

By the mere fact of submitting its tender, the tenderer accepts the full and entire application of the conditions laid down by the above legal provisions as well as by these Tender Specifications and the various documents to which they refer.

Tenderers are invited to report any error or provision that they consider to be irregular or which makes it impossible for them to participate in this DPS as soon as possible after receipt thereof.

Requests or comments deemed admissible by the contracting authority will be included in a correction notice and may, where appropriate, lead to the postponement of the date for submission of applications. The other candidates will be informed at the same time.

- Furthermore, by submitting an application the candidate declares having read and understood the articles about deontology of this public contract as well as Enabel's Policy regarding sexual exploitation and abuse and Enabel's Policy regarding fraud and corruption risk management².

3.4 Confidentiality

3.4.1 Processing of personal data

The contracting authority undertakes to process the personal data that are communicated to it under the framework of this procedure with the greatest care, in accordance with legislation on

²<https://www.enabel.be/content/integrity-desk>

the protection of personal data (General Data Protection Regulation, GDPR). Where the Belgian Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data contains stricter provisions, the contracting authority will act in accordance with said Law.

3.4.2 Confidentiality

The tenderer, admitted candidate or contractor of the specific public contracts and Enabel are bound to secrecy vis-à-vis third parties with regards to any confidential information obtained within the framework of this public contract and will only divulge such information to third parties after receiving the prior written consent of the other party. They will disclose this confidential information only among appointed parties involved in the assignment. They guarantee that said appointed parties will be adequately informed of their obligations in respect of the confidential nature of the information and that they shall comply therewith.

PRIVACY NOTICE OF ENABEL: Enabel takes your privacy serious. We undertake to protect and process your personal data with care, transparently and in strict compliance with privacy protection legislation.

3.5 Applicable law and competent courts

The contract must be performed and interpreted according to Belgian law.

The parties commit to sincerely perform their engagements to ensure the good completion of the public contract.

In case of litigation or divergence of opinion between the contracting authority and the contractor, the parties will consult each other to find a solution.

If agreement is lacking, the Brussels courts are the only courts competent to resolve the matter.

4 Purpose and scope of the purchasing system

4.1 Purpose and nature of the Dynamic Purchasing System

CPV code: 33100000-0 Medical equipments, pharmaceuticals and personal care products.

4.2 Lots

The public contract covers the supply, delivery, assembly, installation, commissioning, training of users and maintenance technicians¹ of the following supplies,

with 3 lots:

- Lot no. 1 Anaesthesia - intensive care / laundry / operating theatre / consultation / gas / medical furniture / pharmacy / sterilisation / functional support / testing and calibration / therapy and functional rehabilitation
- Lot no. 2 Medical imaging
- Lot no. 3 Laboratory

Candidates may apply for one or more lots. Entries will be evaluated by lot.

4.3 Duration of the Purchasing System

The opening date for the first applications is 10 January 2025 at 10:00 a.m.

This DPS is concluded from the day after the notification letter is sent to the selected participant and ends on 31 December 2027.

The duration of the DPS referred to above corresponds to the period during which specific public contracts may be concluded.

However, the duration of each of the specific public contracts resulting from the DPS may not exceed 24 months from the end of the DPS, as defined above, i.e. a total possible duration of services of a maximum of 90 months.

4.4 Maximum value of procurement per user entity

The maximum value of the healthcare portfolio from 2024 to 2027 is **EUR 3 448 000 excluding VAT over 3 years** of which it is estimated that 70% would be covered by this DPS.

The size of the public contract has been estimated on the basis of the needs of the provinces listed below. This information is given for guidance only and does not constitute an estimate of quantities.

Breakdown by province:

- SPSS Kinshasa: (30%)
- SPSS Sud Ubangi: (30%)
- SPSS Tshopo: COD2200911_A010108 (30%)
- LVSI (Fight against Sexual Violence): (10%)

Breakdown by lot: Lot no. 1: 50% - Lot no. 2: 20% - Lot no. 3: 30%

5 Procedure

5.1 Award procedure

Restricted procedure in application of Articles 37 & 44 of the Law of 17 June 2016.

5.2 Publication

5.2.1 Official notification

This DPS is officially published in the Belgian Public Tender bulletin and in the Official Journal of the European Union.

5.2.2 Further notification

This DPS is posted on the website of Enabel (www.enabel.be).

This public contract also is posted on the Development Aid website.

5.3 Information

The selection of candidates is coordinated by Inès Garcia Alonso. Throughout this procedure all contacts between the contracting authority and the (prospective) tenderers about this public contract will exclusively pass through her. (Prospective) tenderers are prohibited to contact the contracting authority in any other way with regards to this public contract, unless otherwise stipulated in these Tender Specifications.

Until 10 days before the application submission deadline, prospective candidates may ask questions about these Tender Specifications and the public contract. Questions will be asked via the internet applications of Belgium's federal *e-Procurement* service: <https://www.publicprocurement.be/> and they will be answered in the order received. When these lead to additional information and/or a correction, the overview of these questions and answers will be available in the Belgian Public Tender bulletin/OJEU. Questions asked after said term will not be dealt with.

The tenderer is to submit his tender after reading and taking into account any corrections made to the tender notice or Tender Specifications that are published in the Official Journal of the European Union and in the Belgian Public Tender bulletin. They are strongly advised to ask about any changes or additional information.

In accordance with Article 81 of the Royal Decree of 18 April 2017, the candidate is required to report immediately any gap, error or omission in the procurement documents that precludes the establishment of his application, within ten days at the latest before the deadline for the receipt of applications.

For more information on registering or connecting with the platform please check with the Help Centre via the "Suppliers" button: [Suppliers - How do I submit an offer/request for participation? \(service-now.com\)](#)

Candidates will in any event be deemed to have taken cognisance of this information and to have taken it into account when preparing and submitting their request for participation.

By submitting their application, candidates acknowledge that they have obtained all the information required to submit their application.

5.4 Requests for participation

5.4.1 Form and content of participation

Candidates must submit their application in French, Dutch or English. If the candidates draw up their application on documents other than the attached form, they are fully responsible for the perfect concordance between the documents they have used and the attached form.

Any interested candidate may submit a request for participation throughout the duration of the Dynamic Purchasing System.

The contracting authority requires candidates to provide documents in addition to the ESPD.

The candidates clearly designate which information is confidential and/or relates to technical or business secrets and may therefore not be divulged by the contracting authority.

5.4.2 List of documents to enclose with your application

Candidates must submit electronically via the federal **e-Procurement** platform: [BOSA - eProcurement \(publicprocurement.be\)](https://www.bosa.be/eProcurement/publicprocurement.be) the following documents:

Applicants must submit the following with their request for participation to the public contract:

- Form 8.1 - Requests for Participation form
- Form 8.2 - Capacity of third parties - Formal undertaking by subcontractors to make the necessary resources available to the candidate for the performance of the public contract
- Form 8.3 - Filled out ESPD
- Form 8.4 - List of subcontractors
- Form 8.5 - Declaration on honour – Exclusion grounds
- Evidence of fulfilling the selection criteria
- All documents attesting to the authority of the person signing the application to bind the enterprise with regard to public contracts.
- A certified copy of the certificate of registration in the Trade and Personal Property Credit Register, dated less than 12 months, certifying that the candidate is registered and that its sector of activity is the supply, installation and maintenance of medical equipment for tenderers registered in DR Congo.

If you are a foreign company, you must present proof of registration as an economic operator in your country.

- If the applicant company is not Belgian, it must enclose with its application proof that it is in a situation of exclusion linked to the existence of tax and/or social debts.
- A document less than ninety days old, drawn up in accordance with the tenderer's national legislation or practice, certifying that the tenderer is not bankrupt or the subject of proceedings for a declaration of bankruptcy, liquidation, judicial settlement, preventive condemnation or any other similar proceedings.
- The statutes and any other document required to establish the power of attorney of the signer(s) (for each participant for application submitted by a group)
- Where the application is submitted by a group of economic operators, the association agreement signed by each participant, clearly showing who represents the association

- If the enterprise is not Belgian, it must enclose with its application all documents attesting to the composition of its Board of Directors (extracts from the statutes, etc.).
- Copies of the criminal records of the enterprise and of the members of the Board of Directors.
- An extract from the subcontractor's criminal record (of the enterprise only, not of the Board of Directors).

Where the application is submitted by a **group of economic operators without legal personality** (including temporary associations), each participant must enclose:

- Form 8.1 - Requests for Participation form
- Form 8.2 - Declaration on honour – Exclusion grounds
- Form 8.3 - Filled out ESPD
 - When not relying on the capacity of third parties (other than the members of the consortium) to meet the public contract selection criteria: one ESPD per member of the consortium (Parts II to IV must be filled out).
 - When relying on the capacity of third parties (other than the members of the consortium) to meet the public contract selection criteria:
 - a separate ESPD for each member of the consortium (parts II to IV must be filled out)
 - a separate ESPD for each third party relied on to meet the public contract selection criteria (parts II, sections A and B and III must be filled out).

The members of the consortium must also indicate in their ESPD (part II, B) which of them represents the consortium vis-à-vis the contracting authority.

- The statutes and any other document required to establish the power of attorney of the signer(s).
- The association agreement signed by each participant, clearly showing who represents the association/

Candidates may rely on the capacity of third parties to meet the economic, financial, technical and/or professional capacity requirements set out above, provided that the third party:

- 1) Either **is clearly identified in the candidate's request for participation** (part II, C of their own ESPD), as well as the share of the contract subcontracted to the third party,
- 2) **Completes an ESPD** (= 1 ESPD per third party) which is **attached to the candidate's request for participation**.
- 3) Is not in a situation of exclusion.
- 4) For the "Profiles: engineers and technicians" criterion, undertakes to carry out the part of the public contract for which the candidate relies on their capacities. To this end, the third party's undertaking (a template for which is appended to these Tender Specifications), duly completed and signed by the third party, must be appended to the request for participation. **As a reminder, the candidate may only rely on the capacity of third parties to meet the "Profiles" criterion if the third party or parties will actually perform the public contract.** The third party's commitment in this respect is appended to the request for participation (template appended to these Tender Specifications).

Reliance on the capacity of third parties is without prejudice to the candidate's own liability.

5.4.3 Digital submission of requests for participation

Candidates may submit only one request for participation.

Each participant in a group of economic operators without legal personality is considered to be a candidate.

In accordance to applicable regulations for means of communication only applications/tenders submitted by electronic means are accepted. Consequently, applications/tenders submitted on paper are not allowed and the contracting authority will only consider tenders submitted by digital means.

For the DPS, electronic submission of an application is by means of the internet applications of Belgium's federal *e-Procurement* service: <https://www.publicprocurement.be/>

The platform is free and open to any service provider interested in participating in the DPS.

For more information on registering or connecting with the platform please check with the Help Centre via the "Suppliers" button: <https://bosa.service-now.com/eprocurement?lang=en>

Applications are opened behind closed doors via the e-Procurement platform.

Documents must be in the .pdf format or equivalent.
For instructions on submitting applications, please check the following (in French):

<http://www.publicprocurement.be/fr/documents/manuel-gestion-dutilisateurs-entreprises-pdf>

In the case of a restricted procedure, the candidate does not have to sign the request for participation individually. The same applies to the ESPD, when it has to be submitted.

However, the two above-mentioned documents can be signed together by adding a signature to the submission report linked to the application for participation, when they are uploaded onto the electronic platform.

If the economic operator does not make use of this option, the ESPD must be attached again to the submission of tenders and signed globally by means of the submission report, as indicated below.

When tenders and their annexes are submitted at a later stage, no individual signature is required when they are uploaded onto the electronic platform. These documents are signed globally by affixing a signature to the relevant submission report.

When the submission report is signed by a mandatary, he or she must clearly indicate whom he or she represents. The mandatary attaches the original electronic deed or private document that transfers these powers to him or her or a scanned copy of that proxy.

If the economic operator is unable to find the relevant information via the Help Centre, he can contact the *e-Procurement* helpdesk on +32 (0)2 740 80 00 or via e.proc@publicprocurement.be

By transferring their application by electronic communication means candidates accept that the data of their application are registered by the reception device.

Applications must be submitted no later than 10 a.m. on Tuesday 3 December 2024 (Belgian time).

Applications submitted after this date will be evaluated by the contracting authority within 15 calendar days of submission.

The contracting authority will evaluate these applications in accordance with the selection criteria **within fifteen working days of receipt** due to the need to examine technical monitoring and maintenance concisely on a document of no more than 5 single-sided A4 pages with the information

5.4.4 Selection of tenderers

5.4.4.1 European Single Procurement Document (ESPD)

By submitting his application together with the completed European Single Procurement Document (ESPD) the tenderer declares officially on his honour that:

- he is not in one of the mandatory or facultative exclusion cases, which must or may lead to his exclusion;
- he fulfils the selection criteria established by the contracting authority in this public contract

The European Single Procurement Document (ESPD) is a self-declaration by economic operators providing preliminary evidence replacing the certificates issued by public authorities or third parties. As provided in Article 73 of the Law of 17 June 2016, it is a formal statement by the economic operator that it is not in one of the situations in which economic operators shall or may be excluded; that it meets the relevant selection criteria.

The candidates generates the ESPD via <https://ESPD.publicprocurement.be/> and then attach it to their application.

An ESPD service manual (in French), including guidelines for enterprises, is available through: https://www.publicprocurement.be/sites/default/files/documents/man_esp_d_entreprise_fr_10_o.pdf

The number of ESPDs to be completed and submitted depends on the structure of the tenderer's response (responding alone, in a group, reliance on third parties, etc.) and the presence of lots:

- The tenderer responds **as an individual** and does not rely on the capacity of third parties to meet the selection criteria of the public contract: a single ESPD for him.
 -
 - Uses the capacity of third parties to meet the selection criteria of the public contract:
 - A single ESPD for him (fill out part II. C of the ESPD);
 - a separate ESPD for each third party relied on to meet the public contract selection criteria (fill out parts II, sections A and B and III).
- The tenderer is a **group without legal personality** (including a temporary association) and:
 - When not relying on the capacity of third parties (other than the members of the consortium) to meet the public contract selection criteria: one ESPD per member of the consortium (Parts II to IV must be filled out).
 - When relying on the capacity of third parties (other than the members of the consortium) to meet the public contract selection criteria:
 - a separate ESPD for each member of the consortium (parts II to IV must be filled out)
 - a separate ESPD for each third party relied on to meet the public contract selection criteria (parts II, sections A and B and III must be filled out).

The members of the consortium must also indicate in their ESPD (part II, B) which of them represents the consortium vis-à-vis the contracting authority.

In accordance with Article 38 §2 of Article 73 of the Royal Decree of 18 April 2017, regarding part IV of the ESPD on the selection criteria, the contracting authority has decided to limit the information to be filled out to one single question, namely whether the economic operator fulfils the required selection criteria, in accordance with the section "Global indication for all selections

criteria" ("Indication globale pour tous les critères de sélection"). So, only this section must be completed.

The contracting authority will ask the applicant, if necessary, at any time during the procedure, to provide all or part of the supporting documents, if necessary to ensure the smooth proceeding of the procedure. The applicant is not required to submit any supporting documents or other evidence if and to the extent that the contracting authority has the possibility to directly obtain certificates or relevant information by accessing a free national database in a Member State.

With the exception of the exclusion grounds relating to tax and social security, the tenderer that is in one of the mandatory or optional exclusion situations can prove on his own initiative that he has paid or undertaken to pay compensation for any prejudice caused by the criminal offence or the fault, clarified totally the facts and circumstances by collaborating actively with the authorities in charge of the enquiry and taken concrete specific technical, organisational and personnel measures to prevent a new criminal offence or a new fault.

5.4.4.2 Exclusion grounds

This section identifies the mandatory grounds for exclusion from participation in the DPS.

As regards the mandatory grounds for exclusion relating to tax and social security debts, the contracting authority will request information or documents electronically. The contracting authority may however ask the tenderers, at any time during the procedure, to provide all or part of the supporting documents, if necessary to ensure the smooth proceeding of the procedure (Art. 73 of the Law of 17 June 2016).

The contracting authority is also required to check whether the tenderer meets the other mandatory grounds for exclusion. Consequently, the contracting authority requires tenderers to enclose with their tender an extract from the criminal record or by default thereof an equally valid document issued by the competent judicial or administrative authority in the country of origin or of establishment of the economic operator showing that these conditions have been met.

With the exception of the grounds for exclusion relating to tax and social security debts, a tenderer who meets one of the mandatory or optional grounds for exclusion may prove that he has taken corrective measures to demonstrate his reliability. For this purpose, the tenderer proves on his own initiative that he has paid or undertaken to pay compensation for any prejudice caused by the criminal offence or the fault, clarified totally the facts and circumstances by collaborating actively with the authorities in charge of the enquiry and taken concrete specific technical, organisational and personnel measures to prevent a new criminal offence or a new fault.

5.4.4.3 Conflicts of interest and revolving doors mechanism

As part of the fight against conflicts of interests, in particular in view of avoiding revolving doors mechanisms as defined in the Law of 8 May 2007 approving the United Nations Convention against Corruption, adopted in New York on 31 October 2003, the tenderer shall refrain from relying on any former (internal or external) collaborator(s) of Enabel, within two years from their resignation, retirement or any other type of departure from Enabel, for whatever reason, directly or indirectly, for the elaboration and/or submission of its tender or any other intervention under the award procedure or for tasks to be conducted as part of the performance of this public contract.

The above provision does however only apply when there is a direct link between the preceding activities conducted for the contracting authority by the person(s) concerned and their activities in this public contract.

Any breach of this measure liable to distort the normal conditions of competition is subject to a sanction in accordance with the provisions of Article 5 of the Law of 17 June 2016 on public procurement and on certain contracts for works, supplies and services. In concrete terms, this sanction, depending on the case, consists of discarding the tender or terminating the public contract.

5.4.4.4 Selection criteria

Moreover, by means of the documents requested below, the tenderer must prove that he is sufficiently capable, from an economic and financial as well as from a technical point of view, to successfully perform this public contract.

Only tenders from tenderers who meet the selection criteria are taken into consideration in order to participate in the comparison of tenders on the basis of the award criteria set out below, subject to the regularity of these tenders.

The tenderer shall fulfil the following needs:

Economic and financial capacity:

[1] Audited balance sheets certified by a registered public accountant and provide current proof of registration of the public accountant certifying the statements or, if not required by the legislation of the candidate's country, other financial statements or bank statements acceptable to the buyer, for the last three financial years shall be submitted demonstrating the candidate's current financial strength and sufficient available financial resources based on the following criteria:

In the case of a group of economic operators, each member of the group of economic operators must provide their own financial statements as indicated above.

Please refer to the form below to provide the required information.

In case the enterprise has not yet published its Financial Statements, an interim balance certified true by a registered accountant or auditor or by the person or body with this function in the country concerned will do.

	Year-2 and currency	Year-1 and currency	Last year and currency	Exchange rate in force on the last day of the respective calendar year (into which the amounts for that year are to be converted).	Equivalent in euros
Annual turnover ^[1]					
Current assets ^[2]					
Debts in the short term ^[3]					

[1] Last accounting period for which the entity's accounts were closed.

[2] The gross inflow of economic benefits (cash, receivables, other assets) resulting from the company's ordinary operating activities (such as sales of goods and services, interest, royalties and dividends) during the year.

A balance sheet account that represents the value of all assets that can reasonably be expected to be converted into cash within one year in the normal course of business. Current assets include cash, receivables, inventories, marketable securities, prepaid expenses and other liquid assets that can be readily converted into cash.

[3] The debts or obligations of a company that are due within one year. Current liabilities appear on a company's balance sheet and include short-term debts, accounts payable, accrued charges and other liabilities.

In case the enterprise has not yet published its Financial Statements, an interim balance certified true by a registered accountant or auditor or by the person or body with this function in the country concerned will do.

a) Liquidity ratio ≥ 1

The current ratio (current assets/current liabilities) for the last financial year must be at least 1. In the case of a consortium of economic operators, this criterion must be met by each member of the consortium.

$$((\text{Current assets}) / (\text{Current liabilities})) \geq 1)$$

b) Solvency ratio $\geq 20\%$

$$(\text{"equity"} / \text{"total liabilities"})$$

In the case of a consortium of economic operators, this criterion must be met by each member of the consortium.

[2] Average annual turnover for supplies similar to this public contract.

This requirement is not cumulative in the case of a call for tenders for several lots, in which case the highest amount will be taken into account.

Annual turnover data			
Year	Amount and Currency	Exchange rate in force on the last day of the respective calendar year (into which the amounts for that year are to be converted).	Equivalent in euros

In order to be selected, the applicant's cumulative sectoral turnover over the last three financial years must be at least: EUR 800 000 excluding VAT.

By similar supplies is meant supplies which have a direct link with the supplies comparable to the present lots described in the annex "List of medical devices by lot" and these Tender Specifications under point 3.1 Technical specifications.

Technical and professional capacity of the tenderer

[1] The applicant will have a **list of principal deliveries of medical devices** ISO QMS certified **performed over the last three years** for public authority customers in the public or private sector, with for each customer cited, the full address and contact details of a contact person.

Requested documents: Two references for ISO 13485 QMS-certified medical devices performed to the highest professional standards and to the complete satisfaction of the customer, for public bodies for each lot in which the candidate wishes to participate:

Lot 1: Anaesthesia - intensive care / laundry / operating theatre / consultation / gas / medical furniture / pharmacy / sterilisation / functional support / testing and calibration / therapy and functional rehabilitation (see annex List of medical devices)

Lot 2: Medical imaging (see annex List of medical devices)

Lot 3: Laboratory (see annex List of medical devices)

[2] The candidate must demonstrate that he is capable of supplying high quality biomedical equipment and meeting the essential safety and performance requirements at the time of application.

To be selected, manufacturers of medical devices supplied by the applicant must have a quality management system (QMS) in place to guarantee the safety and quality of the products or services they market, from design to recycling.

Requested documents:

A copy of a valid ISO 13485 QMS or equivalent from 5 manufacturers per lot applied for.

For non-EU manufacturers, in addition to the ISO 13485 QMS certificate, the designation of an EU certification body is required.

[3] The candidate must demonstrate that he is able to carry out all installation, training, maintenance and repair work on the medical devices to be offered.

The company must have at least 3 qualified staff to carry out corrective and preventive maintenance, to train users in the correct use of medical devices (MD) and to train technicians in equipment maintenance: one technically trained engineer with at least 10 years' experience in the installation and maintenance of medical devices and two technicians with 2 years' higher education qualifications with at least 5 years' experience in the installation and maintenance of medical devices.)

Requested document(s):

The candidates must describe the way in which they carry out technical monitoring and maintenance in a concise document of no more than 5 single-sided A4 pages, including the following information: The technical and human resources available:

- Number and location of technicians and engineers who will be working on site (CVs supplied)

- List of equipment, tools and logistical resources available for maintenance - Description of technical premises (photos and precise address supplied)
- Organisation of the after-sales service
- Reasonable average installation time for MD supplied
- Reasonable average on-site response time during the warranty period
- Reasonable average repair time
- Conditions for submitting requests for assistance (telephone, e-mail, etc.) and full procedure for processing a request for assistance.

If the candidate is not established in the DRC, he must be represented by an agent capable of delivering, assembling, installing and commissioning the equipment, training users and maintenance technicians, and maintaining the equipment.

Proof must be provided at the latest before the public contract(s) is (are) signed. Failing this, the public contract(s) will not be awarded.

5.5 The right to submit a tender and how to submit tenders

Each time a need is expressed, DPS participants will be invited to submit a tender.

This invitation will be sent via the platform <https://www.publicprocurement.be/> to the attention of the contact person indicated in the request for participation form. If the contact person changes, the selected candidate must inform the contracting authority by e-mail.

The contracting authority imposes the use of digital means on pain of nullity of the tender.

The deadline for the submission of tenders is stated in the procurement documents.

Applications must be submitted electronically via the website <https://www.publicprocurement.be/> which guarantees compliance with the conditions set out in Article 14, §6 and 7 of the Law of 17 June 2016.

The contracting authority draws the attention of the candidates to the fact that submitting a tender by mail does not meet the conditions of Article 14, §6 and 7 of the Law of 17 June 2016.

By submitting his tender electronically, the candidate accepts that the data resulting from the operation of the system for receiving his application will be recorded.

The Opening of applications is behind closed doors via the e-Procurement platform.

The contracting authority will evaluate the applications on the basis of the selection criteria as set out in the procurement documents.

5.6 Change or withdrawal of a tender that has already been submitted

When a candidate wants to change or withdraw an application already sent or submitted this must be done in accordance with the provisions of Articles 43 and 85 of the Royal Decree of 18 April 2017.

To change or withdraw an application already sent or submitted a written statement is required, which will be correctly signed by the candidate or his representative. The subject-matter and the scope of the changes must be clearly indicated. Any withdrawal must be unconditional.

Where the submission report issued following modification or withdrawal is not signed by means of an electronic signature, the modification or withdrawal is automatically void. This nullity applies only to the modifications or withdrawal, not to the application itself.

6 Special contractual provisions

This chapter of these Tender Specifications holds the specific provisions that apply to this public contract by way of derogation from the 'General Implementing Rules for public procurement and for concessions for public works' of the Royal Decree of 14 January 2013, hereinafter referred to as 'GIR', or as a complement or an elaboration thereof. The numbering of the articles below (between brackets) follows the numbering of the GIR articles. Unless indicated, the relevant provisions of the General Implementing Rules (GIR) apply in full.

These Tender Specifications derogate Article 26 of the GIR.

6.1 Managing official (Art. 11)

Management of the Dynamic Purchasing System is entrusted to Stefaan Van Bastelaere, Senior Health Expert, e-mail: stefaan.vanbastelaere@enabel.be

The managing official is the main contact for the economic operators involved in the DPS. Any correspondence and any questions concerning the performance of the DPS will be addressed to him.

The managing official is fully competent for the follow-up of the satisfactory performance of the DPS, including issuing service orders, drawing up reports and states of affairs, approving the services, progress reports and reviews. The managing official may order any modifications to the public contract with regards to its subject-matter provided that they remain within its scope.

However, the signing of amendments or any other decision or agreement implying derogation from the essential terms and conditions of the contract are not part of the competence of the managing official. For such decisions, the contracting authority is represented as stipulated under point 3.2 Contracting authority.

Under no circumstances is the managing official allowed to modify modalities (e.g. delivery deadlines) of the public contract, even if the financial impact is nil or negative. Any commitment, change or agreement derogating the conditions in the Tender Specifications and that has not been notified by the contracting authority, will be considered null and void.

For each specific public contract concluded under the DPS, the managing official will be mentioned either in the Invitation to tender, or in the contract award notification.

Once the public contract is concluded, the managing official is the main contact point for the service provider. Any correspondence or any questions with regards to the performance of the public contract will be addressed to him or her, unless explicitly mentioned otherwise in these Tender Specifications (see namely, 'Payments' below).

The managing official is fully competent for the follow-up of the satisfactory performance of the public contract, including issuing service orders, drawing up reports and states of affairs, approving the services, progress reports and reviews. He or she may order any modifications to the public contract with regards to its subject-matter provided that they remain within its scope.

However, the signing of amendments or any other decision or agreement implying derogation from the essential terms and conditions of the contract are not part of the competence of the managing official. For such decisions, the contracting authority is represented as stipulated under point 1.1.2 Contracting authority.

Under no circumstances is the managing official allowed to modify modalities (e.g. delivery deadlines) of the contract, even if the financial impact is nil or negative. Any commitment, change or agreement derogating the conditions in the Tender Specifications and that has not been notified by the contracting authority, will be considered null and void.

6.2 Subcontractors (Art. 12 to 15)

The fact that the contractor entrusts all or part of his commitments to subcontractors does not relieve him of liability to the contracting authority. The latter does not recognise any contractual relation with third parties.

The contractor remains, in any case, solely liable to the contracting authority.

The service provider undertakes to having the public contract performed by the persons indicated in the tender), except for force majeure. The persons mentioned or their replacements are all deemed to effectively be involved in the performance of the public contract. Any replacements must be approved by the contracting authority.

When the contractor uses a subcontractor to carry out specific processing activities on behalf of the contracting authority, the same data protection obligations as those of the contractor are imposed on that subcontractor by contract or any other legal act.

In the same way, the contractor will respect and enforce to his subcontractors, the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation, GDPR). The contracting authority may conduct an audit of the processing carried out in order to validate compliance with this legislation.

6.3 Confidentiality (Art. 18)

Knowledge and information obtained by the contractor, including any persons responsible for the mission and any other person involved in this public contact, are strictly confidential.

Under no circumstances may the information collected, regardless of its origin and nature, be transferred to third parties in any form.

All parties directly or indirectly involved are therefore bound by the duty of discretion.

In accordance with Article 18 of the Royal Decree of 14 January 2013 establishing the general implementing rules for public procurement, the tenderer or contractor undertakes to consider and process in a strictly confidential manner any information, all facts, any documents and/or any data, whatever their nature and support, which have been communicated to him, in any form and by any means, or to which he has access, directly or indirectly, in the context or on the occasion of this public contract. Confidential information covers, in particular, the very existence of this public contract, without this list being limited.

Therefore, he undertakes to:

- Respect and enforce the strict confidentiality of these elements and to take all necessary precautions in order to preserve their secrecy (these precautions cannot in any case be inferior to those taken by the tenderer for the protection of his own confidential information);
- Consult, use and/or exploit, directly or indirectly, all of the above elements only to the extent

strictly necessary to prepare and, where applicable, to carry out this public contract (particularly regarding the privacy legislation with respect to personal data processing);

- Not reproduce, distribute, disclose, transmit or otherwise make available to third parties the above elements, in whole or in part, and in any form, unless having obtained prior and written consent of the contracting authority;
- Return, at the first request of the contracting authority, the above elements;
- In general, not disclose directly or indirectly to third parties, whether for advertising or any other reason, the content of this public contract, or the fact that the tenderer or contractor performs this public contract for the contracting authority, or, where applicable, the results obtained in this context, unless having obtained prior and written consent of the contracting authority. "

6.4 Intellectual property (Art. 19 to 23)

The contracting authority does not acquire the intellectual property rights created, developed or used during performance of the public contract.

Without prejudice to clause 1 and unless otherwise stipulated in the procurement documents, when the subject-matter of the public contract consists of the creation, manufacture or the development of designs or of logos, the contracting authority acquires the intellectual property thereof, as well as the right to trademark them, to have them registered and to have them protected.

For domain names created under the contract, the contracting authority also acquires the right to register and protect them, unless otherwise stipulated in the procurement documents.

Where the contracting authority does not acquire the intellectual property rights, it obtains a patent licence of the results protected by intellectual property law for the exploitation modes that are mentioned in the procurement documents.

6.5 Insurance

The tenderer has professional liability insurance cover for a minimum of three million euros per year; this amount is increased to twelve million euros for assignments carried out for public interest entities, i.e. mainly listed companies, credit institutions and insurance and reinsurance companies.

The policy covers at least all the tasks reserved for registered auditors by or under the Law of 7 December 2016 creating an Institute of Enterprises and organising public supervision of the business auditor profession.

6.6 Performance bond (Art. 25 to 33)

It will be determined by specific public contract if a performance bond is applicable.

6.7 Conformity of performance (Art. 34)

The supplies and services must comply in all respects with the procurement documents. Even in the absence of technical specifications in the procurement documents, the supplies and services must comply in all aspects with good practice.

The contractor of the public contract commits to supply, upon the demand of the contracting authority, any supporting documents related to the performance conditions of the contract. The

contracting authority will be allowed to proceed to any desk review or on-the-spot check which it considers necessary to collect evidence to support the presumption of unusual commercial expenditure. Depending on the gravity of the facts observed, the contractor having paid unusual commercial expenditure is liable to have his contract cancelled or to be permanently excluded.

6.8 Changes to the public contract (Art. 37 to 38/19)

6.8.1 Replacement of the contractor (Art. 38/3)

Provided that he meets the selection and exclusion criteria set out in this document, a new contractor may replace the contractor with whom the initial contract was agreed in cases other than those provided for in Art. 38/3 of the General Implementing Rules (GIR).

The contractor submits his request as quickly as possible by registered post, stating the reasons for this replacement and providing a detailed inventory of the state of the supplies and services already delivered, the new contractor's contact details and the documents and certificates which the contracting authority cannot access free of charge.

The replacement will be recorded in an amendment dated and signed by all three parties. The initial contractor remains liable to the contracting authority for the performance of the remainder of the public contract.

6.8.2 Revision of prices (Art. 38/7)

No price revision is possible for specific public contracts.

6.8.3 Compensation following suspension (Art. 38/12)

The contracting authority reserves the right to suspend the performance of the public contract for a given period, mainly when it considers that the public contract cannot be performed without inconvenience at that time.

The performance period is extended by the period of delay caused by this suspension, provided that the contractual performance period has not expired. If it has expired, the return of fines for late performance will be agreed.

When activities are suspended, based on this clause, the contractor is required to take all necessary precautions, at his expense, to protect the services already performed and the materials from potential damage caused by unfavourable weather conditions, theft or other malicious acts.

The contractor has a right to damages for suspensions ordered by the contracting authority when:

- The suspension lasts in total longer than one twentieth of the performance period and at least ten working days or two calendar weeks, depending on whether the performance period is expressed in working days or calendar days;
- The suspension is not owing to unfavourable weather conditions;
- The suspension occurred during the contract performance period.

Within thirty days of their occurrence or the date on which the contractor or the contracting authority would normally have become aware of them, the contractor reports the facts or circumstances succinctly to the contracting authority and describes precisely their impact on the progress and cost of the contract.

6.8.4 Unforeseen circumstances (Art. 38/11)

As a rule, the contractor is not entitled to any modification of the contractual terms due to circumstances of which the contracting authority was unaware.

6.8.5 Replacement of profiles performing the assignment

The contractor may propose the replacement of the profiles listed in point 5.4.4.4. [3] in accordance with the following terms and conditions.

The EO shall submit to the DPS's managing official, the expert's CV and the agreement of the expert to work for the account of the EO concerned.

The proposed profile must have similar skills and meet the minimum requirements (see point 5.4.4.4). [3].

If the new profile is not accepted, the contractor may either maintain the initial profile, propose another profile or be removed as a DPS participant for the lot concerned.

6.8.6 Submission conditions (Art. 38-14)

The contracting authority or contractor that wants to use one of the re-examination provisions as described in Articles 38/09 to 38/12, must report the facts or circumstances on which it bases itself in writing within 30 days of their occurrence or the date on which the contractor or the contracting authority would normally have become aware of them.

6.9 Preliminary technical acceptance (Art.41-42)

As a general rule, products may not be used if they have not been technically accepted by the managing official or his or her representative.

Products that at a given stage do not satisfy the technical acceptance tests imposed will be declared unfit for technical acceptance. Upon the request of the contractor, the contracting authority in accordance with the procurement documents verifies whether the products have the required qualities or at the very least comply with good practice and satisfy the conditions of the contract. If certain products are destroyed during verification, the contractor replaces these at his own expense. The procurement documents specify the quantity of products to be destroyed.

Where the contracting authority declares that the product presented is not in the required condition for examination, the acceptance request by the building contractor will be considered not having been made. A new request is made when the product is fit for acceptance.

6.10 Performance modalities (Art. 115 et seq.)

6.10.1 Deadlines and terms (Art. 116)

Deadline requirements will be defined when the tender is submitted.

6.10.2 Quantities to be supplied (Art. 117)

Quantities will be defined when the tender is submitted.

6.10.3 Place where the supplies must be delivered and formalities (Art.

149)

The requirements concerning the place of delivery will be defined when the tender is submitted.

6.10.4 Packaging (Art. 119)

Packaging will become the property of the contracting authority, without the supplier having any claim to compensation in this regard.

6.10.5 Inspection of the supplies delivered (Art. 120)

The supplier delivers only goods that have no apparent and/or hidden defects and that correspond strictly to the order (in kind, quantity, quality...) and, if necessary, to the prescriptions of related documents as well as applicable regulations, in compliance with good practice, the state of the art, the highest standards of usage, of reliability and of longevity, and for the purposes that the contracting authority has in mind, which the supplier knows or at least should know.

Acceptance (provisional acceptance) only takes place after the complete inspection by the contracting authority of the conformity of the goods and services delivered. The contracting authority disposes of a period for verification of thirty days starting on the date of delivery. This period will begin on the day after arrival of the supplies at the place of delivery, provided that the contracting authority is in possession of the delivery note or invoice.

The signature of (a staff member of) the contracting authority, in particular in electronic reception devices, upon delivery of the goods, does consequently only count as evidence of taking possession and does not concern the acceptance of the goods.

Acceptance on the premises of the contracting authority or, where applicable, on a site counts as complete provisional acceptance.

Acceptance implies the transfer of ownership and of risks of damage and loss.

In case of full or partial refusal of a delivery, the supplier is bound to take back, at his own costs and risks, the products refused. The contracting authority may ask the supplier to deliver goods that comply as soon as possible, either cancel the order and get supplied by another supplier.

6.10.6 Liability of the supplier (Art. 122)

The supplier shall be liable for his supplies up to the time when the inspection and notification formalities referred to under Art. 120 are carried out, unless losses or damage sustained in the warehouses of the consignee are due to the events or circumstances referred to in Articles 54 and 56.

Moreover, the supplier indemnifies the contracting authority against damages for which it is liable towards third parties due to late performance of the public contract or due to failure of the supplier.

6.11 Zero tolerance Sexual Exploitation and Abuse

In application of Enabel's Policy regarding Sexual Exploitation and Abuse of June 2019 there will be zero tolerance towards any misconduct that could impact the professional credibility of the tenderer.

6.12 Means of action of the contracting authority (Art. 44–51 and 123–126)

The service provider's default is not solely related to services as such but also to the whole of the service provider's obligations.

In order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the public contract, it is strictly forbidden to the service provider to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to appointees of the contracting authority who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the contract, regardless of their hierarchical rank.

In case of violation, the contracting authority may impose a lump-sum fine to the service provider for each violation, which can be up to three times the amount obtained by adding up the (estimated) values of the advantage offered to the employee and of the advantage that the contractor hoped to obtain by offering the advantage to the employee. The contracting authority will decide independently about the application and the amount of this fine.

This clause is without prejudice to the possible application of other measures as of right provided in the GIR, namely the unilateral termination of the contract and/or the exclusion from procurement by the contracting authority for a determined duration.

6.12.1 Failure of performance (Art. 44)

§1 The contractor is considered to be in failure of performance under the public contract:

- 1° when performance is not in accordance with the conditions specified in the procurement documents;
- 2° at any time, when performance has not progressed in such a way that it can be fully completed on the due dates;
- 3° when he does not comply with written orders, which have been given in due form by the contracting authority.

§2 Any failure to comply with the provisions of the public contract, including non-compliance with orders of the contracting authority, is recorded in a report ('process verbal'), a copy of which will be sent immediately to the contractor by registered mail.

The contractor must repair the defects without any delay. He may assert his right of defence by registered letter addressed to the contracting authority within fifteen days from the date of dispatch of the report ('procès-verbal'). Silence on his part after this period shall be deemed acknowledgement of the reported facts.

Any defects detected that can be attributed to the contractor render him liable to one or more of the measures provided for in Articles 45 to 49, 154 and 155.

6.12.2 Fines for delay (Art. 46 and 123)

The fines for delay differ from the penalties referred to in Article 45. They are due, without the need for notice, by the mere lapse of the performance period without the issuing of a report and they are automatically applied for the total number of days of delay.

Regardless of the application of any fines for delay, the contractor indemnifies the contracting authority against damages for which it is liable towards third parties due to late performance of the

public contract.

6.12.3 Measures as of right (Art. 47 and 124)

§1 When, upon expiry of the term given in Article 44, §2, the contractor has not taken action or has presented means deemed unjustified by the contracting authority, the contracting authority may apply the measures as of right described in paragraph 2.

However, the contracting authority may apply measures as of right without waiting for the expiry of the term given in Article 44, §2, when the contractor has explicitly recognised the defects detected.

§2 The measures as of right are:

1° Unilateral termination of the contract. In this case the entire performance bond, or if no bond has been posted an equivalent amount, is acquired as of right by the contracting authority as lump sum damages. This measure excludes the application of any fine for delay in performance in respect of the terminated part;

2° Performance under regime of all or part of the non-performed contract;

3° Conclusion of one or more replacement contracts with one or more third parties for all or part of the contract remaining to be performed.

The measures referred to in 1°, 2° and 3° will be taken at the expense and risk of the defaulting contractor. However, any fines or penalties imposed during the performance of a replacement contract will be borne by the new contractor.

6.13 End of the public contract

6.13.1 Acceptance of the products delivered (Art. 64-65 and 128)

The managing official will closely follow up the delivery.

The products are stored for delivery in the supplier's warehouses. Delivery cannot occur prior to the contracting authority's accepting the goods stored for delivery. The managing official who will carry out acceptance is named in the contract award notification if his/her name has not yet been mentioned in the procurement documents.

Provisional acceptance

Upon expiry of the thirty-day period specified in Article 120, §2, as appropriate, a provisional acceptance report or acceptance refusal report will be drawn up.

Full acceptance is proceeded to at the place of delivery without partial acceptance at the place of manufacture;

Provisional acceptance is carried out in full at the place of delivery. To investigate and test the supplies as well as to notify its decision to accept or reject the delivery, the contracting authority disposes of a period of thirty days

This period will begin on the day after the date of arrival of the supplies at the place of delivery, provided that the contracting authority is in possession of the delivery slip or invoice. It comprises the 30-day period stipulated in Article 120.

6.13.2 Transfer of ownership (Art. 132)

The contracting authority automatically becomes the owner of the supplies as soon as they have been accepted for payment pursuant to Article 127 of GIR.

6.13.3 Guarantee period (Art. 134)

The warranty period commences on the date on which provisional acceptance is given. This will be determined for each specific public contract.

6.13.4 Final acceptance (Art. 135)

Final acceptance occurs upon expiry of the warranty period. It is implicit when the delivery has not led to any claims during said period.

If delivery has led to complaints during the warranty period, a final acceptance or refusal of acceptance report will be issued within 15 days prior to the expiry of said period.

6.14 Invoicing and payment of services (Art. 66 to 72 and 127)

The contractor sends (one copy only of) the invoices and the public contract acceptance report (original copy) to the managing official (see above).

Only delivery that has been performed correctly may be invoiced.

The contracting authority disposes of a period for verification of thirty days starting on the end date of the delivery, established in conformity with the modalities in the procurement documents, to carry out the technical acceptance and provisional acceptance formalities and to notify the result to the supplier.

The amount owed to the supplier must be paid within thirty days with effect from the expiry of the verification term or with effect from the day after the last day of the verification term, if this is less than thirty days. And provided that the contracting authority possesses, at the same time, the duly established invoice and any other documents that may be required.

When the procurement documents do not provide for any separate debt claim, the invoice will constitute the debt claim.

The invoice must be in EUROS.

In order for Enabel to obtain the VAT exemption and customs clearance documents as quickly as possible, the original invoice and all ad hoc documents will be transmitted as soon as possible before provisional acceptance.

6.15 Litigation (Art. 73)

The competent courts of Brussels have exclusive jurisdiction over any dispute arising from the performance of this public contract. French or Dutch are the languages of proceedings.

The contracting authority will in no case be held liable for any damage caused to persons or property as a direct or indirect consequence of the activities required for the performance of this contract. The contractor indemnifies the contracting authority against any claims for compensation by third parties in this respect.

In case of 'litigation', i.e. court action, correspondence must (also) be sent to the following address:

Belgian development agency - Enabel
Legal unit of the Logistics and Acquisitions service (L&A)
To the attention of Inge Janssens
rue Haute 147
1000 Brussels
Belgium

7 Terms of reference

7.1 Technical specifications

For class I and II medical equipment and in vitro diagnostic equipment, all categories must be new and guaranteed original. They must be free of any flaw or defect that could harm their appearance and proper functioning and they must comply with the "Technical forms".

- Class I medical equipment: a medical device used for medical purposes to diagnose, prevent, monitor, treat or alleviate a disease, injury or disability. These devices are considered to have a low risk for the patient.
- Class II medical equipment: products used for medical purposes to diagnose, prevent, monitor, treat or alleviate disease, injury or disability. These devices are considered to have a moderate to high risk for the patient.

The supply of medical devices that do not comply with European Directive 2017/746 is prohibited and may be subject to cancellation of the application.

See annex "List of medical devices by lot".

The tenderer attaches the following to his tender:

- EC declaration of conformity in accordance with Directive 93/42/EC and ISO 13485 QMS-certified manufacturers.
- Certificate of authorisation for sale and after-sales service from the manufacturer in the applicant's name for each model of MD proposed for the public contract.

8 Forms

8.1 Request for Participation form

REQUEST FOR PARTICIPATION IN THE DYNAMIC PURCHASING SYSTEM FOR SUPPLIES
FOR THE ACQUISITION, INSTALLATION AND MAINTENANCE OF CLASS I AND II
MEDICAL EQUIPMENT AND IN VITRO DIAGNOSTIC EQUIPMENT IN THE DEMOCRATIC
REPUBLIC OF THE CONGO

BXL 14628

Enabel, Belgian development agency

Rue Haute 147, 1000 Brussels

Restricted Procedure

Important: this form must be completed in full.

Phase 1 - Selection

Important: this form must be completed in full. The candidate or his authorised representative must sign and date the submission report on the e-Procurement platform.

Identity of the candidate

Natural person

The undersigned (name and first name):

Capacity or profession:

Nationality:

Domicile (full address):

Tel.:

Mobile phone:

Fax:

E-mail:

Contact person:

or (1)

Legal person

Firm (full legal name, social purpose):

Nationality:

Represented by the undersigned (name(s), first name(s) and function(s))

Official registration number:

Full official address:

VAT registration number:

Tel.:

Fax:

E-mail:

All documents must be drawn up or completed by the candidate or by a person authorised and duly authorised to represent the candidate. The candidates attach to their request for participation in the public contract any supporting document attesting to the powers of its representative(s).

When the request for participation in the public contract is signed by a mandatary, he or she must clearly indicate whom he or she represents. The mandatary attaches the original electronic deed or private document that transfers these powers to him or her or a scanned copy of that proxy. He or she refers, where appropriate, to the number of the Annexe to the Belgian Official Gazette in which the excerpt of the deed concerned is published and provides the page(s) and/or passage concerned.

OR Group of economic operators (including temporary associations)

Name and first name(s) or social purpose of the candidates and legal form:

Capacity or profession:

Nationality:

Address or Registered office:

Tel.:

Mobile phone:

Fax:

E-mail:

Contact person:

Name and first name(s) or social purpose of the candidates and legal form:

Capacity or profession:

Nationality:

Address / Registered office

Tel.:

Mobile phone:

Fax:

E-mail:

Contact persons:

These details must be completed for each participant in the consortium.

The group is represented by one of the participants, whose name is:

All documents must be drawn up or completed by the candidate or by a person authorised and duly authorised to represent him (for temporary associations: see Article 44, § 1 of the Royal Decree of 18 April 2017). The candidates attach to their request for participation in the public contract any supporting document attesting to the powers of its representative(s).

When the request for participation in the public contract is signed by a mandatary, he or she must clearly indicate whom he or she represents. The mandatary attaches the original electronic deed or private document that transfers these powers to him or her or a scanned copy of that proxy. He or she refers, where appropriate, to the number of the Annexe to the Belgian Official Gazette in which the excerpt of the deed concerned is published and provides the page(s) and/or passage concerned.

Submits a request for participation in the Dynamic Purchasing System for the acquisition, installation, maintenance and training of medical equipment and in vitro diagnostic equipment in the Democratic Republic of the Congo for the following lots of the above-mentioned public contract.

Lot 1:

Lot 2

Lot 3

General information

National Social Security Office registration number:

Enterprise number (Belgium only):

Subcontractors

Subcontractors will be relied on: YES / NO (*delete as appropriate*)

The following subcontractors will be relied on:

- Company name / name, first name:
- No. with Enterprise Crossroads Bank
- National Social Security Office and/or INASTI/RSVZ registration number(s)
- Registered office
- Legal representative(s)
- Landline / mobile phone
- E-mail
- Commitment to perform the public contract

Subcontractors

- Subcontractors will be relied on: YES / NO (*delete as appropriate*)

Workforce

Employees subject to the social legislation of another EU Member State are employed:

YES / NO (*delete as appropriate*)

To this request for participation I/we enclose:

The ESPD by means of which the economic operator declares that he is not in one of the situations listed in Articles 67 to 69 of the Law of 17 June 2016.

Documents to be attached to the requests for participation

This request for participation must also be accompanied by:

- documents required by the selection guide.

Done at

On

Name of the candidate

8.2 Capacity of third parties – Formal commitment – Declaration on honour

(To be filled out and signed by the third party)

Hereby, I undersigned,
(Name, first name, function)

declaration on my honour that.....
(name of the third-party company and enterprise number)

will put at the disposal of tenderer
(name of the tenderer and enterprise number)

the capacities and resources the latter claims in order to meet the requirements of this Dynamic Purchasing System BXL 14628 for the qualitative selection for the whole term of the DPS.

The resources concerned are the following (to be completed in a clear way):

- ...
- ...
- ...

Company stamp:



Last name, first name:

Function:

Date:

Signature:

8.3 ESPD

For the qualitative selection of the tenderers, tenderers shall fill out the European Single Procurement Document (ESPD).

See also point 1.3.7.1

8.4 List of subcontractors

Name and legal form	Address / Registered office	Subject-matter

8.5 Declaration on honour – Exclusion grounds

Hereby, I / we, acting as legal representative(s) of above-mentioned tenderer declare that the tenderer is not in any of the following cases of exclusion:

1. The tenderer nor any of his directors was found guilty following an **indefeasible judgement** for one of the following offences:
 - 1° involvement in a criminal organisation
 - 2° corruption
 - 3° fraud
 - 4° **terrorist offence**, offence linked to terrorist activities or incitement to commit such offence, collusion or attempt to commit such an offence
 - 5° **money laundering or financing of terrorism**
 - 6° **child labour** and other trafficking in human beings
 - 7° employment of foreign citizens under **illegal status**
 - 8° creation of a shell company.The exclusions on the basis of this criterion apply for a 5-year term from the date of judgement.
2. The tenderer has failed to fulfil his obligations to **pay taxes or social security contributions** for an amount in excess of EUR 3 000, except if the tenderer can demonstrate that a contracting authority owes him one or more unquestionable and due debts which are free of all foreseeable liabilities. These debts are at least of an amount equal to the one for which he is late in paying outstanding tax or social charges.
3. The tenderer is in **a state of bankruptcy, liquidation, cessation of business, judicial reorganisation** or has admitted bankruptcy or is the subject of a liquidation procedure or judicial reorganisation, or in any similar situation resulting from a procedure of the same kind existing under other national regulations.
4. The tenderer or one of his directors has committed **serious professional misconduct which calls into question their integrity.**

Are also considered such serious professional misconduct:

- a. A breach of Enabel's Policy regarding sexual exploitation and abuse – June 2019
- b. A breach of Enabel's Policy regarding fraud and corruption risk management – June 2019
- c. A breach of a regulatory provision in applicable local legislation regarding sexual harassment in the workplace
- d. The tenderer was seriously guilty of misrepresentation or false documents when providing the information required to verify that there are no grounds for exclusion or that selection criteria are satisfied, or concealed information
- e. Where Enabel has sufficient plausible evidence to conclude that the tenderer has committed acts, entered into agreements or entered into arrangements to distort competition.

The presence of this tenderer on one of Enabel's exclusion lists as a result of such an act/agreement/arrangement is considered to be sufficiently plausible an element.

5. When a conflict of interest cannot be remedied by other, less intrusive measures;
6. When **significant or persistent failures** by the tenderer were detected during the execution of an **essential obligation** incumbent on him in the framework of a past contract concluded with another contracting authority, when these failures have given rise to measures as of right, damages or another comparable sanction. Also failures to respect applicable obligations regarding environmental, social and labour rights established by European Union legislation, national law, labour agreements or international provisions on environmental, social and labour rights are considered 'significant'.
The presence of the tenderer on the exclusion list of Enabel because of such a failure serves as evidence.

7. Restrictive measures have been taken vis-à-vis the contractor with a view of ending violations of international peace and security such as terrorism, human-rights violations, the destabilisation of sovereign states and proliferation of weapons of mass destruction.

8. The tenderer or one of his directors are on the lists of persons, groups or entities subject to United Nations, European Union or Belgian financial sanctions:

For the United Nations, the lists can be consulted at the following address:
<https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctions-internationales-nations-unies>

For the European Union, the lists can be consulted at the following address:
<https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctions-europ%C3%A9ennes-ue>

<https://eeas.europa.eu/headquarters/headquarters-homepage/8442/consolidated-list-sanctions>

https://eeas.europa.eu/sites/eeas/files/restrictive_measures-2017-01-17-clean.pdf

For Belgium:

https://finances.belgium.be/fr/sur_le_spf/structure_et_services/administrations_generales/tr%C3%A9sorerie/contr%C3%B4le-des-instruments-1-2

9. If Enabel executes a project for another funder or donor, other grounds for exclusion may be added.

The tenderer formally declares being able, when asked and without delay, to provide the relevant certificates and other kinds of supporting documents, except if:

- a. Enabel can directly obtain the supporting documents concerned by consulting a national database in a Member State that is accessible for free, provided the tenderer has given the required information (website address, responsible authority for providing the information, specific reference of the documents) so Enabel can obtain these, with concomitant permission to access them;
- b. Enabel already has said documents.

The tenderer formally agrees with Enabel accessing the supporting documents substantiating the information provided in this document.

Date

Signature

8.6 Overview of the documents to be submitted

The application will consist of the following documents:

Administrative documents:

- Form 8.1 Request for Participation form (for each participant for tender submitted by a group)
- Form 8.2 Third-party capacity - Formal undertaking by subcontractors to make the necessary resources available to the candidate for the performance of the public contract
- Form 8.3 Filled out ESPD
- Form 8.4 List of subcontractors
- Form 8.5 Declaration on honour – Exclusion grounds (for each participant for tender submitted by a group)
- Evidence of fulfilling the selection criteria
- All documents attesting to the authority of the person signing the application to bind the company with regard to public contracts
- A certified copy of the certificate of registration in the Trade and Personal Property Credit Register, dated less than 12 months, certifying that the candidate is registered and that its sector of activity is the supply, installation and maintenance of medical equipment for tenderers registered in DR Congo.
If you are a foreign company, you must present proof of registration as an economic operator in your country.
- If the applicant company is not Belgian, it must enclose with its application proof that it is in a situation of exclusion linked to the existence of tax and/or social debts.
- A document less than ninety days old, drawn up in accordance with the tenderer's national legislation or practice, certifying that the tenderer is not bankrupt or the subject of proceedings for a declaration of bankruptcy, liquidation, judicial settlement, preventive condemnation or any other similar proceedings.
- The statutes and any other document required to establish the power of attorney of the signer(s) (for each participant for application submitted by a group)
- Where the application is submitted by a group of economic operators, the association agreement signed by each participant, clearly showing who represents the association
- If the enterprise is not Belgian, it must enclose with its application all documents attesting to the composition of its Board of Directors (extracts from the statutes, etc.).
- Copies of the criminal records of the enterprise and of the members of the Board of Directors
- An extract from the subcontractor's criminal record (of the enterprise only, not of the Board of Directors).

Documents pertaining to selection:

- Balance sheets certified by a registered accountant for the last three financial years and proof that the accountant's registration is up to date.
For a group of economic operators, each member of the group of economic operators must provide their own financial statements.
- Form given in point 5.4.4.4 [1]
- Average annual turnover for supplies similar to this public contract. This requirement is not cumulative in the case of a call for tenders for several lots, in which case the highest amount will be taken into account.

- List of main medical device deliveries over the last three years by lot.
- Two medical device references performed to the highest professional standards, subject to European Regulation (EU) 2017/745 and from ISO 13485 QMS-certified manufacturers to the complete satisfaction of the customer, for public bodies per lot
- A copy of a valid ISO 13485 or equivalent QMS from 5 manufacturers per lot. For non-EU manufacturers, in addition to the ISO 13485 QMS certificate, the designation of an EU certification body is required.
- Description of maximum 5 pages A4 recto + CV + list of equipment, tools and logistical resources:
 - Number and location of technicians and engineers who will be working on site (CVs supplied)
 - List of equipment, tools and logistical resources available for maintenance - Description of technical premises (photos and precise address supplied)
 - Organisation of the after-sales service
 - Reasonable average installation time for MD supplied
 - Reasonable average on-site response time during the warranty period
 - Reasonable average repair time
 - Conditions for submitting requests for assistance (telephone, e-mail, etc.) and full procedure for processing a request for assistance.
- Where an economic operator wants to rely on the capacities of other entities (particularly subcontractors) for technical and professional capacity criteria, it shall prove to the contracting authority that it will have at its disposal the resources necessary, for example, by producing a commitment by those entities to that effect.