



INVITATION TO TENDER DOCUMENT

BEAUMONT HOSPITAL

OPEN PROCEDURE

SINGLE-PARTY FRAMEWORK AGREEMENT

For

THE SUPPLY OF HAEMODIALYSIS ON/OFF PACKS

MAXIMUM POTENTIAL DURATION OF AGREEMENT: FOUR YEARS

DEADLINE DATE FOR RECEIPT OF TENDERS: 28/08/2026 AT 12.00 NOON (LOCAL TIME)

Please note that all information relating to this competition, including clarifications and addenda, will be published on the Irish Government Procurement Opportunities Portal (www.etenders.gov.ie). Registration is free of charge and there is no charge for documents. Beaumont Hospital accepts no responsibility for information relayed (or not relayed) via third parties.

DISCLAIMERS

All information contained in this Invitation to Tender document is provided in the strictest confidence and has been made available solely for the purpose of facilitating the production and submission of tenders. No party may disclose the contents of this document without the express permission of Beaumont Hospital (hereinafter 'the Contracting Authority').

Tenderers are recommended to read the Invitation to Tender document thoroughly. While all reasonable steps have been taken to ensure that the information set out in this document is factually correct, no representation or warranty, express or implied, is or will be made or given in relation to the accuracy or the completeness of any information contained in this document or otherwise provided by or on behalf of the Contracting Authority, in writing or otherwise, to any interested party or its advisers. No responsibility or liability for any loss or damage arising as a result of reliance on this document, or for the information contained in this document, or for any omission is or will be accepted by the Contracting Authority or by any of its officers, employees, agents or professional advisers. No officer, employee, agent, or professional adviser of the Contracting Authority has any authority to give or make any representation or warranty, express or implied, in relation to such information. The Contracting Authority's officers, employees, agents and professional advisers expressly disclaim any and all liability arising out of such documentation or information and any errors or omissions in or from the documents and information.

The Contracting Authority reserves the right to discontinue the procurement process at any time.

Without prejudice to the principle of equal treatment, the Contracting Authority is not obliged to engage in a clarification process in respect of tender submissions with missing or incomplete information. Therefore, tenderers are advised to ensure that they return comprehensive tender submissions in order to avoid the risk of elimination from the competition.

CHECKLIST FOR TENDER SUBMISSIONS

In order to allow the Contracting Authority to fully evaluate completed tender submissions, Tenderers are advised to ensure that their responses include all of the following information:

All information required under each Eligibility Criterion (Section 5)	
All information required under each Award Criterion (Section 6)	
The completed and signed Form of Tender (Appendix 1)	
The completed and signed ESPD (Appendix 2)	
All required sample products delivered to Beaumont Hospital	

This checklist has been provided for guidance purposes only and the Contracting Authority accepts no responsibility for omissions of any description. Tenderers are advised to read this Invitation to Tender document and its appendices in full in order to provide a comprehensive and compliant response.

TABLE OF CONTENTS

DISCLAIMERS	2
CHECKLIST FOR TENDER SUBMISSIONS.....	3
TABLE OF CONTENTS.....	4
1. INTRODUCTION	5
2. SPECIFICATION OF REQUIREMENTS	7
3. INSTRUCTIONS TO TENDERERS	12
4. GROUNDS FOR EXCLUSION.....	18
5. ELIGIBILITY CRITERIA.....	22
6. AWARD CRITERIA	26
APPENDIX 1 – FORM OF TENDER.....	32
APPENDIX 2 – EUROPEAN SINGLE PROCUREMENT DOCUMENT (ESPD).....	34
APPENDIX 3 – DRAFT TERMS AND CONDITIONS OF THE FRAMEWORK AGREEMENT ..	46

1. INTRODUCTION

1.1 About the Contracting Authority

Beaumont Hospital, incorporating St. Joseph's Hospital Raheny, employs approximately 4,300 whole-time equivalent staff and has a total capacity of 913 beds with an additional treatment capacity of 40 places. It is the principal teaching hospital for the Royal College of Surgeons in Ireland and enjoys close links with Dublin City University, especially in the area of nurse training, and with other academic institutions in respect of training and research. Further information regarding the hospital is available online: www.beaumont.ie/aboutus.

1.2 About the Competition

The Contracting Authority is employing the open procedure to establish this framework agreement. In accordance with the provisions governing the conduct of the open procedure, any interested economic operator may tender for appointment as the successful framework member. In the first instance, tenders received will be assessed against the eligibility criteria and rules contained in Section 5 of this document. Tenders that meet the requirements of the eligibility criteria will then be evaluated against the award criteria, rules and weightings contained in Section 6 of this document in order to identify the most economically advantageous tender.

1.3 About the Framework Agreement

A framework agreement constitutes a means of establishing overall terms and conditions in accordance with which, for a specified duration, individual contracts may or not be awarded. In the context of a single-party framework agreement, the successful framework member does not have to compete for each new contract. It is emphasised that a framework agreement constitutes no guarantee to purchase a specific quantity of services from a particular economic operator. Indeed, the Contracting Authority reserves the right to operate outside of the framework agreement at its discretion, particularly should it become apparent that doing so would offer greater value for money. Notwithstanding the foregoing, the Contracting Authority has adopted a framework agreement approach to this project in order to leverage efficiencies and maximise cost savings over a four year period.

1.4 Duration of the Framework Agreement

This framework agreement will have a maximum potential duration of four years. In the first instance, it is anticipated that a contract of two years' duration will be entered into with the successful framework member. Following expiry of this contract, matters such as supplier performance and the continued strategic appropriateness of the agreement will be assessed in order to determine whether subsequent contract(s) will be placed.

1.5 Award to Runner-up

In the event that, following the award of this single-party framework agreement, the successful framework member cannot, for whatever reason, execute the framework agreement or any contract awarded under it to the satisfaction of the Contracting Authority, the Contracting Authority reserves the right to award the agreement to the next highest-ranked tenderer emerging from this competitive process at any time during the tender validity period. This shall be without prejudice to the right of the Contracting Authority to terminate the agreement and commence a new competitive process.

1.6 Termination

Once established, there is no obligation upon the Contracting Authority to make use of this framework agreement. Notwithstanding this fact, the framework agreement may be terminated in accordance with the framework agreement terms and conditions, a draft version of which is contained in Appendix 3 of this document.

2. SPECIFICATION OF REQUIREMENTS

2.1 Background to Current Requirement

The Contracting Authority intends to establish a single-party framework agreement for the supply of Haemodialysis On/Off Packs. In the first instance, a contract of two years' duration will be awarded for the supply of the three varieties of packs specified in Section 2.2 below. Over the course of the framework agreement, the successful framework member may be required to provide additional packs and/or components, depending upon clinical need.

2.2 Functional Specification of Required Packs

Sterile single use custom Haemodialysis On/Off Packs are required for use in a busy acute hospital environment. The following mandatory provisions shall apply to the required products:

- 2.2.1 All products must be of good quality and suitable for clinical use.
- 2.2.2 All products must be CE marked and manufactured to the relevant standard. The manufacturing process must be certified to a relevant quality management standard.
- 2.2.3 The proposed packs must conform to the layout and structure of packs required by the clinical users.
- 2.2.4 The packaging must be easy to open and the sterility of the contents must not be compromised while handling.
- 2.2.5 The proposed packs must include the appropriate lot number to provide full traceability from date of manufacture.
- 2.2.6 No trays are required in the packs.
- 2.2.7 The proposed packs must be appropriately designed to minimise cross contamination and damage to the central venous catheters.

2.2.8 Central Line On/Off Pack

It is a mandatory requirement that the Central Line On/Off Pack contains the following components in the specified quantities:

Central Line On/Off Pack

Central Line On Pack	
	Soft blister in soft blister (off part in soft blister, placed in the soft blister of the complete pack) Sticker with ON Pack & Sticker with OFF Pack. On the outside of the total set, traceability label X2
1	Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive
1	Enveloping drape
1	High filtration mask with ear loops (Not ties)
1	50x50cm drape
10	Woven swab 10x10cm 12 ply
2	Syringe 5ml Luer lock suitable for the extraction of blood and the flushing of the dialysis device
2	Syringe NaCl 0,9% Luer Lock 10 ml
2	Closure cap Luer Lock male/female blue
1	Forceps 13cm plastic
2	Strip adhesive tape 15cms x 3.5cms
Central Line Off Pack	
1	Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive
1	High filtration mask with ear loops (Not Ties)
1	Enveloping drape
1	50x50cm drape
10	Woven swab 10x10cm 12 ply
2	Syringe NaCl 0,9% Luer Lock 10 ml
2	High quality male/female Luer lock cap to close off the ports of CVC line. Threading of the male Leur to match that of the CVC line.
3	Strip adhesive tape 15cms x 3.5cms
1	Tweezers Forceps 13cm plastic

2.2.9 AVF On/Off Pack

It is a mandatory requirement that the CVC Intervention Pack contains the following components in the specified quantities:

AVF On/Off Pack

AVF On Pack	
	Soft blister in soft blister (off pack in soft blister, placed in the soft blister of the complete pack) On the outside of the total set, traceability label X2
1	Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive
1	Enveloping drape
1	50x50 cm drape
1	Strip adhesive 2,5 x 15 cm (1 strip)
5	Woven swab 10x10cm 12 ply
2	Syringe NaCl 0,9% Luer Lock 10 ml
1	Tourniquet Adult 2cm Latex free (Single use) non slip
AVF Off Pack	
1	Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive
10	Swab gauze 12 ply 17 thr. 10 x 10 cm
1	Syringe NaCl 0,9% Luer Lock 10 ml
1	Drape 50cm x 50cm
1	Enveloping drape
	Sticker with OFF Pack

2.2.10 CVC Intervention Pack

It is a mandatory requirement that the CVC Intervention Pack contains the following components in the specified quantities:

CVC Intervention Pack	
1	Plastic bag 35x45cm folded 9x12cm Yellow – draw string closure
1	High filtration mask with ear loops (Not Ties)
1	Enveloping drape
1	50x50cm drape
10	Woven swab 10x10cm 12 ply
2	High quality Syringe 20ml Luer lock suitable for the extraction of blood and the flushing of the dialysis device
1	Interlink Bare Cannula with an appropriate size cover to prevent cross contamination or similar needle free device
1	Tweezers Forceps 13cm plastic
3	Strip adhesive tape 15cms x 3.5cms

2.3 Completeness of Tender Submissions

Tenderers are required to tender for all packs specified. Failure to tender for a particular pack or product will result in the elimination of the tender submission as a whole.

2.4 Minor Variations

In accordance with Regulation 72 of the European Union (Award of Public Authority Contracts) Regulations 2016, any award decision by the Contracting Authority may be contingent upon the successful tenderer designate agreeing to propose alternative options for some products (i.e., should a small number of products be deemed unacceptable). Such alternatives must be provided at the prices tendered by the successful tenderer designate. The Contracting Authority's discretion in this regard shall have no bearing upon the obligation of all tenderers to ensure that the products proposed in response to this Invitation to Tender document comply in full with the specification of requirements contained in the Invitation to Tender document.

2.5 Brand Names and Trade Descriptions

Any specifications provided by the Contracting Authority comprising a reference to a particular manufacturer, make, model, brand name or proprietary process are to be interpreted as being accompanied by the phrase 'or equivalent.' For the avoidance of doubt, all products of comparable technical or clinical functionality and characteristics will be considered by the Contracting Authority.

2.6 Product Samples

Two samples (non sterile) of each pack must be provided for evaluation. These must be delivered to the Procurement Department, Beaumont Hospital and marked for the attention of David McHugh. These must be delivered by the closing date and time that applies to this tender. Following the evaluation of these samples, tenderers may be requested to provide additional sterile samples of all packs for patient trials, if the products are deemed suitable for clinical use. These samples must be provided within an acceptable timeframe to Beaumont Hospital. **All samples must be provided free of charge to facilitate the evaluation process.**

2.7 Reliability and Continuity of Supply

The successful framework member will be required to have a robust and comprehensive tracking system, involving batch numbers and the efficient identification of individual packs. Additionally, the successful framework member will be required to have a policy to deal with product recalls, including an appropriate system for notification and the effective management of hazards and/or recalls.

2.8 Delivery

The successful framework member will be required to deliver all required products on a weekly basis and must hold four months' stock for ready use by the Contracting Authority.

2.9 General Data Protection Regulations (GDPR)

As a service provider engaged in providing services to the Contracting Authority, the successful tenderer will be required to adhere to the following provisions:

- (i) To the extent that it may be deemed a 'data processor' for the purposes of the 'GDPR,' the successful tenderer will make itself fully aware of all applicable obligations under the GDPR and will put in place sufficiently robust mechanisms to ensure adherence to the relevant provisions of the GDPR;
- (ii) To the extent that it may be deemed a 'data processor' for the purposes of the GDPR, the successful tenderer will comply with the provisions of Article 28(3)(a) to 28(3)(h) of the GDPR;
- (iii) To the extent that it may be deemed a 'sub-processor' for the purposes of the GDPR, the successful tenderer will comply with the provisions of Article 28(4) of the GDPR.
- (iv) To the extent that it may be deemed a 'data processor' for the purposes of the GDPR, the successful tenderer will implement appropriate technical and organisational measures in such a manner that any processing activities undertaken will meet the requirements of the GDPR and ensure the protection of the rights of the data subject.

3 INSTRUCTIONS TO TENDERERS

3.1 Compliance with Instructions to Tenderers

Tenderers are required to comply with these Instructions to Tenderers when preparing their tender submissions. By submitting a tender, each tenderer acknowledges and agrees to be bound fully by these Instructions to Tenderers. Non-compliance with these Instructions may, and in stated circumstances shall, invalidate the submitted tender, subject always to the discretion of the Contracting Authority. The decision of the Contracting Authority in relation to compliance with these Instructions to Tenderers is final and binding.

3.2 Ambiguities, Discrepancies, Errors or Omissions in the Tender Document

If you consider that you are missing any documents or information, the absence of which would preclude you from submitting a comprehensive tender, or should you become aware of any ambiguity, discrepancy, error or omission in this Invitation to Tender document, please raise the matter by sending an e-mail through the eTenders question and answers function (www.etenders.gov.ie) as soon as possible.

3.3 Queries

All queries regarding this competition should be submitted through the eTenders question and answers function (www.etenders.gov.ie), clearly marked with the subject line 'QUERY – THE SUPPLY OF HAEMODIALYSIS ON/OFF PACKS.' The closing date for receipt of such queries is close of business on 21/08/2026. The following additional conditions govern the submission of queries:

- (a) No approach of any kind should be made to any other person within, or associated with, the Contracting Authority in connection with this Invitation to Tender. Any such approach may, at the absolute discretion of the Contracting Authority, result in the elimination of the tenderer in question from this process.
- (b) The Contracting Authority will endeavour to respond to all reasonable queries received but does not undertake to respond to all queries indiscriminately. In particular, queries seeking interpretation of this Invitation to Tender document may not result in a response.
- (c) In the event that a tenderer considers a query confidential or commercially sensitive, it must mark the query accordingly. If the Contracting Authority considers, at its absolute discretion, that the query or related response should be properly regarded as confidential or commercially sensitive, the nature of the query and its response will be held as confidential, subject to the Contracting Authority's obligations under law.

If the Contracting Authority is of the opinion that it would be inappropriate to answer the query on a confidential basis, it will notify the tenderer accordingly and require the tenderer to either withdraw the query or agree to its release, accompanied by a response, to all tenderers.

3.4 Qualification of Tenders

Please note that qualifications to a tender submission may render the tender submission invalid.

3.5 Tender Submission

The deadline date and time for receipt of tenders is 28/08/2026 at 12.00 noon (local time). Tenders must be submitted through the eTenders web portal (www.etenders.gov.ie) **only**. The completed tender submission, which is to include all information identified in the Checklist for Tender Submissions contained in this Invitation to Tender document, must be compiled in such a manner such that it can be read immediately upon opening of the post-box. Tenderers must ensure electronic documents are not corrupt. The Contracting Authority is not responsible for corruption in electronic documents.

Each tenderer is fully responsible for the uploading of the tender document to the post-box. The post-box will close automatically at 12.00 noon exactly on the closing date; in this regard, tenderers are advised to commence the uploading process substantially in advance of this time to avoid missing the deadline. E-mailed, faxed, hard copy, posted or late tenders will not be considered under any circumstances.

3.6 Extension of Tender Period

The Contracting Authority reserves the right, at its sole discretion, to revise the deadline date for receipt of tender submissions by giving notice in writing to tenderers at any point up to the deadline date contained in this Invitation to Tender document.

3.7 Notice of Addenda

The Contracting Authority reserves the right to update or alter the information contained in this document at any time, but not later than seven (7) days before the deadline date for the receipt of tender submissions. Any such notification will automatically become part of this Invitation to Tender document.

3.8 Modifications to Tenders (Prior to Deadline Date for Receipt of Tenders)

Modifications to tender submissions will be accepted in the form of supplementary information and/or addenda, provided they are submitted via the eTenders web portal before the deadline date for the receipt of tender submissions.

3.9 Cost of Preparation of Tender Submissions

The Contracting Authority will not be liable for any costs incurred by tenderers in the preparation and submission of tenders and/or any associated work effort or costs (legal or otherwise) arising as a result of participation in this competition, regardless of the outcome or conduct of the competitive process.

3.10 Clarification of Abnormally Low Tenders

In the event that the Contracting Authority considers the tender submission to be commercially unsustainable or otherwise problematic in light of the tendered price or any other financial matter, the tenderer shall be invited to provide clarification to the Contracting Authority in respect of all elements of the tender submission that the Contracting Authority deems relevant. Any failure to satisfactorily comply with such a request, or to satisfactorily address the Contracting Authority's concerns, may, at the discretion of the Contracting Authority, result in the elimination of the tender in question.

3.11 Tender Validity Period

To allow sufficient time for tender assessment, a tender validity period of twelve months is required, commencing on the deadline date for receipt of tender submissions.

3.12 Currency

Tender prices and any other financial information must be submitted in Euro (€) only. **All invoices and payments will be in Euro (€) only.**

3.13 Confidentiality

The distribution of this Invitation to Tender document is for the sole purpose of obtaining tender submissions as referred to therein. The distribution of this document does not grant permission or licence to use the documents for any other purpose. Tenderers are required to treat the details of all documentation provided in connection with this competition as private and confidential. Similarly, the Contracting Authority undertakes to use all reasonable endeavours to ensure that any confidential information received from tenderers is not disclosed to third parties, subject always to its obligations under law and the applicable provisions of the Freedom of Information Acts.

In this regard, tenderers are asked to consider if any of the information supplied by them in response to this Invitation to Tender document should not be disclosed because of its sensitivity. Tenderers must specify the precise information that is sensitive and the reasons for its sensitivity. Tenderers are advised that it is not sufficient to merely include a statement of confidentiality encompassing all information contained in a tender submission.

The Contracting Authority cannot guarantee that any information provided by tenderers, either in response to this Invitation to Tender or in the course of any framework agreement established as a result thereof, will not be released pursuant to the Contracting Authority's obligations under law, including the Freedom of Information Acts 1997 and 2003, European Procurement Directives and all Irish procurement legislation and guidance. The Contracting Authority accepts no liability whatsoever in respect of any information provided that is subsequently released or in respect of any consequential damage suffered as a result of such obligations.

3.14 Conflict of Interest

Any conflict of interest involving a tenderer must be fully disclosed to the Contracting Authority. Any registrable interest involving the tenderer and the Contracting Authority, or employees of the Contracting Authority or their relatives, must be fully disclosed in the tender submission. In the event that the tenderer becomes aware of the conflict of interest only after a tender submission has been made, the conflict of interest must be immediately disclosed to the Contracting Authority. The terms 'registrable interest' and 'relative' will be interpreted in accordance with Section 2 of the Ethics in Public Office Act, 1995. Failure to disclose a conflict of interest may disqualify a tenderer or invalidate the establishment of any framework agreement, depending upon when the conflict of interest is made known to the Contracting Authority.

3.15 National Legislation

Tenderers are advised that national legislation applies in respect of matters such as employment, working hours, official secrets, data protection and health and safety. Tenderers must have regard to statutory terms relating to minimum pay and to legally binding industrial or sectorial agreements in preparing tenders. Moreover, tenderers are advised that the laws of Ireland will govern this competitive process. This competitive process, any resulting framework agreement and any resulting contract will be subject to the exclusive jurisdiction of the Irish courts.

3.16 Determination of Responsiveness

After opening tender submissions, the Contracting Authority will determine whether each tender submission is substantially responsive to the requirements of this Invitation to Tender document. If a material deviation exists that limits in any substantial way the Contracting Authority's rights or the tenderer's obligations under any framework agreement to be established, the tender shall be rejected.

3.17 Clarification of Tenders

To assist in the evaluation and associated comparison of tender submissions, the Contracting Authority may ask tenderers to clarify and supplement certain aspects of their tender submissions, including financial proposals. A request for such clarifications should not be construed as an indication of success in the competition.

3.18 Interference

Any effort by a tenderer to unduly influence the Contracting Authority, its personnel or any other relevant persons or bodies regarding the process of examination, clarification, evaluation and comparison of tenders and any decisions concerning the establishment of the framework agreement shall result in the elimination of said tenderer's tender submission. In accordance with Section 38 of the Ethics in Public Office Act 1995, any money, gift or other consideration from a person seeking success in a public tendering competition will be deemed to have been paid or given corruptly unless the contrary is proved.

3.19 Prohibition on Canvassing

Any tenderer who, in connection with this competition:

- (a) offers any inducement, fee or reward to any member, officer or employee of the Contracting Authority or any person acting as an advisor to the Contracting Authority in connection with the competition; or
- (b) takes any step constituting a breach of the Prevention of Corruption Acts 1989 to 2010; or
- (c) canvasses any of the persons referred to in paragraph (a) above in connection with the competition; or
- (d) contacts any officer or employee of the Contracting Authority prior to the framework agreement being established about any aspect of the competition in manner not permitted by this Invitation to Tender document

may be eliminated from the competition, without prejudice to any other civil remedies available to the Contracting Authority and without prejudice to any criminal liability such conduct by a tenderer may attract.

3.20 Prohibition on Collusion

Any tenderer who, in connection with this competition:

- (a) fixes or adjusts the amount or terms of his/her tender submission by or in accordance with any agreement or arrangement with any other tenderer (other than a member of his own grouping or consortium); or
- (b) enters into any agreement or arrangement with any other tenderer that he/she shall refrain from tendering or as to the amount or terms of any tender to be submitted; or
- (c) causes or induces any person to enter into such an agreement or arrangement as referred to in paragraphs (a) or (b) above; or
- (d) informs any tenderer of the amount, approximate amount or terms of any rival tender; or
- (e) canvasses any other tenderer in connection with this competition; or
- (f) offers or agrees to pay or give, or does pay or give, any sum of money, inducement or valuable consideration directly or indirectly to any person for any information in connection with any rival tender submission; or

- (g) communicates to any person other than the Contracting Authority the amount or approximate amount or terms of his proposed tender submission (except in the event that such disclosure is made in confidence and is necessary for the preparation of the tender submission); or
- (h) contacts any officer or employee of the Contracting Authority prior to the framework agreement being established about any aspect of the competition in manner not permitted by this Invitation to Tender document

may be eliminated from the competition, without prejudice to any other civil remedies available to the Contracting Authority and without prejudice to any criminal liability such conduct by a tenderer may attract.

3.21 Notification of Tender Evaluations

All tenderers will be informed in writing of the outcome of this tender competition following the completion of the evaluation of tender submissions.

4. GROUNDS FOR EXCLUSION

This Section of the Invitation to Tender document details the grounds for exclusion that apply to this competition in accordance with Regulation 57 of the European Union (Award of Public Authority Contracts) Regulations 2016.

A tenderer's position under each of these grounds will be assessed by reference to the completed European Single Procurement Document (ESPD) contained in Appendix 2 of this document. The completed ESPD will comprise a 'self declaration' by the tenderer that the grounds for exclusion detailed hereunder do not apply. The information contained in this Section of the Invitation to Tender document informs tenderers of how the completed ESPD will be interpreted by the Contracting Authority.

For the avoidance of doubt, the Contracting Authority reserves the right to request any tenderer to provide all supporting documentation necessary to demonstrate the inapplicability of any ground for exclusion detailed hereunder. Such a request may be made at any point during the competitive process. **In particular, before reaching an award decision, the Contracting Authority may require the successful tenderer to provide all supporting documentation necessary to demonstrate the inapplicability of any ground for exclusion detailed hereunder.** In the event that the supporting documentation demonstrates that a ground for exclusion does, in fact, apply, the tenderer will be eliminated from this competition.

(Grounds detailed overleaf)

EXCLUSION GROUND		REG.
(i)	An economic operator will be excluded from this competition if the economic operator, or a member of its administrative, management or supervisory body, has been convicted of participation in a criminal organisation, within the meaning of Article 2 of Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime.	57.1(a)
(ii)	An economic operator will be excluded from this competition if the economic operator, or a member of its administrative, management or supervisory body, has been convicted of corruption, as defined by Regulation 57.1(b) of the European Union (Award of Public Authority Contracts) Regulations 2016.	57.1(b)
(iii)	An economic operator will be excluded from this competition if the economic operator, or a member of its administrative, management or supervisory body, has been convicted of fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests drawn up under the Council Act of 16 July 1995.	57.1(c)
(iv)	An economic operator will be excluded from this competition if the economic operator, or a member of its administrative, management or supervisory body, has been convicted of terrorist offences or offences linked to terrorist activities, within the meaning of Articles 1 and 3 respectively of Council Framework Decision 2002/475/JHA of 13 June 2002 on combating terrorism or inciting or aiding or abetting or attempting to commit an offence referred to in Article 4 of that Council Framework Decision.	57.1(d)
(v)	An economic operator will be excluded from this competition if the economic operator, or a member of its administrative, management or supervisory body, has been convicted of money laundering or terrorist financing, within the meaning of Article 1 of Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing.	57.1(e)
(vi)	An economic operator will be excluded from this competition if the economic operator, or a member of its administrative, management or supervisory body, has been convicted of child labour and other forms of trafficking in human beings, within the meaning of Article 2 of Directive 2011/36/EU41 of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims and replacing Council Framework Decision 2002/629/JHA.	57.1(f)
<i>NOTE #1: In respect of each of the exclusion grounds detailed under points (i) to (vi) above, an economic operator may provide evidence to the effect that it has undertaken sufficient measures to demonstrate its reliability, despite the existence of the ground for exclusion. Where, in the opinion of the Contracting Authority, such evidence is sufficient, the economic operator shall not be excluded from the competition. Appropriate evidence is detailed in Regulation 57.14 of the European Union (Award of Public Authority Contracts) Regulations 2016.</i> <i>NOTE #2: In the event that a conviction listed under points (i) to (vi) above occurred more than five years prior to the date of advertisement of this competition, the relevant ground for exclusion shall not apply.</i>		

(vii)	An economic operator will be excluded from this competition if the economic operator is in breach of its obligations relating to the payment of taxes or social security contributions and said breach has been established by a judicial or administrative decision having final and binding effect in accordance with the law of the country in which the operator is established or the Member State of the Contracting Authority. <i>NOTE #1: This provision will not apply when the economic operator has fulfilled its obligations by paying, or entering into a binding arrangement with a view to paying, the taxes or social security contributions due, including, where applicable, any interest accrued or fines.</i> <i>NOTE #2: At the discretion of the Contracting Authority, this provision may not apply when only minor amounts of taxes or social security contributions are in question or when the economic operator did not have time, between being made aware of the breach of obligations and the commencement of this competition, to pay, or to enter into an arrangement to pay, the amounts in question.</i> <i>NOTE #3: In the event that the breach of obligations referred to above occurred more than five years prior to the date of advertisement of this competition, this ground for exclusion shall not apply.</i>	57.3(a), 57.3(b)
(viii)	An economic operator will be excluded from this competition if the economic operator, in performance of a public contract, has not complied with all applicable obligations in the fields of environmental, social and labour law that apply at the place where the works are carried out or the services provided and that have been established by European Union law, national law, collective agreements or by international, environmental, social and labour law.	57.8(a)
(ix)	An economic operator will be excluded from this competition if the economic operator is bankrupt or is the subject of insolvency or winding-up proceedings, where its assets are being administered by a liquidator or by the court, where it is in an arrangement with creditors, where its business activities are suspended or it is in any analogous situation arising from a similar procedure under the law of the State. <i>NOTE: The Contracting Authority may, at its discretion, decide not to exclude an economic operator on this ground for exclusion if it is possible for the Contracting Authority to establish that the economic operator would be able to perform the contract, taking into account national rules, measures and laws relating to the continuation of business.</i>	57.8(b)
(x)	An economic operator will be excluded from this competition where the Contracting Authority can demonstrate, by appropriate means, that the economic operator is guilty of grave professional misconduct, which renders its integrity questionable.	57.8(c)
(xi)	An economic operator will be excluded from this competition where the Contracting Authority has sufficiently plausible indications to conclude that the economic operator has entered into arrangements with other economic operators aimed at distorting competition.	57.8(d)

(xii)	An economic operator will be excluded from this competition where a conflict of interest, as defined by Regulation 34 of the European Union (Award of Public Authority Contracts) Regulations 2016, cannot be effectively remedied by other, less intrusive, measures.	57.8(e)
(xiii)	An economic operator will be excluded from this competition where a distortion of competition from the prior involvement of the economic operator in the preparation of the procurement procedure cannot be remedied by other, less intrusive, measures.	57.8(f)
(xiv)	An economic operator will be excluded from this competition where the economic operator has shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity or a prior concession contract, which led to early termination of that prior contract, damages or other comparable sanctions.	57.8(g)
(xv)	An economic operator will be excluded from this competition where the economic operator has been guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria, has withheld such information or is not able to submit supporting documents required under Regulation 59 of the European Union (Award of Public Authority Contracts) Regulations 2016	57.8(h)
(xvi)	An economic operator will be excluded from this competition where the economic operator has undertaken to unduly influence the decision-making process of the Contracting Authority, or obtain confidential information that may confer upon it undue advantages in the procurement procedure or where the economic operator has negligently provided misleading information that may have a material influence on decisions concerning exclusion, selection or award.	57.8(i)
<i>NOTE #1: In respect of each of the grounds for exclusion detailed under points (viii) to (xvi) above, an economic operator may provide evidence to the effect that it has undertaken sufficient measures to demonstrate its reliability, despite the existence of the ground for exclusion. Where, in the opinion of the Contracting Authority, such evidence is sufficient, the economic operator shall not be excluded from the competition. Appropriate evidence is detailed in Regulation 57.14 of the European Union (Award of Public Authority Contracts) Regulations 2016.</i> <i>NOTE #2: In respect of each of the exclusion grounds detailed under points (viii) to (xvi) above, in the event that the situation referred to occurred more than three years prior to the date of advertisement of this competition, the relevant ground for exclusion will not apply.</i>		

5. ELIGIBILITY CRITERIA

5.1 *Eligibility Criteria and Associated Rules*

The Contracting Authority is using the open procedure for the establishment of this framework agreement. While any interested party may submit a tender, only those tenderers meeting the stated levels of financial and technical capacity will be considered for appointment to this framework agreement.

In order to enable the Contracting Authority to ascertain tenderers' financial and technical capacity, all tenderers must complete the ESPD contained in Appendix 2 of this document. In particular, Part IV of the ESPD constitutes a 'self declaration' to the effect that the tenderer complies with each of the eligibility criteria and rules detailed hereunder. Once the ESPD has been completed, no additional response to these eligibility criteria is required.

For the avoidance of doubt, the Contracting Authority reserves the right to request any tenderer to provide all supporting documentation necessary to demonstrate compliance with all eligibility criteria detailed hereunder. Such a request may be made at any point during the competitive process. **In particular, before reaching an award decision, the Contracting Authority may require the successful tenderer to provide all supporting documentation necessary to demonstrate compliance with all eligibility criteria detailed hereunder.** In the event that the supporting documentation demonstrates that any eligibility criterion is not complied with, the tenderer will be eliminated from this competition.

(Criteria detailed overleaf)

(a) INSURANCES

REQUIREMENT
It is a requirement that tenderer's either possess the following forms and levels of insurance, or are in a position to implement the following forms and levels of insurance if successful in the competition: (a) Employer's Liability- €13m (b) Public Liability - €6.5m (c) Product Liability – €6.5m
ESPD REFERENCE AND MEANS OF PROOF
By completing the ESPD contained in Appendix 2, tenderers are confirming that they either possess the forms and levels of insurance indicated or, alternatively, that they are in a position to obtain the forms and levels of insurance indicated if successful in this competition. Should the Contracting Authority elect to seek supporting evidence from tenderers confirming the assertions made in the ESPD in respect of this eligibility criterion, the following means of proof will be acceptable to the Contracting Authority to confirm that this criterion is complied with: (a) Evidence of the possession of the required forms and levels of insurance (i.e., certificates of insurance provided by brokers or underwriters); (b) A signed letter from the tenderer's insurance broker to the effect that the required forms and levels of insurance can be implemented should the tenderer prove successful in this competition.
ELIMINATION
Should a tenderer fail to provide appropriate supporting evidence within five working days of a request to do so, the tenderer in question will be eliminated from further consideration.

(b) FINANCIAL CAPACITY

REQUIREMENT
It is a requirement that tenderers have attained a turnover of at least €750,000 in any one of the three previous financial years.
ESPD REFERENCE AND MEANS OF PROOF
By completing the ESPD contained in Appendix 2, tenderers are confirming that they have attained a turnover of at least €750,000 in any one of the three previous financial years. Should the Contracting Authority elect to seek supporting evidence from tenderers confirming the assertions made in the ESPD in respect of this eligibility criterion, the following means of proof will be acceptable to the Contracting Authority to confirm that this criterion is complied with: (a) Financial statements or extracts from financial statements; (b) An objectively verifiable statement of the tenderer's overall turnover (e.g. an auditor's statement).
ELIMINATION
Should a tenderer fail to provide appropriate supporting evidence and means of proof within five working days of a request to do so, the tenderer in question will be eliminated from further consideration.

(c) TAX CLEARANCE

REQUIREMENT
It is a requirement that tenderers either possess a Tax Clearance Certificate issued by the Irish Revenue Commissioners, or will possess such certification prior to the establishment of this framework agreement. For the avoidance of doubt, it is emphasised that the Contracting Authority is precluded from processing invoices submitted by economic operators not in possession of an Irish Tax Clearance Certificate.
ESPD REFERENCE AND MEANS OF PROOF
By completing the ESPD contained in Appendix 2, tenderers are confirming that they either possess a Tax Clearance Certificate issued by the Irish Revenue Commissioners or have applied for such a certificate. Should the Contracting Authority elect to seek supporting evidence from tenderers confirming the assertions made in the ESPD in respect of this eligibility criterion, the following means of proof will be acceptable to the Contracting Authority to confirm that this criterion is complied with: (a) A reference to electronic evidence of tax clearance status issued by the Irish Revenue Commissioners (i.e., a screenshot, a hyperlink or any other appropriate material); (b) Copies of correspondence between the tenderer and the Irish Revenue Commissioners.
ELIMINATION
Should a tenderer fail to provide appropriate supporting evidence and means of proof within five working days of a request to do so, the tenderer in question will be eliminated from further consideration.

6. AWARD CRITERIA

This contract will be awarded to the tenderer submitting the most economically advantageous tender, identified following application of the award criteria, sub-criteria and weightings detailed hereunder. It is emphasised that the Contracting Authority is not bound to accept the most economically advantageous tender or any tender received, and reserves the right to accept or reject in whole or in part any or all Tenders received.

AWARD CRITERIA AND WEIGHTINGS				
CRITERION		%	MAXIMUM SCORE ACHIEVABLE	MINIMUM SCORE REQUIRED
A	Ultimate Cost	50	5,000	N/A
B	Clinical Suitability and Appropriateness of Proposed Packs	40	4,000	2,400
C	Reliability and Continuity of Supply	5	500	300
D	Proposed Delivery Schedule	5	500	300

6.2 Award Criteria Explained

As a general condition of evaluation, the Contracting Authority will utilise the evaluation process in order to determine whether each tender submission is substantially responsive to the requirements of this Invitation to Tender document. If a material deviation exists that limits in any substantial way the Contracting Authority's rights or the tenderer's obligations under the contract to be awarded, the tender submission may, depending upon the severity of the deviation in question, be rejected.

The assessment of tender submissions against the stated award criteria will be carried out by reference to completed detailed specification (see Section 2). In particular, and for the avoidance of doubt, each qualitative criterion will be assessed by reference to the following sections of the detailed specification:

- **Criterion A, 'Ultimate Cost,'**

Tenderers are required to complete in full the Form of Tender contained in Appendix 1. The Form of Tender details the manner in which a single cost figure will be arrived at for evaluation purposes. The lowest notional ultimate cost tender that also meets all minimum requirements described in this document will attain the highest score available under this criterion. The scores of all other valid tenders will be calculated as follows:

Points awarded = (the maximum score achievable) multiplied by (the cost of the lowest-cost valid tender) divided by (the cost of the valid tender in question).

- **Criterion B, 'Clinical Suitability and Appropriateness of Proposed Packs**

Tenderers are required to provide, for evaluation purposes, two non-sterile samples of each pack listed in section 2.2.8, 2.2.9 and 2.2.10 of this document. Samples must be provided by the tender closing date and sent directly to:

David McHugh, Procurement Department, Beaumont Hospital

In order to attain the minimum required score associated with this criterion, the following conditions must be met:

- All products must be of good quality and suitable for clinical use.
- All products must be CE marked and manufactured to the relevant standard.
- The proposed packs must conform to the layout and structure of packs required by the clinical users.
- The packaging must be easy to open and the sterility of the contents must not be compromised while handling.
- The proposed packs must include an appropriate lot number to provide full traceability from date of manufacture.
- The proposed packs must be appropriately designed to minimise cross contamination and damage to the central venous catheters.

Scores in excess of the minimum required score will be apportioned by reference to the overall quality, suitability and appropriateness of the pack's components. Additionally, the layout and structure of the packs will also be taken into consideration in the context of the day-to-day use of the packs by clinicians.

- **Criterion C, 'Reliability and Continuity of Supply,'**

Tenderers will be assessed by reference to Section 2.7 of this document. Tenderers are required to provide comprehensive information in respect of the following:

- The proposed tracking system, which must include batch numbers to allow for the efficient identification of individual packs;
- The proposed products recall policy, which must include an appropriate system for notification and the effective management of hazards and/or recalls.

The Contracting Authority reserves the right to contact previous clients of the tenderer, independently and without further reference to the tenderer, in order to ascertain that full

confidence may be placed in the tenderer's ability to successfully deliver the required products in a sufficiently reliable manner.

- **Concerning Criterion D, 'Proposed Delivery Schedule'**

Tenderers will be assessed by reference to Section 2.8 of this document. Tenderers are required to outline their proposed delivery schedules. In order to attain the minimum required score associated with this criterion, proposed delivery schedules must contain a commitment to deliver all required products on a weekly basis and must contain a commitment to hold four months' stock for ready use by the Contracting Authority.

6.3 Minimum Qualitative Score Required

Tenderers should note that they must achieve a minimum rating of 'acceptable,' or 60% of the total marks available, for certain criteria. For the avoidance of doubt, a failure to attain any minimum required score will result in the elimination of the Tender Submission in question from further consideration. Should a Tender Submission fail to attain a minimum required score, Tenderer's attention is drawn to the fact that the following provisions shall apply:

6.3.1 The Tender Submission in question shall not be subject to a comparative assessment against other Tender Submissions.

6.3.2 The financial proposal contained in the Tender Submission in question shall not be subject to evaluation under Award Criterion A (Ultimate Cost).

6.3.3 The Tenderer in question will be notified of the reasons for the failure to attain the minimum required score. Additionally, the Tenderer in question shall be informed of the name of the successful Tenderer and shall be informed of the duration of the standstill period.

6.3.4 On the basis that no comparative assessment will have taken place (see Section 6.3.1) and the financial proposal of the Tenderer in question will not have been assessed (see Section 6.3.2), the characteristics and relative advantages of the successful Tenderer under any qualitative or financial criterion **will not be provided**, by virtue of the fact that the Contracting Authority will not have access to such information.

6.4 Assessment of Qualitative Responses

As a general condition of evaluation, the Contracting Authority will utilise the evaluation process in order to determine whether each tender submission is substantially responsive to the requirements of this Invitation to Tender document. If a material deviation exists that limits in any substantial way the Contracting Authority's rights or the tenderer's obligations under the contract to be awarded, the tender submission may, depending upon the severity of the deviation in question, be rejected.

The evaluation team shall rely upon the following scoring bands for the purposes of apportioning scores under the qualitative sub-criteria:

ELIMINATED	0% of marks available	No response
	20% of marks available	Poor
	40% of marks available	Mediocre
ELIGIBLE	60% of marks available	Acceptable
	70% of marks available	Good
	80% of marks available	Very Good
	90% of marks available	Excellent
	100% of marks available	Outstanding

6.5 Verification and Clarification Meetings

Meetings for the purpose of verification and/or clarification may be carried out with certain tenderers as an element of the evaluation process and solely in order to identify the most economically advantageous tender. Such meetings may be required in order to verify the scores achieved by tenderers in respect of their written tender submissions, or to resolve any procedural ambiguities. Following such meetings, any scores provisionally awarded by the Contracting Authority may legitimately be revised and/or amended in order to take into account matters discussed. For the avoidance of doubt, tenderers should note that mere performance at interview will not of itself be evaluated. A request to attend a clarification or verification meeting should not be construed as an indication of success in this competition; no legitimate expectations should arise from any such request.

Notwithstanding the foregoing, without prejudice to the principle of equal treatment, the Contracting Authority is not obliged to engage in a clarification process in respect of tender submissions involving missing or incomplete information. Therefore, tenderers are advised to ensure that they return comprehensive tender submissions in order to avoid the risk of elimination from the competition.

The Contracting Authority expressly warrants that any clarification or verification activities will not introduce new conditions to the competition, will not have the effect of amending the assessment methodology described in this Invitation to Tender documentation and will not pejoratively impact upon the principles of equal treatment and transparency in accordance with which this procurement exercise is being conducted. In particular, any information becoming apparent during any verification or clarification meeting will be relied upon only in the context of the award criteria, sub-criteria, weightings and specification of requirements contained in this Invitation to Tender documentation.

6.6 Demonstrations and Equipment Trials

The Contracting Authority reserves the right to request that the equipment constituting the subject-matter of this competition is made available to the Contracting Authority on a trial basis. In the event that a trial of any proposed equipment is requested, the trial will afford the Contracting Authority the opportunity to verify the scores achieved by tenderers in respect of their written tender submissions. Following any such trial or demonstration, any scores provisionally awarded by the Contracting Authority may legitimately be revised and/or amended in order to take into account matters becoming apparent during the trial or demonstration. A request to facilitate a product demonstration or equipment trial should not be construed as an indication of success in this competition; no legitimate expectations should arise from any such request.

It is emphasised that the Contracting Authority shall exercise its discretion in determining which equipment to trial. In this regard, tenderers' attention is drawn to the following conditions:

- The Contracting Authority may legitimately elect to award this contract without requesting a trial or demonstration of any tendered equipment.
- The Contracting Authority may request trials or demonstrations of products offered by certain tenderers. In particular, in the event that the evaluation of written tender submissions demonstrates that a particular tenderer has not submitted an admissible tender, or has submitted a tender that cannot, mathematically, be identified as the most economically advantageous tender submission, said tenderer will not be required to facilitate a trial or demonstration.
- Conversely, in the event that the Contracting Authority is already familiar with the equipment tendered by a particular tenderer (e.g., on the basis that it is already in use by the Contracting Authority or by staff members of the Contracting Authority), said tenderer will not be required to facilitate a trial or demonstration.

The Contracting Authority expressly warrants that any demonstrations or trials will not introduce new conditions to the competition, will not have the effect of amending the assessment methodology described in this Invitation to Tender documentation and will not pejoratively impact upon the principles of equal treatment and transparency in accordance with which this procurement exercise is being conducted. In particular, any information becoming apparent during any trial or demonstration will be relied upon only in the context of the award criteria, sub-criteria, weightings and specification of requirements contained in this Invitation to Tender documentation.

In the event that a tenderer is required to facilitate a demonstration or trial for evaluation purposes, the equipment and any required consumables must be provided to the Contracting Authority without charge for a period of time sufficient to enable the Contracting Authority to fully assess its technical merit. In the event that equipment cannot be provided for trial or demonstration purposes within 21

calendar days of a request from the Contracting Authority, the tenderer in question will be at a distinct disadvantage in respect of the evaluation process.

6.7 Acceptance of Assessment Methodology

By submitting a tender, each tenderer acknowledges that the evaluation of tender submissions will be conducted in accordance with the procedures laid down in this Invitation to Tender document. Any queries, reservations or observations should properly be raised by tenderers via the communications protocol contained in Section 3.3 of this document prior to the submission of a tender.

APPENDIX 1 – FORM OF TENDER

This form of tender must be completed, signed and returned by tenderers. Any amendment to the structure of this document, or any qualification of financial offers, may, at the sole discretion of the Contracting Authority, result in the elimination of the tender in question.

Contracting Authority: Beaumont Hospital

Competition: Single-Party Framework Agreement for the Supply of Haemodialysis On/Off Packs

From: _____

I/We, having read the full Tender Documents and associated Appendices, do hereby offer to provide the whole of the services described all to the entire satisfaction of the Client, for the following prices, and establish a framework agreement a contract accordingly:

TYPE OF PACK	UNIT PACK PRICE (€, Exc. VAT)	NOTIONAL QUANTITY FOR EVALUATION PURPOSES	SUBTOTAL
Central Line On/Off Pack	<i>Insert, €</i>	34,000	<i>Insert, €</i>
AVF On/Off Pack	<i>Insert, €</i>	24,000	<i>Insert, €</i>
CVC Intervention Pack	<i>Insert, €</i>	2,000	<i>Insert, €</i>
ULTIMATE COST FOR EVALUATION PURPOSES		<i>Insert Total €</i>	

I/We confirm that I/we:

- Will keep this offer open for acceptance by the Contracting Authority for a period of twelve months from the date of deadline for submission of tenders;
- Agree that you are not bound to accept the most economically advantageous tender or any tender you may receive;
- Have read and thoroughly examined the tender document;
- Fully understand the tender document and the Contracting Authority's requirements;
- Undertake to treat the details of this invitation to tender document, the resulting tender submission and any subsequent clarifications as private and confidential;

- Acknowledge that acceptance by the Contracting Authority of a tender will not constitute a binding and enforceable agreement and that a legally enforceable agreement will not exist until and unless the framework agreement has been formally established by the Contracting Authority;
- Have availed of all offers for additional information or have otherwise satisfied myself/ourselves as to conditions that may in any manner affect the performance of the framework agreement;
- Have included everything necessary for the performance of this contract, including all elements that are either expressly stated in the tender document or contained in any supplementary information or which could reasonably be inferred there from;
- Have found no errors, omissions, conflicts or ambiguities in the tender document, except those which I/We have brought to the attention of the Contracting Authority before the latest date for submitting queries;
- Have included for compliance with all statutory requirements applicable in Ireland and those applicable in any country where parts of the framework agreement may be performed that are in force seven days prior to the deadline for receipt of tenders;
- Will not, if awarded membership of the framework agreement, employ labour in a manner that is discriminatory in relation to gender, race, religious beliefs, age, etc.;
- Will not, if awarded membership of the framework agreement, source any goods or services in countries subject to official international trading sanctions.

SIGNATURE	<i>(Insert)</i>	Date	<i>(Insert)</i>
Name	<i>(Insert)</i>	Position	<i>(Insert)</i>
Telephone	<i>(Insert)</i>	Email	<i>(Insert)</i>

A Tenderer's failure to sign and date this Form of Tender and to complete all sections will invalidate the tender submission.

APPENDIX 2 – EUROPEAN SINGLE PROCUREMENT DOCUMENT (ESPD)

- a) This document must be completed and returned by tenderers. The completed version of this document will constitute a 'self-declaration' that the grounds for exclusion detailed in Section 4 of the Invitation to Tender document do not apply to the tenderer and that the tenderer is in a position to comply with each of the eligibility criteria detailed in Section 5 of the Invitation to Tender document.
- b) Failure to complete all sections of this document will result in the tenderer's elimination from this competition. Moreover, failure to provide sufficient detail in respect of any field may, at the discretion of the Contracting Authority, result in the elimination of the tenderer in question.
- c) Any misrepresentation in respect of the completed document will result in the tenderer's elimination from this and future procurement competitions.
- d) Tenderers may reuse a European Single Procurement Document previously submitted in respect of another competition. Alternatively, in the event that a tenderer has previously completed an electronic version of this document, the tenderer may provide the Contracting Authority with electronic access to the relevant document. In both instances, it is imperative that the completed version of the European Single Procurement Document contains all of the information sought by this document.
- e) For the avoidance of doubt, the Contracting Authority reserves the right to request any tenderer to provide all supporting documentation necessary to demonstrate the inapplicability of any ground for exclusion detailed in Section 4 of the Invitation to Tender document. Additionally, the Contracting Authority reserves the right to request any tenderer to provide all supporting documentation necessary to demonstrate compliance with the eligibility criteria detailed in Section 5 of the Invitation to Tender document. Such requests may be made at any point during the competitive process. **In particular, before reaching an award decision, the Contracting Authority may require the successful tenderer to provide all supporting documentation necessary to confirm the assertions made hereunder.**
- f) If a tenderer fails to provide supporting documentation necessary to confirm the assertions made hereunder within five working days of a request to do so from the Contracting Authority, the tenderer in question will be eliminated from the competition.

PART I – INFORMATION CONCERNING THE PROCUREMENT PROCEDURE AND THE CONTRACTING AUTHORITY

IDENTITY OF THE PROCURER:	ANSWER:
Name:	Beaumont Hospital
Which procurement is concerned?	Single-party framework agreement for the supply of Haemodialysis On/Off Packs
Title or short description of the procurement:	Single-party framework agreement for the supply of Haemodialysis On/Off Packs
File reference number attributed:	3079

PART II – INFORMATION CONCERNING THE ECONOMIC OPERATOR	
A: INFORMATION ABOUT THE ECONOMIC OPERATOR	
IDENTIFICATION:	ANSWER:
Name:	<i>Insert</i>
VAT-number, if applicable: <i>(If no VAT-number is applicable, please indicate another national identification number, if required and applicable)</i>	<i>Insert</i>
Postal Address:	<i>Insert</i>
Contact Person or Persons:	<i>Insert</i>
Telephone:	<i>Insert</i>
E-mail:	<i>Insert</i>
Internet address, if applicable:	<i>Insert</i>
GENERAL INFORMATION:	ANSWER:
Is the economic operator a Micro, a Small or a Medium-Sized Enterprise?	Yes ☐ No ☐ Define which: <i>Insert</i>
Only in the case the procurement is reserved, is the economic operator a sheltered workshop, a 'social business,' or will it provide for the performance of the contract in the context of sheltered employment programmes?	NOT APPLICABLE
If yes, what is the corresponding percentage of disabled or disadvantaged workers? If required, please specify which category or categories of disabled or disadvantaged workers the employees concerned belong to.	NOT APPLICABLE
If applicable, is the economic operator registered on an official list of approved economic operators or does it have an equivalent certificate (e.g., under a national [pre]qualification system)?	Yes ☐ No ☐ Not Applicable ☐
<i>If you have answered 'yes' to the above question, answer the remaining parts of this Section, Section B and, where relevant, Section C of Part II. Then complete and sign Part VI. (i.e., if you have answered 'yes' to the above question, there is no need to complete Parts III and IV of this Appendix).</i>	
Please provide the name of the list or certification and the relevant registration or certificate number, if applicable:	<i>Insert</i>
If the certificate of registration or certification is available electronically, please state:	<i>Insert web address, issuing authority or body, precise reference of the documentation.</i>
Please state the references on which the registration or certification is based and, where applicable, the classification obtained in the official list:	<i>Insert</i>

Does the registration or certification cover all of the required selection criteria? <i>(If 'no,' please complete and sign Appendix IV of this document.)</i>	Yes ☐ No ☐
Will the economic operator be able to provide a certificate with regard to the payment of social security contributions and taxes or provide information enabling the Contracting Authority or Contracting Entity to obtain it directly by accessing a national database in any Member State that is available free of charge?	Yes ☐ No ☐ <i>(If the relevant documentation is available electronically, please insert the web address, the issuing authority or body and the precise reference of the documentation).</i>
FORM OF PARTICIPATION	ANSWER:
Is the economic operator participating in the procurement procedure together with others?	Yes ☐ No ☐
<i>If you have answered 'yes' to the above question, please ensure that the others concerned provide a separate ESPD document and please answer the questions below:</i>	
If 'yes,' please indicate the role of the economic operator in the group (e.g., leader, responsible for specific tasks, etc.):	<i>Insert</i>
If 'yes,' please identify the other economic operators participating in the procurement procedure together:	<i>Insert</i>
Where applicable, please insert the name of the participating group:	<i>Insert</i>
LOTS:	ANSWER:
Where applicable, please indicate the lot(s) for which the economic operator wishes to tender:	NOT APPLICABLE
B: INFORMATION ABOUT REPRESENTATIVES OF THE ECONOMIC OPERATOR	
<i>Where applicable, please indicate the name(s) and address(es) of the person(s) empowered to represent the economic operator for the purposes of this procurement procedure:</i>	
REPRESENTATION, IF ANY:	ANSWER:
Full Name: <i>(Accompanied by the date and place of birth, if required)</i>	<i>Insert</i>
Position / Acting in the capacity of:	<i>Insert</i>
Postal Address:	<i>Insert</i>
Telephone:	<i>Insert</i>
E-mail:	<i>Insert</i>
If necessary, please provide detailed information regarding the representation (e.g., its form, extent, purpose, etc).	<i>Insert</i>

C: INFORMATION ABOUT RELIANCE ON THE CAPACITIES OF OTHER ENTITIES	
RELIANCE:	ANSWER:
Does the economic operator rely on the capacities of other entities in order to meet the eligibility criteria for this competition as set out in Section 5 of the associated Invitation to Tender document?	Yes ☐ No ☐
<i>If 'yes,' please provide a separate ESPD form setting out the information required under Sections A and B of this Part and Part III of this Appendix for each of the entities concerned, duly completed and signed by the entities concerned. Please note that this should also include any technicians or technical bodies, not belonging directly to the economic operator's undertaking, especially those responsible for quality control and, in the case of public works contracts, the technicians or technical bodies upon whom the economic operator can call in order to carry out the work.</i> <i>Insofar as it is relevant for the specific capacity or capacities on which the economic operator relies, it may also be necessary for some or all of the entities concerned to complete Part IV of this Appendix.</i>	
D: INFORMATION CONCERNING SUBSUCCESSFUL TENDERERS ON WHOSE CAPACITY THE ECONOMIC OPERATOR DOES NOT RELY	
SUBCONTRACTING	ANSWER:
Does the economic operator intend to subcontract any share of the contract to third parties?	Yes ☐ No ☐ If 'yes,' and so far as is known, please list the proposed subcontractors.
<i>If 'yes,' please provide the information required under Sections A and B of this part for each of the subcontractors concerned.</i>	

PART III – EXCLUSION GROUNDS

A: GROUNDS RELATING TO CRIMINAL CONVICTIONS

Article 57.1 of Directive 2014/24/EU sets out the following reasons for exclusion:

- 1. Participation in a criminal organisation;*
- 2. Corruption;*
- 3. Fraud;*
- 4. Terrorist offences or offences linked to terrorist activities;*
- 5. Money laundering or terrorist financing;*
- 6. Child labour and other forms of trafficking in human beings.*

GROUND:	ANSWER:
Has the economic operator itself or any person who is a member of its administrative, management or supervisory body or has powers of representation, decision or control therein been the subject of a conviction for one of the reasons listed above, by a conviction rendered at the most five years ago or in which an exclusion period set out directly in the conviction continues to be applicable?	Yes ☐ No ☐ <i>If the relevant documentation is available electronically, please insert the web address, the issuing authority or body and the precise reference of the documentation.</i>
<i>If 'yes,' please provide the following information:</i>	
Date of conviction, which of the grounds for conviction (points 1 to 6 above) is concerned and the reason(s) for the conviction:	<i>Insert dates, points and reasons.</i>
Identify who has been convicted:	<i>Insert</i>
Insofar as is established directly in the conviction:	<i>Insert the length of the period of exclusion and the point(s) concerned.</i> <i>If the relevant documentation is available electronically, please insert the web address, the issuing authority or body and the precise reference of the documentation.</i>
In cases of convictions, has the economic operator taken measures to demonstrate its reliability despite the existence of a relevant ground for exclusion (as per Article 57.6 of Directive 2014/24/EU)?	Yes ☐ No ☐ <i>If 'yes' please insert a comprehensive description of the measures taken.</i>
B: GROUNDS RELATING TO THE PAYMENT OF TAXES OR SOCIAL SECURITY CONTRIBUTIONS	
PAYMENT OF TAXES / SOCIAL SECURITY:	ANSWER:
Has the economic operator met all of its obligations relating to the payment of taxes or social security contributions, both in the country in which it is established and in the Member State of the Contracting Authority if other than the country of establishment?	Yes ☐ No ☐
If the relevant documentation concerning payment of taxes or social contributions is available electronically, please indicate:	<i>Please insert the web address, the issuing authority or body and the precise reference of the documentation.</i>

<i>If the economic operator has not met all of its obligations relating to the payment of taxes or social security contributions, please provide the following information:</i>		
Country or member state concerned:	Taxes	Social Contributions
	<i>Insert</i>	<i>Insert</i>
What is the amount concerned?	<i>Insert</i>	<i>Insert</i>
How has this breach of obligations been established?	<i>Insert</i>	<i>Insert</i>
If through a judicial or administrative decision, is this decision final and binding?	Yes ☐ No ☐	Yes ☐ No ☐
If through a judicial or administrative decision, please indicate the date of conviction or decision:	<i>Insert</i>	<i>Insert</i>
If through a judicial or administrative decision, and in the case of a conviction, please provide the length of the period of exclusion:	<i>Insert</i>	<i>Insert</i>
If this breach of obligations has been established by other means, please indicate the other means in question:	<i>Insert</i>	<i>Insert</i>
Has the economic operator fulfilled its obligations by paying or entering into a binding arrangement with a view to paying the taxes or social security contributions due, including, where applicable, any interest or accrued fines?	Yes ☐ No ☐	Yes ☐ No ☐
If the relevant documentation concerning payment of taxes or social contributions is available electronically, please indicate:	<i>Please insert the web address, the issuing authority or body and the precise reference of the documentation.</i>	
C: GROUNDS RELATING TO INSOLVENCY, CONFLICTS OF INTEREST OR PROFESSIONAL MISCONDUCT		
GROUNDS:	ANSWER:	
Has the economic operator, to its knowledge, breached its obligations in the fields of environmental, social and labour law?	Yes ☐ No ☐	
If the economic operator has breached its obligations in the fields of environmental, social and labour law, has the economic operator taken measures to demonstrate its reliability despite the existence of a relevant ground for exclusion (as per Article 57.6 of Directive 2014/24/EU)?	Yes ☐ No ☐ <i>If 'yes' please insert a comprehensive description of the measures taken.</i>	
Is the economic operator in any of the following situations: • Bankrupt; • The subject of insolvency or winding-up proceedings; • In an arrangement with creditors; • In any analogous situation arising from a similar procedure under national laws and regulations; • That its assets are being administered by a liquidator or the court;	Yes ☐ No ☐	

• That its business activities are suspended?	
If the economic operator is in any of the situations mentioned in the immediately preceding question, please provide comprehensive details of the situation:	<i>Insert</i>
Please provide the reasons for nevertheless being able to perform the contract or framework agreement, taking into account the applicable national rules and measures on the continuation of business in those circumstances, as per Article 57.4 of Directive 2014/24/EU.	<i>Insert</i>
If the relevant documentation is available electronically, please indicate:	<i>Please insert the web address, the issuing authority or body and the precise reference of the documentation.</i>
Is the economic operator guilty of grave professional misconduct?	Yes ☐ No ☐ <i>If 'yes' please insert a comprehensive description of the matter.</i>
If the economic operator is guilty of grave professional misconduct, has the economic operator taken measures to demonstrate its reliability despite the existence of a relevant ground for exclusion (as per Article 57.6 of Directive 2014/24/EU)?	Yes ☐ No ☐ <i>If 'yes' please insert a comprehensive description of the measures taken.</i>
Has the economic operator entered into arrangements with other economic operators aimed at distorting competition?	Yes ☐ No ☐ <i>If 'yes' please insert a comprehensive description of the arrangements in question.</i>
If the economic operator has entered into arrangements with other economic operators aimed at distorting competition, has the economic operator taken measures to demonstrate its reliability despite the existence of a relevant ground for exclusion (as per Article 57.6 of Directive 2014/24/EU)?	Yes ☐ No ☐ <i>If 'yes' please insert a comprehensive description of the measures taken.</i>
Is the economic operator aware of any conflict of interest due to its participation in the procurement procedure?	Yes ☐ No ☐ <i>If 'yes' please provide a comprehensive description of the conflict(s) in question.</i>
Has the economic operator or an undertaking related to it advised the Contracting Authority or otherwise been involved in the preparation of the procurement procedure?	Yes ☐ No ☐ <i>If 'yes' please provide a comprehensive description of the matter.</i>
Has the economic operator experienced that a prior public contract, framework agreement or concession contract was terminated early, or that damages or other comparable sanctions were imposed in connection with a prior contract?	Yes ☐ No ☐ <i>If 'yes' please insert a comprehensive description of the matter.</i>

If the economic operator experienced that a prior public contract, framework agreement or concession contract was terminated early, or that damages or other comparable sanctions were imposed in connection with a prior contract, has the economic operator taken measures to demonstrate its reliability despite the existence of a relevant ground for exclusion (as per Article 57.6 of Directive 2014/24/EU)?	Yes ☐ No ☐ <i>If 'yes' please insert a comprehensive description of the measures taken.</i>
Can the economic operator confirm the following: • That it has not been guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria? • That it has not withheld such information? • That it has been able, without delay, to submit the supporting documents required by a contracting authority or contracting entity? • That it has not undertaken to unduly influence the decision making process of a contracting authority or contracting entity, to obtain confidential information that may confer upon it undue advantages in a procurement procedure or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award?	Yes ☐ No ☐

PART IV – ELIGIBILITY CRITERIA

α: GLOBAL INDICATION FOR ALL SELECTION CRITERIA

Concerning the eligibility criteria, the economic operator declares that it satisfies the required eligibility criteria for this competition as detailed in Section 5 of the Invitation to Tender document:

Yes ☐ No ☐

PART V – REDUCTION OF THE NUMBER OF QUALIFIED CANDIDATES

NOT APPLICABLE

PART VI – CONCLUDING STATEMENTS

The undersigned formally declare that the information stated under Parts II – III of this Appendix is accurate and that it has been set out in full awareness of the consequences of serious misrepresentation.

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

- (a) The Contracting Authority has the possibility of obtaining the supporting documentation concerned directly by accessing a national database in any Member State that is available free of charge;
- (b) As of **XX/XX/XXXX** at the latest, the Contracting Authority already possesses the documentation concerned.

The undersigned formally consent to Beaumont Hospital gaining access to documents supporting all information provided in this European Single Procurement Document for the purposes of this competition.

Signed (Authorised Signatory):	<i>Insert</i>
Block Capitals:	<i>Insert</i>
Position:	<i>Insert</i>
Company:	<i>Insert</i>
Registered Office:	<i>Insert</i>
Date:	<i>Insert</i>

APPENDIX 3 – DRAFT TERMS AND CONDITIONS OF THE FRAMEWORK AGREEMENT

*The following terms are provided as an indication of the intended format of the framework agreement to be signed with the framework operator emerging from this competition. Tenderers are **not** requested to sign these terms as part of their tender submission but should review them carefully and indicate any areas of interest by submitting a written query during the tender period.*

Single Party Framework Agreement for the Supply of Sterile Haemodialysis On/Off Procedure Packs

PARTIES

Beaumont Hospital
(Hereinafter referred to as ‘the Contracting Authority’)

XXX
(Hereinafter referred to as ‘the Framework Operators’ or ‘Operators’)

BACKGROUND

The Contracting Authority has conducted a tender competition for the establishment of a single party framework agreement for the supply of sterile single use Haemodialysis On/Off procedure packs.

- a. The framework agreement was advertised via the Irish Government’s Procurement Opportunities Portal (www.etenders.gov.ie).
- b. The open procedure was used and an Invitation to Tender was issued with a deadline date for tender submissions of 28/08/2026.
- c. Following evaluation of the submitted tender against the published award criteria, the Framework Operator is now appointed as the single operator under this Framework Agreement.

DEFINITIONS

‘*Contract*’ means a contract falling within the advertised scope of this Framework Agreement, constituting a defined and agreed piece of work to be performed by a Framework Operator;

‘*Framework Agreement*’ means these terms and conditions, including the Schedules hereto;

‘*Framework Period*’ means the period in years set out in Clause 2.1;

‘*Invitation to Tender*’ means the Invitation to Tender document issued by the Contracting Authority on 07/08/2026;

'Price' means the amount in Euro chargeable by the Framework Operators in respect of any item, supply or associated services purchased by the Contracting Authority;

'Request for Supplementary Tender' means a document issued by the Contracting Authority at any point during the Framework Period requesting a proposal for the provision of either supplies or services;

'Supplementary Tender' means the written submission of the Framework Operator in response to a Request for Supplementary Tender;

'Tender' means the submission of the Framework Operator in response to the Invitation to Tender together with any clarifications, additions or amendments accepted by the Contracting Authority.

'Commencement Date' means the date upon which this Framework Agreement shall come into effect, being XX/XX/2026.

'Initial Contract' means the first contract to be awarded under this Framework Agreement, constituting the supply of the required products for a period of two years, commencing upon the Commencement Date.

1. Appointment of Framework Operator

- 1.1 In consideration of payment by the Contracting Authority of good and valuable consideration, receipt of which is hereby acknowledged, the Framework Operator accepts their appointment under the terms and conditions of this Framework Agreement.
- 1.2 Appointment to this Framework does not entitle the Operator to be consulted in respect of, or awarded, any contract during the Framework Period. The Contracting Authority may at its sole discretion choose not to enter into any contracts falling within the scope of this Framework Agreement, or to terminate the Agreement in accordance with Clause 11.
- 1.3 While this Framework Agreement will, in general, form the basis for the award of contracts falling within the scope set out in Clause 3.1 during the Framework Period, the Contracting Authority may at its sole discretion decide to carry out a separate contract award procedure for contracts falling within the specified scope. In this event, the Contracting Authority shall observe all applicable public procurement rules and shall not afford any advantage to any Framework Operator.

2. Period of Framework Agreement

- 2.1 The Framework Agreement shall take effect on the Commencement Date and will be for a maximum potential duration of four years.

3. Scope of Framework Agreement

- 3.1 This Framework Agreement relates to the supply of sterile single use wound care products and small procedure packs as described in the specification of requirements contained in the Invitation to Tender document and appended to this Agreement at Schedule 4.

4. Award of Contracts

- 4.1 Upon appointment, the Framework Operator is automatically awarded an Initial Contract of two years' duration for the supply of the required products.
- 4.2 Subsequent Contracts under this Framework Agreement may be awarded either on foot of the Invitation to Tender or on foot of a Request for Supplementary Tender in accordance with the procedure set out in Clause 5.

5. Procedure for Supplementary Tenders

- 5.1 In general, it is envisioned that the majority of work required under this framework agreement will be directly awarded on foot of the Invitation to Tender document. From time-to-time, however, in accordance with Article 32.3 of Directive 2004/18/EC, the Contracting Authority may elect to issue a Request for Supplementary Tender during the Framework Period, in accordance with the following procedure. It is emphasised that Supplementary Tenders will be sought solely in respect of work falling under the advertised scope of the framework agreement.
- 5.1.1 The Contracting Authority will issue a Request for Supplementary Tender to the Framework Operator in writing, specifying the conditions that will apply in respect of the Supplementary Tender.
- 5.1.2 The Contracting Authority shall specify the scope of the Supplementary Tender, and in particular whether the applicable terms and fees will be determined by reference to the Tender or, where relevant, the Supplementary Tender.
- 5.1.3 The Contracting Authority shall fix a deadline for the receipt of the Supplementary Tender taking into account the complexity of the Contract and the time needed to prepare an appropriate proposal.
- 5.1.4 Following evaluation of the Supplementary Tender, the Contracting Authority shall determine whether it meets its stated requirements and whether a Contract will be awarded.
- 5.2 The Contracting Authority shall not be responsible for any costs incurred by the Framework Operator in the preparation of a Supplementary Tender or any related site visits.

- 5.3 The Contracting Authority shall not be obliged to award any Contract on foot of a Request for Supplementary Tender and may terminate the award procedure at any time at its sole discretion.

6. Conditions for Award of Contracts

- 6.1 Award of any Contract under the Framework Agreement may be subject to the Framework Operator to whom it is intended to award the Contract facilitating, upon request, the drafting and implementation of a Service Level Agreement, to include agreed key performance indicators, response times, escalation procedures and penalties.

7. Pricing

- 7.1 The maximum price chargeable in respect of all Items contracted during the initial twenty four months of the Framework Period shall be that set out in the Form of Tender or Pricing Schedules submitted as part of the Tender (Schedule 1 of this Agreement). Following the expiry of this twenty four month period, the price chargeable may be adjusted for inflation on each annual anniversary of the Commencement Date of the framework, subject to agreement by the Contracting Authority. This adjustment shall be in accordance (whether positive or negative) with the CPI index.
- 7.2 The Contracting Authority may seek, or the Framework Operator may offer, lower prices at any time during the Framework Period. In particular, where a given item, supply or service is being offered to other purchasers at a lower price, the Contracting Authority may request adjustment of a Framework Operator's Pricing Schedules or Form of Tender to reflect this fact. The Contracting Authority may reject any aspect of a Mini-Tender on the grounds that the Price offered is not acceptable.

8. Personnel

- 8.1 The personnel assigned by a Framework Operator to deliver any Contract under this Framework Agreement shall be those identified in the Framework Operator's Tender or Mini-Tender, or other personnel of equivalent qualifications, skills, professional expertise and experience expressly approved by the Contracting Authority.

9. Obligations of Framework Operators

- 9.1 The Framework Operator is required to inform the Contracting Authority of any conflict of interest of which it becomes aware during the period of the Framework Agreement. Any registrable interest involving the Framework Operator and the Contracting Authority or employees of the Contracting Authority or their relatives must be communicated to the Contracting Authority immediately. The terms 'registrable interest' and 'relative' shall be interpreted as per Section 2 and the Second Schedule of the Ethics in Public Office Act, 1995.

- 9.2 The Framework Operator is required to maintain, as a minimum, the forms of insurance set out in Schedule 3. These forms and levels of insurance may be subject to revision during the lifetime of the Agreement, in which case the Contracting Authority shall notify the Framework Operator in question of the revised requirements and allow thirty (30) days for the provision of evidence that the required policies are in place. The levels of insurance required in respect of individual Contracts may vary, in which case the Contracting Authority shall notify the Framework Operator in question of the required levels of insurances in the relevant Request for Mini-Tender, if appropriate, or at the earliest opportunity.
- 9.3 The Framework Operator shall retain a copy of its submitted European Single Procurement Document (ESPD), as used during the evaluation of tender submissions prior to the establishment of this Framework Agreement, and as appended to this Agreement as Schedule 2. If at any point during the Framework Period or during the lifetime of a Contract an Operator becomes aware of circumstances that might affect the validity of any of the statements in its ESPD, it shall notify the Contracting Authority in writing of such circumstances at the earliest possible opportunity.
- 9.5 No Framework Operator shall give, provide or offer to any staff or agent of the Contracting Authority a loan, fee, reward, gift, advantage, benefit or other payment during the Framework Period as an inducement or reward for doing or forbearing to do, or for having done or forborne to do, any action in relation to the obtaining or execution of this Agreement or any Contract.
- 9.6 No Framework Operator shall assign the benefit of its appointment under this Framework Agreement, or under any Contract, or any part thereof without the written permission of the Contracting Authority.

10. Review Meetings

- 10.1 The Contracting Authority and the Framework Operator may liaise to address any issues arising that may impact on the performance of this Framework Agreement and to agree milestones, compliance schedules and operational protocols as required from time-to-time.

11. Termination of Appointment

- 11.1 Without prejudice to any other rights or remedies to which it may be entitled, the Contracting Authority shall be entitled to terminate the appointment of a Framework Operator forthwith and without liability by giving notice at any time if:
- 11.1.1 The Framework Operator in question commits a material breach of any term or condition of this Framework Agreement, or a Contract concluded under the Framework Agreement;
- 11.1.2 The Framework Operator in question fails to perform any obligation or responsibility under this Agreement or a Contract concluded under the Framework Agreement

either at all or to a standard that the Contracting Authority, acting reasonably, considers satisfactory and, if such breach is capable of being remedied, fails to remedy the breach within fourteen (14) days of notice given by the Contracting Authority requiring the Operator to do so;

- 11.1.3 The Framework Operator in question repeatedly fails to supply the required services to the Contracting Authority and has been afforded all reasonable opportunities to rectify this situation;
- 11.1.4 The Framework Operator in question performs an obligation under a Contract in a manner that is not in accordance with the terms of this Framework Agreement, including its Schedules, or any agreed Service Level Agreement, or fails to meet any standard prescribed by law (in this regard, and as detailed in the Service Level Agreement appended to this Framework Agreement as Schedule 5, any two month stock level breach of any pack during the lifetime of the Framework Agreement will result in cancellation of the Framework Agreement and any Contract in force under the Framework Agreement. The Framework Operator must continue to supply remaining stock while the Contracting Authority sources replacement product. The Framework Operator shall have no claim for damages or otherwise against the Contracting Authority as a result of the Contracting Authority's reliance upon this clause);
- 11.1.5 Any person employed by the Framework Operator in question, or acting on its behalf, offers or appears to offer a corrupt gift or inducement in the sense set out in Clause 9.5 above, whether with or without the knowledge of the Framework Operator;
- 11.1.6 The Framework Operator in question convenes a meeting for the purposes of, or proposes to enter into any arrangement or composition for the benefit of its creditors;
- 11.1.7 The Framework Operator in question ceases or threatens to cease to carry on business or takes or suffers any analogous action under any applicable law;
- 11.1.8 The Framework Operator in question is unable to pay its debts within the meaning of Section 214 of the Companies Act, 1963 (as amended by Section 123 of the Companies Act, 1990) or any analogous provision of law;
- 11.1.9 An order is made or an effective resolution is passed for the winding up of the company of the Framework Operator in question, other than for the purpose of a restructuring, the terms of which have been agreed by the Contracting Authority;
- 11.1.10 A petition is presented or an order is made or a resolution passed or any analogous proceedings or action is taken for the appointment of an examiner, administrator,

receiver, trustee or any similar officer over the company of the Framework Operator in question;

- 11.1.11 An encumbrancer takes possession, or a receiver is appointed, of any of the property or assets of the Framework Operator in question;
- 11.1.12 The Contracting Authority reasonably believes that any of the events mentioned above is about to occur in relation to the Framework Operator in question and notifies the Framework Operator accordingly;
- 11.1.13 The Framework Operator in question has committed any fraudulent act or any criminal activity or is guilty of gross negligence in the performance of this agreement or the relevant Contract;
- 11.1.14 Any representation made by the Framework Operator in question in connection with this Agreement or a Contract shall in the opinion of the Contracting Authority prove to be untrue or incorrect in a material respect as of the date when made;
- 11.1.15 Any event analogous to those contemplated above occurs to the Framework Operator in question within the laws of any other jurisdiction.

The Framework Operator in question shall have no claim for damages or otherwise against the Contracting Authority as a result of the termination of its appointment in accordance with this Clause.

12. General

- 12.1 The Framework Operator acknowledges that the Contracting Authority is subject to the Freedom of Information Acts 1997-2003, as amended. Accordingly, information furnished to the Contracting Authority by the Framework Operator may be released pursuant to the Contracting Authority's statutory obligations. If a Framework Operator considers that any of the information supplied by it to the Contracting Authority under this Framework Agreement or any Contract should not be disclosed because of its sensitivity, the Framework Operator in question must, when providing the information, indicate this and specify the reason for its sensitivity. The Contracting Authority accepts no liability whatsoever in respect of any information provided which is subsequently released or in respect of any consequential damage suffered as a result of such obligations.
- 12.2 This Agreement shall be governed by and construed in accordance with the laws of Ireland.
- 12.3 Should any part of this Framework Agreement be or subsequently be found to be invalid, unlawful or unenforceable, then such parts shall be severed from the Framework Agreement and the remainder of the Agreement shall continue in full force and effect.
- 12.4 Force Majeure

- 12.4.1 If through no fault of a party, its performance has been affected or delayed by force majeure, such party shall be at no liability to the other providing the performances are recommenced as soon as possible after such force majeure has ceased to operate.
- 12.4.2 If however, force majeure causes a delay or failure in performance for a period longer than seven days, the Contracting Authority shall have the right to remove the Framework Operator in question from the Framework Agreement by giving seven days' notice in writing.
- 12.4.3 Force majeure shall mean an occurrence beyond the control and without the fault or negligence of the party affected in which it is unable to prevent or provide against by the exercise of reasonable diligence including, but not limited to, acts of God or the public enemy, ex-procreation or confiscation of facilities, government intervention, war, hostilities, rebellion, terrorist activities, local or national emergency, sabotage or riots, floods, or unusually severe weather conditions which could not be reasonably anticipated, fires, explosions, or other catastrophe, national or district strikes or other concerted acts of workmen or other similar occurrences other than strikes or concerted acts of a Framework Operator's workforce.
- 12.5 Nothing in this Agreement shall prevent the Contracting Authority from complying with its obligations under public procurement legislation. If necessary this Framework Agreement and any Contract concluded hereunder may be abridged, modified, or amended without penalty to the Contracting Authority so as to enable it to comply with said obligations.

13. General Data Protection Regulations (GDPR)

As a service provider engaged in providing services to the Contracting Authority, the successful tenderer will be required to adhere to the following provisions:

- (i) To the extent that it may be deemed a 'data processor' for the purposes of the 'GDPR,' the successful tenderer will make itself fully aware of all applicable obligations under the GDPR and will put in place sufficiently robust mechanisms to ensure adherence to the relevant provisions of the GDPR;
- (ii) To the extent that it may be deemed a 'data processor' for the purposes of the GDPR, the successful tenderer will comply with the provisions of Article 28(3)(a) to 28(3)(h) of the GDPR;
- (iii) To the extent that it may be deemed a 'sub-processor' for the purposes of the GDPR, the successful tenderer will comply with the provisions of Article 28(4) of the GDPR.
- (iv) To the extent that it may be deemed a 'data processor' for the purposes of the GDPR, the successful tenderer will implement appropriate technical and organisational

measures in such a manner that any processing activities undertaken will meet the requirements of the GDPR and ensure the protection of the rights of the data subject.

14. Notices

- 14.1 The address, e-mail address, facsimile and telephone numbers of the parties for the purpose of the giving of notices under this Agreement are as follows:

For the Contracting Authority:
[XXXX]

For the Framework Operator:
[XXXX]

- 14.2 All notices to the Contracting Authority or a Framework Operator from the other party under this Agreement or the relevant Contract shall be in writing and sent to the appropriate address set out above.

- 14.3 All notices, documents and communications provided under this Agreement or the relevant Contract shall be in the English language.

IN WITNESS whereof the parties hereto have executed this Framework Agreement the day and year first herein WRITTEN

SIGNATURES

SIGNED for and on behalf of by:

Signed: _____

Date: _____

Witnessed by: _____

SIGNED for and on behalf of the Contracting Authority by:

Signed: _____

Date: _____

Witnessed by: _____

Schedules and Appendices

Schedule 1 – Form of Tender

Schedule 2 – Submitted ESPD

Schedule 3 – Forms and Levels of Insurance

Schedule 4 – Specification of Requirements

Schedule 5 – Service Level Agreement

SCHEDULE 1 & 2
FORM OF TENDER & ESPD

SCHEDULE 3
FORMS AND LEVELS OF INSURANCE

REQUIREMENT
It is a requirement that tenderers either possess the following forms and levels of insurance, or are in a position to implement the following forms and levels of insurance if successful in the competition: (d) Employer's Liability Insurance - €13m (e) Public Liability Insurance - €6.5m (f) Product Liability Insurance - €6.5m
ESPD REFERENCE AND MEANS OF PROOF
By completing the ESPD contained in Appendix 2, tenderers are confirming that they either possess the forms and levels of insurance indicated or, alternatively, that they are in a position to obtain the forms and levels of insurance indicated if successful in this competition. Should the Contracting Authority elect to seek supporting evidence from tenderers confirming the assertions made in the ESPD in respect of this eligibility criterion, the following means of proof will be acceptable to the Contracting Authority to confirm that this criterion is complied with: (c) Evidence of the possession of the required forms and levels of insurance (i.e., certificates of insurance provided by brokers or underwriters); (d) A signed letter from the tenderer's insurance broker to the effect that the required forms and levels of insurance can be implemented should the tenderer prove successful in this competition.
ELIMINATION
Should a tenderer fail to provide appropriate supporting evidence within five working days of a request to do so, the tenderer in question will be eliminated from further consideration.

SCHEDULE 4 - SPECIFICATION OF REQUIREMENTS

2.1 Background to Current Requirement

The Contracting Authority intends to establish a single-party framework agreement for the supply of Haemodialysis On/Off Packs. In the first instance, a contract of two years' duration will be awarded for the supply of the three varieties of packs specified in Section 2.2 below. Over the course of the framework agreement, the successful framework member may be required to provide additional packs and/or components, depending upon clinical need.

2.2 Functional Specification of Required Packs

Sterile single use custom Haemodialysis On/Off Packs are required for use in a busy acute hospital environment. The following mandatory provisions shall apply to the required products:

- 2.2.1 All products must be of good quality and suitable for clinical use.
- 2.2.8 All products must be CE marked and manufactured to the relevant standard. The manufacturing process must be certified to a relevant quality management standard.
- 2.2.9 The proposed packs must conform to the layout and structure of packs required by the clinical users.
- 2.2.10 The packaging must be easy to open and the sterility of the contents must not be compromised while handling.
- 2.2.11 The proposed packs must include the appropriate lot number to provide full traceability from date of manufacture.
- 2.2.12 No trays are required in the packs.
- 2.2.13 The proposed packs must be appropriately designed to minimise cross contamination and damage to the central venous catheters.

2.2.8 Central Line On/Off Pack

It is a mandatory requirement that the Central Line On/Off Pack contains the following components in the specified quantities:

Central Line On/Off Pack

Central Line On Pack	
	Soft blister in soft blister (off part in soft blister, placed in the soft blister of the complete pack) Sticker with ON Pack & Sticker with OFF Pack. On the outside of the total set, traceability label X2
1	Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive
1	Enveloping drape
1	High filtration mask with ear loops (Not ties)
1	50x50cm drape
10	Woven swab 10x10cm 12 ply
2	Syringe 5ml Luer lock suitable for the extraction of blood and the flushing of the dialysis device
2	Syringe NaCl 0,9% Luer Lock 10 ml
2	Closure cap Luer Lock male/female blue
1	Forceps 13cm plastic
2	Strip adhesive tape 15cms x 3.5cms
Central Line Off Pack	
1	Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive
1	High filtration mask with ear loops (Not Ties)
1	Enveloping drape
1	50x50cm drape
10	Woven swab 10x10cm 12 ply
2	Syringe NaCl 0,9% Luer Lock 10 ml
2	High quality male/female Luer lock cap to close off the ports of CVC line. Threading of the male Luer to match that of the CVC line.
3	Strip adhesive tape 15cms x 3.5cms
1	Tweezers Forceps 13cm plastic

2.2.9 AVF On/Off Pack

It is a mandatory requirement that the CVC Intervention Pack contains the following components in the specified quantities:

AVF On/Off Pack

AVF On Pack	
	Soft blister in soft blister (off pack in soft blister, placed in the soft blister of the complete pack) On the outside of the total set, traceability label X2
1	Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive
1	Enveloping drape
1	50x50 cm drape
1	Strip adhesive 2,5 x 15 cm (1 strip)
5	Woven swab 10x10cm 12 ply
2	Syringe NaCl 0,9% Luer Lock 10 ml
1	Tourniquet Adult 2cm Latex free (Single use) non slip
AVF Off Pack	
1	Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive
10	Swab gauze 12 ply 17 thr. 10 x 10 cm
1	Syringe NaCl 0,9% Luer Lock 10 ml
1	Drape 50cm x 50cm
1	Enveloping drape
	Sticker with OFF Pack

3.2.10 CVC Intervention Pack

It is a mandatory requirement that the CVC Intervention Pack contains the following components in the specified quantities:

CVC Intervention Pack	
1	Plastic bag 35x45cm folded 9x12cm Yellow – draw string closure
1	High filtration mask with ear loops (Not Ties)
1	Enveloping drape
1	50x50cm drape
10	Woven swab 10x10cm 12 ply
2	High quality Syringe 20ml Luer lock suitable for the extraction of blood and the flushing of the dialysis device
1	Interlink Bare Cannula with an appropriate size cover to prevent cross contamination or similar needle free device
1	Tweezers Forceps 13cm plastic
3	Strip adhesive tape 15cms x 3.5cms

3.2.11 CVC Intervention Pack

It is a mandatory requirement that the CVC Intervention Pack contains the following components in the specified quantities:

CVC Intervention Pack	
1	Plastic bag 35x45cm folded 9x12cm Yellow – draw string closure
1	High filtration mask with ear loops (Not Ties)
1	Enveloping drape
1	50x50cm drape
10	Woven swab 10x10cm 12 ply
2	High quality Syringe 20ml Luer lock suitable for the extraction of blood and the flushing of the dialysis device
1	Interlink Bare Cannula with an appropriate size cover to prevent cross contamination or similar needle free device
1	Tweezers Forceps 13cm plastic
3	Strip adhesive tape 15cms x 3.5cms

2.3 Completeness of Tender Submissions

Tenderers are required to tender for all packs specified. Failure to tender for a particular pack or product will result in the elimination of the tender submission as a whole.

2.4 Minor Variations

In accordance with Regulation 72 of the European Union (Award of Public Authority Contracts) Regulations 2016, any award decision by the Contracting Authority may be contingent upon the successful tenderer(s) designate agreeing to propose alternative options for some products (i.e., should a small number of products be deemed unacceptable). Such alternatives must be provided at the prices tendered by the successful tenderer designate. The Contracting Authority's discretion in this regard shall have no bearing upon the obligation of all tenderers to ensure that the products proposed in response to this Invitation to Tender document comply in full with the specification of requirements contained in the Invitation to Tender document.

2.5 Brand Names and Trade Descriptions

Any specifications provided by the Contracting Authority comprising a reference to a particular manufacturer, make, model, brand name or proprietary process are to be interpreted as being accompanied by the phrase 'or equivalent.' For the avoidance of doubt, all products of comparable technical or clinical functionality and characteristics will be considered by the Contracting Authority.

2.6 Product Samples

Two samples (non sterile) of each pack must be provided for evaluation. These must be delivered to the Procurement Department, Beaumont Hospital and marked for the attention of David McHugh. These must be delivered by the closing date and time that applies to this tender. Following the evaluation of these samples, tenderers may be requested to provide additional sterile samples of all packs for patient trials, if the products are deemed suitable for clinical use. These samples must be provided within an acceptable timeframe to Beaumont Hospital. **All samples must be provided free of charge to facilitate the evaluation process.**

2.7 Reliability and Continuity of Supply

The successful framework member will be required to have a robust and comprehensive tracking system, involving batch numbers and the efficient identification of individual packs. Additionally, the successful framework member will be required to have a policy to deal with product recalls, including an appropriate system for notification and the effective management of hazards and/or recalls.

2.8 Delivery

The successful framework member will be required to deliver all required products on a weekly basis and must hold four months' stock for ready use by the Contracting Authority.

2.9 General Data Protection Regulations (GDPR)

As a service provider engaged in providing services to the Contracting Authority, the successful tenderer will be required to adhere to the following provisions:

- (v) To the extent that it may be deemed a 'data processor' for the purposes of the 'GDPR,' the successful tenderer will make itself fully aware of all applicable obligations under the GDPR and will put in place sufficiently robust mechanisms to ensure adherence to the relevant provisions of the GDPR;
- (vi) To the extent that it may be deemed a 'data processor' for the purposes of the GDPR, the successful tenderer will comply with the provisions of Article 28(3)(a) to 28(3)(h) of the GDPR;
- (vii) To the extent that it may be deemed a 'sub-processor' for the purposes of the GDPR, the successful tenderer will comply with the provisions of Article 28(4) of the GDPR.
- (viii) To the extent that it may be deemed a 'data processor' for the purposes of the GDPR, the successful tenderer will implement appropriate technical and organisational measures in such a manner that any processing activities undertaken will meet the requirements of the GDPR and ensure the protection of the rights of the data subject.

SCHEDULE 5 – SERVICE LEVEL AGREEMENT

SERVICE LEVEL AGREEMENT FOR THE SUPPLY OF STERILE SINGLE USE HAEMODIALYSIS ON/OFF PACKS

1. PARTIES

1. Beaumont Hospital, incorporating St. Joseph's Hospital, and Raheny Community Nursing Unit (hereinafter referred to collectively as 'the Contracting Authority'); and
2. (hereinafter referred to as 'the Service Provider').

2. SCOPE, EFFECTIVE DATE AND DURATION

- (a) This Service Level Agreement shall govern an Initial Contract comprising the supply of sterile single use haemodialysis on/off procedure packs for a period of two years. The Commencement Date of the Initial Contract is XX/XX/2026. The scope of the Initial Contract is the supply of the following products:

	PRODUCT DESCRIPTION	SUPPLIER PRODUCT CODE	QUANTITY PER BOX/CASE	PRICE PER BOX/CASE	SINGLE UNIT PRICE
1	Central line on/off pack				
2	AVF on/off pack				
3	Intervention pack				

- (b) For the avoidance of doubt, the Initial Contract may be terminated in accordance with the terms of this Service Level Agreement, terminated in accordance with the terms of the associated Framework Agreement, otherwise lawfully terminated or extended under the terms of the associated Framework Agreement at the sole discretion of the Contracting Authority.

3. PRECEDENCE OF FRAMEWORK AGREEMENT

- (a) This Service Level Agreement has been entered into under the terms of an associated Framework Agreement. For the avoidance of doubt, both parties hereby acknowledge that in the event of any discrepancy or conflict between the terms of this Service Level Agreement and the associated Framework Agreement, the associated Framework Agreement shall take precedence.

4. OBLIGATIONS OF THE SERVICE PROVIDER

- (a) The Service Provider shall provide the products specified in Schedule 4 of the associated Framework Agreement. In particular the haemodialysis on/off procedure packs contents will be exactly as agreed and as stated in Schedule 4 of the associated Framework Agreement. A minimum of one delivery a week will be required. Urgent orders are to be delivered the next working day, if the order is placed before 12.00 noon or the following working day if after 12.00 noon.
- (b) The Service Provider shall hold four months stock of all products. The Service Provider shall maintain at a minimum the following stock levels of each product at the logistics hub listed in 4(d) below, for use exclusively by the Contracting Authority. Penalties will apply when the stock level falls below the following minimum stock levels which are based on the anticipated two months stock requirement:

Product Description	Product Code	Number of Single Units
Central line on/off pack		
AVF on/off pack		
Intervention pack		

- (c) These minimum stock levels may be increased or decreased by the Contracting Authority from time to time due to changes in clinical practice. Sufficient notice will be given to the Service Provider in such circumstances.
- (d) The Service Provider shall provide a report detailing the current stock level of each product covered by this contract by email to the following email addresses on the first working day of each month. The report must also show any increase in demand for any product over the previous one month and three month periods:

ashleydown@beaumont.ie

- (d) The Service Provider will ensure that representatives of the Contracting Authority can without giving notice, gain access to the Service Provider logistics/storage hub during normal working hours to inspect the stock held for sole use of the Contracting Authority. The Service Provider must also advise the Contracting Authority if their logistics/storage hub is moved from the following location:

5. REPORTING MECHANISMS

- (a) The Service Provider shall make available the following individuals to the Contracting Authority in accordance with any agreed frequency in order to ensure the correct operation of this Service Level Agreement:

RESOURCE	POSITION

6. KEY PERFORMANCE INDICATORS AND PENALTIES

- (a) The penalties detailed under Clause 6(b) shall apply to breaches of the stock levels as set out in clause 4(b). For the avoidance of doubt, no provisions of Clause 6 shall prevent the Contracting Authority exercising any right of termination detailed elsewhere in this Service Level Agreement or the associated Framework Agreement.
- (b) The following penalties shall apply:

3 Month Stock Level Breach

Description	Penalty
Any pack	20% of the value of one month's sales of all products covered by this contract

One month's stock level is half the stock amount in clause 4(b)

2 Month's Stock Level Breach

Description	Penalty
Any pack	Loss of the contract to supply all products

The minimum stock levels in clause 4(b) is the stock level considered to be two months stock

- (c) The Contracting Authority shall be credited with the relevant penalty from clause 6(b), with such credit to be deducted from the next payable monthly invoice.
- (d) For the avoidance of doubt, any 2 month stock level breach of any pack during the lifetime of the contract will result in cancellation of the contract. The Service Provider must continue to supply their remaining stock while the Contracting Authority sources replacement product. The Service Provider shall have no claim for damages or otherwise against the Contracting Authority as a result of the Contracting Authority's reliance upon this clause.
- (e) For the avoidance of doubt, any failure to comply with a Key Performance Indicator may, depending upon its severity, give rise to immediate termination of this Service Level Agreement and/or the associated Framework Agreement as a whole.

7. DISPUTE RESOLUTION

- (a) Subject to the rights of the Service Provider and the Contracting Authority to apply to the Courts upon any cause of action at any time, the Service Provider and the Contracting Authority shall seek to resolve any disputes between them, arising out of or relating in any way to the issues covered by this Service Level Agreement, amicably.

8. REMEDIES

- (a) The Service Provider shall be liable for and shall indemnify the Contracting Authority for and in respect of all and any losses, claims, demands, damages or expenses that the Contracting Authority may suffer due to and arising directly as a result of the negligence, act or omission, breach of contract, breach of duty, insolvency, recklessness, bad faith, wilful default or fraud of the Service Provider, its employees, subcontractors or agents.

9. TERMINATION

- (a) Without prejudice to any other rights or remedies to which it may be entitled, the Contracting Authority shall be entitled to terminate the appointment of the Service Provider forthwith and without liability by giving notice at any time if:
- The Service Provider commits a material breach of any term or condition of this Service Level Agreement;
 - The Service Provider's performance of an obligation under this Service Level Agreement is not in accordance with the terms of this Service Level Agreement or fails to meet any standard prescribed by law.
 - For the avoidance of doubt, it is emphasised that the grounds for termination described in the associated Framework Agreement also apply to the Service Provider's appointment under this Service Level Agreement. Moreover, in the event that grounds for termination arise under this Service Level Agreement, they may, depending upon their severity, result in the termination of the Framework Agreement as whole in accordance with the terms thereof.
 - The Service Provider shall have no claim for damages or otherwise against the Contracting Authority as a result of the termination of its appointment in accordance with Clause 9.

10. SIGNATURE

IN WITNESS whereof the parties hereto have executed this SLA the day and year first herein WRITTEN

SIGNATURES

SIGNED for and on behalf of by:

Signed: _____

Date: _____

SIGNED for and on behalf of Beaumont Hospital by:

Signed: _____

Date: _____