



Leids Universitair
Medisch Centrum

Descriptive Document

“FLI-BLI CT System”

Reference L-EU-23-08

On behalf of the LUMC

September 2023

Final version



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Definitions

A number of terms are capitalised in this Descriptive Document. The definitions of these terms are provided below.

Contracting Party

The legal entity governed by public law named Leiden University Hospital, acting under the name Leiden University Medical Center and registered in the Chamber of Commerce under number 27366422, henceforth referred to in this document as the LUMC.

Tender Documents

All documents that the LUMC has written or mentioned for describing or determining parts of the tender or the procedure. This concerns but is not limited to this Descriptive Document, the Appendices and the Information Note(s), i.e. tender documentation.

Public Procurement Act of 2012

The revised Public Procurement Act of 2012 took effect on 1 July 2016. European procurement directives 2014/23, 2014/24 and 2014/25 were implemented with these changes.

General Purchasing Conditions

General Purchasing Conditions of Leiden University Medical Center (LUMC), version dated May 2021.

Descriptive Document

This Tender Document, with which Tenderers who comply with the minimum requirements are invited to submit a Tender.

Appendices

Appendices that belong to this Descriptive Document that form an integral part of the Tender Document.

Third Party

A Tenderer on whom a Tenderer calls upon to meet the eligibility requirements and/or to implement a part of the Contract.

Award Decision

The LUMC's choice of Tenderer(s) with whom it wants to conclude the Agreement to which this procedure relates, including the choice not to conclude an Agreement.

Tenderer

An entrepreneur (contractor, supplier or service provider) who has submitted a Tender, either independently, as a general contractor or in a Joint Venture (alliance partnership) or who behaves during the tender procedure as if he might intend to submit a Tender.

Tender

Quotation submitted by a Tenderer within the framework of this tender.

Information Notes

Written response from the LUMC to questions that were asked by the Tenderer in a timely and correct fashion based on the Tender Documents. The Information Note can also contain messages from the LUMC. If questions are answered in an electronic system, then every individual response should be considered as an Information Note.

Contract

The deliveries and/or services that are executed by the winning Tenderer(s) pursuant to the Agreement.

Contractor

The Tenderer with whom the Client has concluded the Agreement.

Client

See Contracting Party.

Agreement

The mutual framework agreement, service provision agreement and/or delivery agreement based on which the Contract is executed and whose creation this tender procedure intends.

Joint Venture (alliance partnership)

An alliance partnership of Tenderers in the capacity of the Tenderer who are individually severally liable for the Tender and the execution of the Contract.

Written/In Writing

Every entity consisting of words or numbers that can be read, reproduced and communicated, including information transferred or saved using electronic means.

TenderNed

The electronic tender system as referred to in Article 4.13 of the Public Procurement Act of 2012. See www.tenderned.nl

ESPD

European Single Procurement Document (ESPD), also called 'individual statement'. Declaration completed, signed and submitted at tender submission pursuant to the standard form as intended by Implementing Regulation (EU) of the European Committee dated June 2021.

Chapter 1 Introduction

1.1 Summary

This Descriptive Document is part of the European public tender for the delivery of a FLI-BLI CT System whereby an Agreement will be concluded with one (1) Contractor.

The announcement of this Contract will be published at www.tenderNed.nl and in the Supplement to the European Union's Official Journal (T.E.D.). All Tenderers who meet the minimum requirements are invited to submit a Tender either individually, in a Joint Venture (alliance partnership) or through Third Parties.

This Descriptive Document and associated Appendices explain the Contract, the tender procedure, the requirements which the Tenderers and their Tenders must meet and the manner in which the most economically advantageous Tender is chosen.

1.2 Choice of tender procedure

The Public Procurement Act of 2012 applies to this tender. Because the European threshold amount for deliveries and services for local authorities (in 2022: € 215,000 excl. VAT) is expected to be exceeded and no legal exceptions apply, an European tender must be held. In principle, there is a choice between two procedures: a public or a so-called non-public procedure.

It was decided that this Contract would undergo a European tender procedure through a public tender procedure. This choice is mainly based on the scope and complexity of the contract and the number of potential Tenderers.

1.3 Digital tender submission with TenderNed

The entire tender procedure is digital using TenderNed. This means that:

- a) All Tender Documents will be made available digitally and free of charge via TenderNed
- b) Questions can be asked using the TenderNed question-and-answer function.
- c) Tenders must be submitted digitally.
- d) All additional correspondence will essentially take place using the TenderNed messaging module.

1.4 Contact during the tender procedure

Until the time of the definitive contract awarding, Ms. Chantal van Es, Senior Purchaser, or his/her deputy is the only point of contact for Tenderers with regard to this tender procedure. In principle, all correspondence takes place via TenderNed. Should this not be possible for technical reasons or should other contact be truly necessary, then Tenderers can initiate contact through Aanbestedingen@lumc.nl.

If Tenderers experience technical problems, they should contact the TenderNed Service Desk and not the LUMC. The Service Desk is available on business days from 8:30 AM to 17:00 PM at 0800-

836 33 76 (NL) or +31 70 379 88 99 (from abroad). Also Tenderers can find manuals and how-to videos on TenderNed.

1.5 Planning (indicative)

Within a tender procedure, Tenderers must take timely action at various moments. The LUMC strives to carry out the planning as indicated in TenderNed. If no explicit notice to the contrary is received, Tenderers should assume that said planning will be adhered to.

1.6 Reading guide

The rest of this Descriptive Document consists of five chapters, a checklist and various Appendices:

- Chapter 2 discusses the goal of the tender, the type, scope and duration of the Contract and the context in which it takes place.
- Chapter 3 describes the tender requirements and the course of the procedure.
- Chapter 4 describes the minimum requirements that Tenderers must meet in order to submit a Tender.
- Chapter 5 describes the contract awarding criteria and the way the Tenders are assessed.

The following Appendices are an inseparable part of this Descriptive Document:

- European Single Procurement Document (ESPD)
- Price List
- Core Competencies Document
- Schedule of Requirements Document
- Purchase Agreement
- LUMC General Purchasing Conditions

Chapter 2 The LUMC and the Contract

This chapter describes the Contract, the background of the tender, the objectives the LUMC is aiming for, the type and scope of the activities and the most important characteristics of the Agreement on the basis of which the Contract will be executed.

2.1 About the LUMC

The LUMC is a modern university medical centre for research, education and patient care with an excellent quality profile and a strong scientific focus. With a unique research practice of fundamental beta medical to applied clinical research, the LUMC is a global player in its field. The LUMC can hence also offer patient care and education based on the latest international insights and standards - and contribute to improving medicine and health care at its own institution and outside of it. The LUMC also acts as a knowledge centre for social issues regarding public health, plays a regional guiding role and is a centre for training and continuing education for medical professionals. The triangle formed with the University of Leiden and the Bio Sciencepark creates unique possibilities for medical innovation in and around Leiden.

For more information about the LUMC, please refer to the website www.lumc.nl.

2.2 Reason for the tender

The reason for this tender is the need to replace the current equipment. The current FLI/BLI – CT System was purchased many years ago and has now reached its technical lifespan. There are several suppliers that can offer such a system. For this reason, it was decided to start a tender competition to purchase a new FLI-BLI – CT System.

2.3 Objective of the tender

The LUMC hopes to achieve the following objectives with this tender and the agreement resulting from it:

1. Get a high-quality device delivered for a competitive price;
2. Gain access to professional support and pro-active services;
3. User-friendly workflow and data processing, facilitating good laboratory practices.

The LUMC translated these objectives into the demarcations of the Contract, the requirements for the execution of the Contract, the requirements for the Tenderers in order to be eligible for the Contract and the manner in which the most economically advantageous Tender will be chosen.

2.4 Merging of Contracts and separation into parcels

In the opinion of the LUMC, there will be no merging of Contracts for this Contract. The assignment is considered uniform. Therefore, differentiation in parcels is unnecessary.

2.5 Type of Contract

The tender concerns the delivery and (corrective) maintenance of a FLI/BLI – CT System. This device will be used as a preclinical imaging system for bioluminescence and fluorescence in small laboratory animals. It consists of two parts:

1. Device to measure fluorescence and bioluminescence;
2. CT device.

Both parts must be supplied by the same Tenderer.

The equipment is intended for the preclinical imaging facility of the LUMC. It will therefore be used by many different departments and users of the LUMC. The main user groups are the departments:

- Radiology
- Immunology
- Parasitology
- Cell and chemical biology
- The Central Animal Facility
- Heart disease
- Anatomy
- Hematology

The device is not a medical device in accordance with the MDR and/or IVDR regulations.

The minimum requirements that the Contractor must meet are specified in the Tender Documents. By submitting a Tender, Tenderers unconditionally declare that they meet these requirements, under penalty of exclusion.

Chapter 3 Procedural aspects and rules

This chapter describes the procedural aspects regarding the tender and the tender requirements. Tenderers must fully comply with these rules. If this is not the case, the LUMC may decide to exclude the Tenderer from participation.

3.1 General tender rules

1. The LUMC is not obligated to award the Contract.
2. The LUMC will in no way reimburse costs incurred by the Tenderers relating to this tender procedure. The LUMC intends to successfully complete the tender procedure. However, if situations arise (such as no budget is allocated) that result in a decision being made to stop the tender process in part or in its entirety, temporarily or definitively, and/or not to award the Contract, then the participating Tenderer has no right to compensation of any type whatsoever.
3. Exclusively Dutch law applies to this tender. A dispute between the parties involved in the tender, including a dispute that is only considered as such by one of the parties involved, which occurs due to this tender will be adjudicated by the competent court in the district of The Hague.

3.2 Communication, confidentiality of data and publicity

1. The Tenderer may only use the data that the LUMC makes available in connection with this tender for the objective for which the data were provided: (possible) participation in the tender.
2. The Tenderer is obligated to treat the data provided by the LUMC confidentially. A Tenderer will also impose this obligation on any auxiliary agents that he hires, such as a consulting firm that assists the Tenderer with compiling the Tender or a Third Party that may be solicited. It goes without saying that this confidentiality will also remain in effect after the tender procedure has been completed.
3. Publicity or advertising regarding, due to or with reference to this tender by or on behalf of the Tenderer, during or after completion of the tender is only permitted after prior Written consent from the LUMC.
4. The Tenderer is not permitted to approach persons working for the LUMC organisation in connection with this tender procedure, other than the contact described in chapter 1, unless the reason is to obtain reference contracts that can be used by the Tenderer during this tender procedure to demonstrate his eligibility.
5. Verbal announcements, commitments or agreements are not permitted within the scope of this tender and have no legal force. This also applies to verbally asked questions during an inspection or informational meeting; these must also be posed in Writing and be answered by the LUMC in an Information Note before they have legal force.

6. All data exchanges, activities and correspondence during the tender procedure and when executing the Contract will take place in Dutch or English, unless expressly specified otherwise.

3.3 Rules for asking questions

1. The LUMC invites Tenderers to ask questions, which includes making text proposals and comments, etc.
2. Questions can be submitted in TenderNed.
3. In order to enable proper processing by the LUMC, every question must be asked separately, with a clear reference to the part of the Tender Documents to which the question refers and without mentioning company information.
4. The LUMC will answer the questions asked in Writing in one or more Information Note(s).
5. These Tender Documents have been compiled with care. Should the Tenderer nevertheless come across contradictions and/or deficiencies (in the broadest sense of the word), then the Tenderer must notify the LUMC of this as quickly as possible but at the latest before the last deadline for asking questions as stipulated in the planning on penalty of forfeiture of rights and loss of rights. The LUMC is not obligated to answer questions received after this deadline.
6. If a Tenderer believes that there are (still) contradictions and/or deficiencies after receiving an Information Note, then the Tenderer must, on penalty of forfeiture of rights and loss of rights, apply for an interim injunction against the LUMC as soon as possible but at the latest before submission of his Tender.
7. The LUMC expects a proactive attitude from Tenderers that contributes to the success of this tender. It is expressly not permitted to wait to voice objections until after the moment when the LUMC makes decisions within the scope of this tender (such as the announcement of the contract award decision). Objections must be voiced in accordance with the Tender Documents at a time when any contradictions and/or deficiencies can be eliminated (if necessary).
8. By submitting a Tender, the respective Tenderer expressly agrees to all aspects of this tender. If no questions or comments or an interim injunction as specified above are forthcoming, then the LUMC will trust that the tender process can be continued and that it can start receiving the Tenders. Tenderers who do not object to the content of the Tender Documents or submit an interim injunction in a timely fashion will forfeit the right to later take legal action against the supposed contradictions and/or deficiencies within the scope of this tender procedure.

3.3.1 Asking individual questions

1. Based on Art. 2:53, section 3 of the Public Procurement Act of 2012, Tenderers have the opportunity to ask questions individually if disclosure of this information would harm the company's legitimate economic interests. The assumption is that information will

not be individually provided unless the Tenderer has provably demonstrated in the LUMC's opinion that the above-mentioned case regarding harming of interests applies. If a Tenderer wishes to make use of this possibility, he must substantiate the reasons for this in his question. If substantiation is missing or is insufficient in the LUMC's opinion, then the question will be rejected and will have to be asked again, if desired, as a non-individual question.

2. The LUMC will respond to the Written individual questions which it considers eligible for an individual answer in an individual Information Note.

3.3.2 Complaints procedure

1. A complaint is a written notification by a Tenderer in which said Tenderer indicates, with substantiation, the points in the Tender Documents or of the tender procedure with which he disagrees. Complaints may stipulate that a certain action or lack of action on the part of the LUMC is in conflict with legal provisions or other regulations that apply to this tender.
2. Complaints about this tender must first be voiced by Tenderers by asking questions in a timely fashion. If the complaint is not adequately answered in the Information Note(s), then a complaint can be submitted to kma@lumc.nl. A complaint is a Written notification from a Tenderer who has a vested interest in this tender. In the complaint the Tenderer must indicate, with substantiation, the points of the tender or parts thereof with which he does not agree. A complaint must be clearly indicated as such.
3. Submission of a complaint will not suspend the tender by definition, as this will be assessed by the LUMC. A Tenderer who files a complaint can also go to court in order to settle the matter with an interim injunction. Processing of a complaint that has already been filed can be suspended during an interim injunction procedure until the judge has issued a decision.
4. The LUMC will process the complaint as soon as possible and will expeditiously investigate whether or not the complaint is justified. The LUMC will make haste when making a decision about the complaint and any measures stemming from this decision, taking into consideration the interests of the complainant and other parties involved in the tender.

3.4 Rules for submitting a Tender

1. The Tender has a period of validity of at least six months starting on the deadline for submitting the Tender. If an interim injunction is pending within the scope of this tender, the period of validity will end one month after the interim injunction ruling.
2. Variations will not be accepted.
3. A Tenderer may only submit a tender once, either independently or as a participant in a Joint Venture (alliance partnership). A partnership is considered as one Tenderer. The same applies to individual operating companies within one holding company; one holding company will hence have multiple Tenderers.

4. A Third Party may act as a subcontractor for multiple Tenderers. A Third Party may act as a guarantor for multiple Tenderers if the eligibility criteria regarding financial and economic standing are in accordance with Art. 2:403 sub f of the Dutch Civil Code.
5. A Tender submitted other than via TenderNed will not be accepted.
6. The complete Tender must be submitted prior to the deadline mentioned in the most recent planning. No more Tenders will be able to be submitted after the submission deadline has expired. Late receipt, regardless of the reason, is at the expense and risk of the Tenderers.
7. In the event of a general failure of TenderNed at the moment of or close to the submission deadline, the LUMC retains the right to move the deadline so that the safe with Tenders is not yet opened, even if the deadline has already passed. This is a right, not an obligation on the part of the LUMC, and therefore does not change the fact that late receipt, regardless of the reason, is at the expense and risk of the Tenderers.
8. If a Tender is not complete, the LUMC can decide not to process it.
9. All documents, information, explanations and the like must be submitted as requested in the Tender Documents. If applicable, the formats that are provided must be used.
10. By submitting a Tender, the Tenderer fully and unconditionally agrees to the requirements and conditions stipulated in the Tender Documents. Submitting a Tender under different conditions is not permitted and will result in exclusion. If the Tender Documents contradict each other, the following ranking will apply with respect to the Agreement:
 - a) Information Notes, whereby the provisions in the most recent Information Note will prevail;
 - b) Draft Agreement, if applicable including Waiting Room Agreement and Processing Agreement;
 - c) This Descriptive Document, including other Appendices;
 - d) General Purchasing Conditions;
 - e) The Tenderer's Tender.

Tenderers must fully take note of these documents given that they contain important obligations that may not be bypassed before a Tenderer submits a Tender. Submission of a Tender means complete acceptance without any reservation of all the conditions stipulated in the Tender Documents by the Tenderer. General conditions of the Tenderer or other general or specific conditions, such as sector-specific conditions, are expressly rejected.

Suggestions regarding the conditions can only be made by means of asking questions. The Information Note(s) indicate(s) whether and how these suggestions are taken into consideration. Thereafter the conditions will be definitive.

11. Tenderers must complete the **European Single Procurement Document (ESPD)**, legally sign it and enclose it with the Tender. The legal signing of the **ESPD** stands for the legal signing of the entire Tender. The LUMC has already filled in/checked everything that

applies in Part I and Part III; the Tenderer must complete the rest. Part V of the ESPD is not relevant for this tender.

12. The validity of the signing by one or more natural persons must be clear from the excerpt of the company's registration in the commercial register. To this end, the Tenderer must submit an excerpt from the commercial register that is not older than six months upon first request. If the Tenderer is part of a holding company, it may be necessary to submit the excerpts of the holding company in order to show that the Tender has legally signed. If directors are limited and/or jointly authorised, it must be demonstrated that the authorisation was sufficient for being able to legally sign the Tender.
13. A legal signature is defined as a legal electronic signature or a legal 'wet' signature, after which the documents are scanned.
14. If the Tender contains ambiguities, the LUMC may ask for clarification from the Tenderer. This explanation must be provided in Writing and will be an inseparable part of the Tender. The explanation may not result in a significant change of the Tender.
15. The LUMC retains the right, without further approval, to check all information submitted by the Tenderer for accuracy and to contact the listed references.
16. Tenders will not be returned upon completion of this tender procedure.

3.4.1 Submitting a Tender as a Joint Venture (alliance partnership)

1. A Joint Venture of Tenderers (alliance partnership) can participate as one Tenderer. The additional provisions below apply to submitting a Tender as a Joint Venture (alliance partnership).
2. All Tenderers (alliance partners) who participate in the Joint Venture (alliance partnership) must submit an individual, legally signed ESPD in the Tender. Upon first request by the LUMC, additional supporting documents must be submitted for verification of statements, as stipulated in other sections of this Descriptive Document
3. All alliance partners must indicate the following in Part IIA of the ESPD under 'Manner of participation': a. the names of the other alliance partners; b. their own role; and c. which Tenderer will preside over the Joint Venture (alliance partnership) as the authorised representative ('coordinator') on behalf of the Joint Venture (alliance partnership) in dealings with the LUMC. The coordinator is hence the Tenderer who is adequately authorised by each alliance partner to enter into obligations within the scope of this tender on behalf of the Joint Venture. In addition, the distribution of activities must be described.
4. By completing and legally signing the ESPD, each alliance partner declares that he is jointly and severally responsible for complying with the obligations stemming from the Tender and the Agreement.
5. A Joint Venture (alliance partnership) that is in the process of being set up or a Joint Venture (alliance partnership) that does not organise as one legal entity does not need to submit proof of registration in a national professional or commercial register as a

Joint Venture (alliance partnership). The individual alliance partners must, however, do this in such a case.

6. The reasons for exclusion that apply to this tender apply to the Joint Venture (alliance partnership) as a whole and to the individual alliance partners separately. If a reason for exclusion applies to one of the alliance partners, this will result in the exclusion of the entire Joint Venture (alliance partnership).
7. When reviewing the Tender, the Joint Venture (alliance partnership) will be considered as one entity with regard to the eligibility requirements that apply to this tender, unless expressly provided otherwise.
8. During the term of the Agreement, the Joint Venture (alliance partnership) may only change its composition after Written approval from the LUMC.

3.4.2 Soliciting a Third Party

1. Tenderers can solicit a Third Party for two reasons: 1. To be able to meet the eligibility requirements and/or 2. for the purposes of implementing a part of the Contract, whereby the Third Party acts as a subcontractor. The following additional provisions apply if a Third Party is solicited.
2. All Third Parties solicited by the Tenderer during the Tender must submit an individual, legally signed ESPD with regard to the information that is requested on Part IIA, IIB and III. With the ESPD, Third Parties also declare that the Tenderer can truly have at his disposal all the Third Party's necessary resources. Upon first request by the LUMC, Third Parties must also submit additional supporting documents for verification of statements, as stipulated in other sections of this Descriptive Document.
3. Tenderers who solicit a Third Party in order to meet the eligibility requirements must check 'yes' in Part IIC of the ESPD. These Tenderers must then comprehensively describe in the associated information field which Third Party has been solicited in order to meet the eligibility requirements.
4. Tenderers who decide at the time of the Tender to outsource a part of the Contract to subcontractors, including Third Parties, must check 'yes' in Part IID and list the respective subcontractors and also describe the distribution of the activities.
5. If a Tenderer solicits a Third Party in order to meet the eligibility requirements and with regard to executing the Contract, then the Tenderer must check 'yes' both under 'Solicitation' as well as under 'Subcontractor' and repeatedly enter information, if necessary.
6. The reasons for exclusion that apply to this tender also apply to all Third Parties solicited by the Tenderer at every moment.
7. When reviewing the Tender, the tenderer and the Third Party so appointed will be considered as one entity with regard to the eligibility requirements that are solicited for the appointed Third Party, unless expressly provided otherwise.

8. With respect to eligibility requirements regarding financial and economic standing, the Third Party does not actually need to be used for executing the Contract.
9. When solicitation of a Third Party extends to soliciting the financial standing of the parent company to which the Tenderer belongs for the purposes of meeting the eligibility requirements, then a letter of intent in the sense of Article 2:403 sub f of the Dutch Civil Code must be submitted after the Award Decision. This letter of intent must state the parent company provides an unconditional guarantee for the obligations that the subsidiary is assuming. This letter must be legally signed by the company/parent company.
10. If the Tenderer solicits a Third Party for the requirements regarding the technical and professional aptitude, then this Third Party must actually be used to execute the Contract for the part that the respective eligibility requirement relates to unless expressly provided otherwise.
11. If a Tenderer is awarded the Contract, then he will in principle be obligated to award the part of the Contract described in the Tender to the appointed Third Party/parties as the contractor.
12. The Tenderer is fully and severally responsible for complying with all obligations stemming from the Tender and the Agreement, including the obligations that are subcontracted. A fraudulent declaration by a Third Party regarding the Tender does not release the Tenderer from his full and several responsibilities.
13. In the event of solicitation of a Third Party, all communication will solely be directed to the Tenderer, unless expressly provided otherwise.
14. During the term of the Agreement, a different Third Party than the one solicited during the Tender can only be solicited after Written consent from the LUMC and if this is not in violation of the Public Procurement Act of 2012. If the LUMC determines that reasons for exclusion are applicable to a Third Party as these applied during the time of the tender or if use of a Third Party during the term of the Agreement results in a significant change of the Contract, then consent can be withheld in any case.

3.4.3 Submitting a Tender with multiple Tenderers from a holding company

1. Multiple Tenderers (read: operating companies) may submit a Tender from a holding company, either independently or as a member of a Joint Venture (alliance partnership) or as a Third Party that is solicited by another Tenderer, provided that all involved Tenderers can demonstrate, at the request of the LUMC, that the Tenders came about independently and the competition was not harmed. If this cannot be demonstrated in the LUMC's opinion, then this will result in the exclusion of all involved Tenderers.

3.5 Opening procedure

1. The digital safe with Tenders will be opened by the LUMC after the deadline.
2. An official report will be compiled of the opening.

3. The content of the Tenders will not be reviewed during the opening.
4. Tenderers will not be invited to attend the opening procedure. The opening of the Tenders is a formality.

3.6 Award Decision, Agreement and legal protection

1. After opening, the LUMC will review and assess the Tenders. This is described in the following chapters. Ultimately, this culminates in an Award Decision, against which rejected and bypassed Tenderers may file an objection. The following provisions apply in this regard.
2. The LUMC will notify the Tenderers of the Award Decision as soon as possible, simultaneously and in Writing, including the relevant reasons for the decision.
3. The LUMC will not share certain information regarding the awarding if disclosure of such data could impede enforcement of the law, be in conflict with the public interest, damage the legitimate commercial interests of Tenderers or compromise fair competition.
4. Every attempt will be made to inform the Tenderers of the Award Decision in accordance with the deadline mentioned in the planning. If this deadline cannot be met due to circumstances, the LUMC will inform the Tenderers about this.
5. Tenderers who wish to request an effective remedy against the Award Decision must notify the LUMC of this in a timely fashion, prior to expiration of the objection period of 20 calendar days, in Writing and with simultaneous submission of a copy of the subpoena and with a mention of the date on which the court will process the case. If an interim injunction is not pending within this deadline, then the Tenderer can no longer object to the Award Decision and will have forfeited his rights, also with respect to setting up a procedure on the merits which, for example, extends to claiming compensation for damages. In this case, the LUMC will be free to respond to the expressed decision, provided that there are no (other) impediments to this, such as unsuccessful verification of the winning Tender.
6. The awarding will only be definitive after the LUMC has informed the winning Tenderer(s) about this in Writing.
7. The definitive awarding does not signify the creation of an Agreement pursuant to the Civil Code. The Agreement will come into being when the Agreement is signed by the LUMC and the Contractor. Leiden University Medical Centre (LUMC) has digitalized the signature process. The employee authorised to sign on behalf of the contractor receives by email the request for putting his or her digital signature in place within the contract.

Chapter 4 Evaluation of the Tender

This chapter explains the evaluation process for determining whether the conditions for participating in the tender have been met. The Tender evaluation process consists of three steps, and its basic principle is that the next step can only commence if it has not been determined in the preceding step that the Tender has to be rejected and the Tenderer excluded from participation.

4.1 Step 1: Evaluation to see whether the tender requirements have been met

After opening, the Tender will first be evaluated based on procedural aspects and requirements. If a Tenderer or Tender does not comply with this, the Tenderer can be excluded from participation.

4.2 Step 2: Evaluation to see whether no reasons for exclusion apply

The second step consists of an evaluation to see whether any reasons for exclusion apply to the Tenderer. Reasons for exclusion concern circumstances that affect the Tenderer's natural person/legal entity and justify the Tenderer's exclusion from participating in this tender procedure.

All legally mandatory reasons for exclusion and a number of optional reasons for exclusion for tenders that exceed the European limits apply to this Tender. The legally mandatory reasons for exclusion are listed in Part IIIA and IIIB of the ESPD, the applicable optional reasons for exclusion are checked under Part IIIC. The LUMC has opted for this because it does not wish to do business with a Tenderer to whom one of these circumstances applies.

With respect to provision of proof, the basic principle is that it is sufficient for Tenderers to add the ESPD to their Tender. If a Tenderer indicates that one of the reasons for exclusion applies to him, then the Tenderer will be excluded from the tender procedure, unless the Public Procurement Act of 2012 provides for an exception and the LUMC decides to apply this exception, after either having or not having received a standpoint on this matter from the Tenderer.

After the Award Decision, the LUMC will request further supporting documents from the winning Tenderer. This being said, the LUMC may still ask for this proof at any time earlier in the procedure in order to determine whether the Tenderers should be excluded, if this is necessary to ensure a seamless procedure in the LUMC's opinion. All requested information described in the table below must be able to be provided within five days. A Tenderer cannot derive any rights from the request for supporting documents. If, after having submitted supporting documents, a Tenderer learns of facts and/or circumstances that still could lead to the application of a reason for exclusion, he must notify the LUMC of this immediately.

If it appears at any time that the Tenderer does not meet the stipulated requirements or cannot submit the supporting documents in a timely fashion, he will be excluded. If this fact comes to light after the Award Decision, a new Award Decision will be made.

Reason for exclusion	ESPD	Additional supporting documents
Reasons related to criminal convictions	IIIA	A Tenderer can prove by means of a declaration of conduct for tenderers, which is not older than two years at the time of the Tender submission, that the reasons for exclusion do not apply to him - provided that the conviction concerns a final conviction without appeal or a final decision without appeal due to a violation of competition laws.
Distortion of competition	IIIC	A Tenderer can prove by means of a declaration from the tax authorities, which is not older than six months at the time of the Tender submission, that the reasons for exclusion do not apply to him.
Reasons related to payment of taxes or social contributions	IIIB	A Tenderer can prove by means of an excerpt from the commercial register, which is not older than six months at the time of the Tender submission, that the reasons for exclusion do not apply to him.
Bankruptcy, insolvency or similar	IIIC	Situational, according to the reasonable opinion of the LUMC. If the LUMC has an indication that this reason for exclusion applies, it will notify the Tenderer of this, after which the Tenderer will be given the opportunity to give his standpoint. The LUMC will consider this standpoint in its decision, while taking into account the Public Procurement Act of 2012.
Breach of obligations based on environmental, social security or labour law	IIIC	Public Procurement Act of 2012.
Conflict of interest	IIIC	
Involvement in the preparations	IIIC	
False declaration	IIIC	
Wrongful manipulation	IIIC	

4.3 Step 3: Evaluation to see whether the eligibility requirements have been met

If no reasons for exclusion apply to a Tenderer, his eligibility will be evaluated based on a number of requirements regarding his technical and professional aptitude and/or professional competence. The LUMC stipulates these requirements with the goal of hiring a Contractor who has the legal capacity, financial capacity and technical and professional aptitude to be able to execute the Contract.

If a Tender does not meet the stipulated eligibility requirements, the Tender will be rejected. Here too the basic principle is that it is sufficient for Tenderers to add the ESPD to their Tender in which they indicate in Part IV that they meet all the eligibility requirements ('yes') listed below (also 'Selection Criteria' in the ESPD), unless expressly stated that additional information must be submitted with the Tender. The (additional) supporting documents per eligibility requirement are specified below.

4.3.1 Technical and professional aptitude

It is important to the LUMC that the final Contractor is eligible to execute the Contract with respect to his technical and professional aptitude. This is why the below eligibility requirements are specified:

4.3.1.1 Core Competencies

The LUMC has identified core competencies that it believes the Tenderer has to possess in order to be able to successfully execute the Contract. This regards the following core competencies:

1. *The tenderer must submit a reference (of the delivery, installation, preparation and acceptance) for each subsystem (i.e. optical and CT) from a research facility or hospital within Europe, to prove the maturity of the system(s) and to provide confidence in a strong preclinical research and development community that enables international multi-center studies under standardized conditions.*

Other than the fact that the Tenderer has to complete the ESPD (Part IV), the Tenderer must submit one reference for each subsystem that demonstrates that the requested activities were performed to the satisfaction of the reference organisation. This hence concerns a maximum of two (2) references.

The Tenderer has to use the **Core Competencies Document** for submitting reference contract(s). Note: If the Tenderer uses one reference contract to demonstrate that he meets the core competencies for both systems, which is allowed, then the same information has to be provided repeatedly. The form hence always has to be completed in full.

With regard to the reference(s) to be submitted, the following requirements apply in addition to the core competency. If this is not met, the reference will be considered as invalid:

1. The requested core competencies have been performed to the satisfaction of the reference organisation in the period of 36 months prior to the deadline for submitting a Tender. The reference contract does not need to be fully completed yet, but the parts that concern the core competencies do need to have been executed and evaluated.
2. For verification purposes, the current contact information of the contact persons must be provided in full and accurately for the reference contracts. Verification can be performed without additional consent of and consultation with the Tenderer. The Tenderer must inform the contact person of the reference organisation of the fact that he or she may be approached within this framework.
3. If the declaration of the reference organisation does not correspond to the declaration of the Tenderer or the reference organisation does not wish to cooperate with the verification and it is hence not possible to verify whether the requirement has been met, the reference can be deemed as invalid, resulting in exclusion of participation in the tender.
4. References are only deemed to be valid if the respective reference contract was executed by the Tenderer. In the event of a Joint Venture (alliance partnership), this will be one of the partnerships with which a tender will be submitted for this contract. If the Tenderer solicits a Third Party, then this must be the Tenderer or the respective Third Party.

The LUMC retains the right to have the Tenderer submit additional supporting documents which prove that the declarations have been made truthfully.

4.3.1.2 Certifications

Furthermore, the Tenderer has to possess the following certificates at the moment he submits the Tender and during the term of the Agreement.

- **Quality management system:** *NEN-EN-ISO 9001:2015 or equivalent;*

Quality assurance can be demonstrated by the systems delivered and the services provided and is determined in particular by the way in which this is organised, carried out and monitored.

This implies that:

1. Your company has certificates or company documents and procedures proving this; and
2. Your management and executive staff are familiar with this and have the necessary information and tools to comply with it.

Standard of this requirement:

The Tenderer must demonstrate the measures he has taken to guarantee quality by means of a Quality Certificate, drawn up by an independent body, NEN ISO 9001:2015 or an equivalent certificate, which shows that all provisions as stated in this standard are met. The certificate must be valid on the closing date of the tender period for this invitation to tender. The LUMC assesses whether an equivalent certificate is regarded as full-fledged alternative or not.

The ESPD (Part IV) suffices for the Tender. Upon the first request of the LUMC, the Tenderer must be able to submit a copy of the respective certificate or other proof within five days that irrefutably shows that the requirement has been met.

- **Environmental management system:** ISO 14001:2015 or equivalent;

A sound environmental management system shall be subject to the following requirements:

3. Continuous improvement of performance and protection of the environment (e.g. by preventing environmental pollution).
4. Management of the environmental risks resulting from the activities of the organization.
5. At least comply with the applicable legal requirements.

Standard of this requirement:

The Tenderer must demonstrate the measures he has taken to ensure quality by means of a certificate, drawn up by an independent body, ISO 14001, or an equivalent certificate, attesting that all the provisions set out in this standard are complied with. The certificate must be valid on the closing date of the tender period for this invitation to tender. The LUMC assesses whether an equivalent certificate is regarded as full-fledged alternative or not.

The ESPD (Part IV) suffices for the Tender. Upon the first request of the LUMC, the Tenderer must be able to submit a copy of the respective certificate or other proof within five days that irrefutably shows that the requirement has been met.

4.3.2 Professional qualifications

Tenderers, including all participants in the Joint Venture (alliance partnership) and also any solicited Third Party/Parties must be registered with the national commercial register of the country in which they are located.

If the Tenderer does not comply with this, he will be excluded from the tender. The fact that the Tenderer complies with the requirements regarding professional qualifications must be stated in the ESPD when submitting the Tender. In addition, an excerpt from the registration in the commercial register, which is not older than six months at the time of the Tender submission, must be enclosed within five days of the LUMC's request. Upon the first request of the LUMC, the Tenderer has to be able to submit additional supporting documents that demonstrate that this declaration was submitted truthfully.

Chapter 5 Evaluation of the Tenders

If a Tender has not been excluded based on previous reasons, the content of the Tenderer's offer will be evaluated on top of the minimum requirements. The Tender will be reviewed to see whether it unconditionally complies with the specified requirements (par. 5.1). The Tender will then be evaluated and ranked based on the award criterion (par. 5.2).

5.1 Award requirements

The Tenderer's offer must unconditionally meet the minimum requirements that are stipulated by the LUMC regarding the execution of the contract. These minimum requirements are listed in the **Schedule of Requirements Document**. If the Tender does not comply with this, it will be rejected (knock-out).

5.2 Award criterion

The LUMC will determine which Tender is the most economically advantageous, based on the 'best price-quality ratio' award criteria. The Tenderer with the best price-quality ratio will hence be awarded the Contract.

5.3 Evaluation method

There are a total of **1,000 points** to be had, distributed over the Quality and Price sub-award criteria. These sub-award criteria, in turn, consist of one or more components. The overview below shows how many maximum points can be allotted to a Tender.

Sub-award criterion	Part	Maximum number of points
Quality	Wishes ('Should' in the Schedule of Requirements Document)	800 points
Price	Price List Document	200 points
Total		1,000 points

5.4 Evaluation procedure

For the qualitative evaluation of the Tenders, an evaluation committee will be set up.

Initially, the members of the evaluation committee will evaluate the individual Tenders with regard to the Quality sub-award criterion. The evaluation committee will do this without knowing the prices. Then the final scores will be determined by all members of the evaluation committee based on consensus. Therefore, no average score will be calculated.

If multiple Tenders with the same score (in points) are ranked and the LUMC is unable, to make an Award Decision based on this ranking, then the number of points awarded to the sub-award criterion ‘Quality’ will be decisive. If this does not provide a decisive answer either, then lots will be drawn.

5.5 The Quality sub-award criterion

The various parts of the sub-award criterion ‘Quality’ are described below: The LUMC’s wishes, how the Tenderer will meet these wishes and how this will be evaluated by the evaluation committee. The elaboration of the Quality sub-award criterion must be enclosed in the Offer of a Tenderer.

The Quality sub-award criterion are the Wishes (Nice-to-haves) which are characterized as ‘Should’ in the **Schedule of Requirements Document**. In that Document Tenderers can find the maximum of points to be achieved and the evaluation method of each Wish.

The maximum number of points in total that can be allotted to the Tender for this part is shown in the table above under 5.3.

5.6 Price sub-award criterion

Tenderers are asked to exclusively use the **Price List** for submitting their price quote.

Unless expressly stated otherwise in de Tender Documents, prices are all-in, DDP (incoterms) and including VAT. Indexing of offered prices is not possible in accordance with the provisions of the conceptual Agreement.

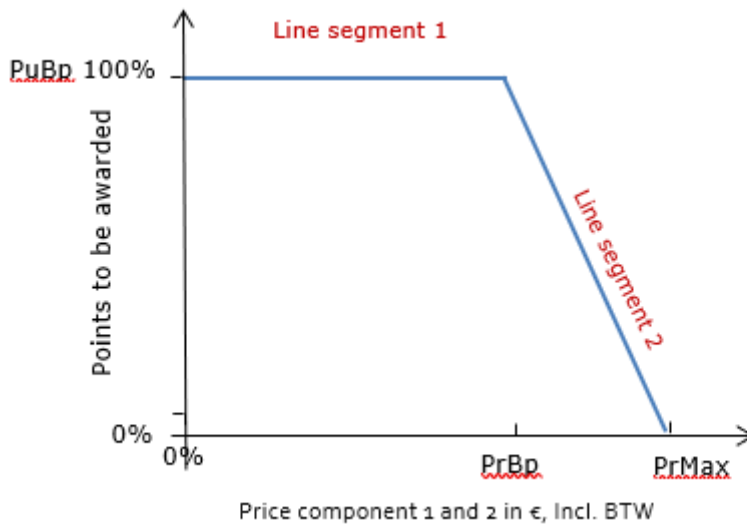
The LUMC works with a minimum price and a maximum price. Points are awarded for the tender price based on the graph below.

Price	Abbreviation	Omschrijving
Price break point	PrBp	The maximum score that can be achieved for the price component is 200 points. For a price (incl. VAT) that is lower than the price break point, the maximum points (= 200) are awarded.
Price Maximum	PrMax	The Tenderer can score points between the price break point and the maximum price. The Tenderer will receive 0 points for submitting the maximum price. When submitting a price that is higher than the maximum price, the Tender will be declared invalid (knock-out).

Part	Price Break point	Price Maximum	Points Break point	Points price Maximum
Tender Price	€ 800.000,-	€ 900.000,-	200	0

The Tenderer must enter his price in the **Price List**. If the prizes are not or not fully filled in, the Tender will be discarded.

The price assessment mechanism is as follows:



Explanation of the graph and formula:

The graph consists of 2 line segments, with a price break point at PrBp. Graph part 1 consists of a horizontal line segment; with a total price (incl. VAT) lower than PrBp, it does not yield any extra points. Graph part 2 consists of a segment PrBp and PrMax. For the subscription Price, fewer points are awarded pro rata. The following formula is used to award points:

- Graph formula: Points = A x Subscription price + B, where Price is the amount in €, and incl. VAT.

Formula to calculate A and B is:

- PuBp = Points Breakpoint
- PrBp = Price Breakpoint
- PrMax = Price Maximum

Formula A & B:

- $A = (0 - \text{PuBp}) / (\text{PrMax} - \text{PrBp})$
- $B = \text{PrMax} * \text{PuBp} / (\text{PrMax} - \text{PrBp})$

Checklist

Below you will find a checklist of all documents that Tenderer must submit, which formats you need to use and how you must compile your Tender.

Checklist	
Documents	Action
– European Single Procurement Document (ESPD)	<p>European Single Procurement Document (ESPD) complete, sign and enclose.</p> <p><i>By legally signing the ESPD, the Tenderer indicates that all tender documents have been fill in completely and truthfully and been approved.</i></p> <p>For each ESPD, the NAME of the legal representative must also be stated on the last page in addition to the signature.</p>
– Core Competencies Document	Core Competencies Document complete and enclose.
– Schedule of Requirements Document	Schedule of Requirements Document complete and enclose. <u>Including</u> the explanation (if asked), supporting documents and answers to the wishes
– Price List	Price List complete and enclose, in .pdf and .xls(x).