



DPS Invitation

Dynamic Purchasing System (DPS) Invitation
For the Supply of NRFit™ Consumable Products

On Behalf Of

Health Service Executive (which expression shall include its successors in title, assigns and agents)
and the other Contracting Authorities (as listed in Appendix 1 of this document)

Project Reference: HSE 27385

Initial Deadline for submission of Applications:	15.00 hours on: 22/09/2025
Deadline for Queries:	15.00 hours on: 16/09/2025

SECTION 1: DEFINITIONS

“Applicant”	means those economic operators that submit an Application for admission into the DPS;
“Application”	means the submission from an Applicant for admission into the DPS;
“Ceiling Pricing”	means a maximum price payable per product for a defined period of time, initially two years. DPS appointees will be required to submit pricing for subsequent competitions at or below ceiling pricing and will not be entitled to exceed the ceiling pricing for any purchases made by the DPS Purchasers.
“Contract”	means a Contract or Drawdown Framework Agreement for the supply of the Goods awarded to a DPS Appointee pursuant to a DPS Tender or direct draw down under the DPS;
“Contract Agreement”	means an executed agreement setting out the scope and terms for supply of the Goods to a DPS Purchaser by a DPS Appointee who has been successful pursuant to a DPS Tender under the DPS. Also includes within its definition executed Drawdown Framework Agreements between a DPS Purchaser and a number of DPS Appointees.
“Deadline for Queries”	means the date specified on the cover page of this document as being the last date for submission of queries in relation to this process;
“Direct Drawdown”	means draw down of goods from a DPS appointee without recourse to further competition, or following a DPS tender;
“DPS Appointee”	means an Applicant who has been successful in their Application for admission to the DPS;
“DPS Document Pack”	means the following documents: • Dynamic Purchasing System (DPS) Invitation (this document); Information Only • European Single Procurement Document (ESPD); To be completed and submitted with Application • DPS Questionnaire; To be completed and submitted with Application • Compulsory Product Information (CPI) and Pricing Schedule; To be completed and submitted with Application • HSE Tender Competition Rules V14; Information Only • HSE Standard Terms for Supplies and Services; Information Only • MDR_IVDR HSE Compliance Document; Information Only
“DPS Purchasers”	means the HSE or any of its constituent parts, and/or some or all of the Contracting Authorities as listed in Appendix 1 of this document, who may from time to time wish to conduct a DPS Tender for the purchase of the Goods on their own behalf or on behalf of other DPS Purchasers on a collaborative basis;
“Drawdown Contract”	means a contract whereby a DPS Purchaser(s) may draw down the supply of Goods from DPS Appointees to a DPS Purchaser(s).
“Dynamic Purchasing System” or “DPS”	means a completely electronic system used by a Contracting Authority to purchase commonly used goods, works or services.
“DPS Tender”	means a subsequent competition between all DPS Appointees conducted in accordance with Section 7 of this DPS Invitation, whereby all DPS Appointees are



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	invited to Tender for the supply of specific Goods by a DPS Purchaser, or any group of DPS Purchaser(s) acting collaboratively;
“European Single Procurement Document” or “ESPD”	means the European Single Procurement Document which must be completed and submitted by Applicants with their Application for admission to the DPS;
“Exclusion Grounds”	means any of the grounds which would cause the exclusion of the Applicant pursuant to Article 57 of the Regulations;
“Goods”	means the supply of NRFit™ Consumable Products in total or in any part thereof, which are the subject matter of this DPS;
“HSE”	means the Health Service Executive, which expression shall include its successors in title, assigns and agents;
“Initial Application”	means an Application which has been submitted for admission at the initial creation of the DPS.
“Initial Deadline”	means the date specified on the cover page of this document for the submission of Initial Applications;
“Invitation to Tender”	means the document which will be issued to all DPS Appointees by a DPS Purchaser as part of a DPS Tender;
“Regulations”	means the European Union (Award of Public Contracts) Regulations 2016 (S.I. 284-2016);
“Selection Criteria”	means the mandatory criteria which an Appointee must demonstrate in their Application in order to be admitted into the DPS;
“Tender”	means a response submitted by Appointees in respect of a DPS Tender;



SECTION 2: INTRODUCTION

- 2.1 This DPS Invitation has been prepared for the purpose of providing information to economic operators interested in participating in a public procurement process for the establishment of a Dynamic Purchasing System (hereafter the **DPS**) for the supply of NRFit™ Consumable Products which comply with ISO 80369 Standard (hereafter the **Goods**). In 2010, a new international safety standard for small bore connectors (ISO 80369) was developed by an international group of experts from 31 countries. This included a dedicated connector for neuraxial (spinal) applications (NRFit™ ISO 80369-6) defined as “those for administering medications to neuraxial sites, wound infiltration anaesthesia delivery and other regional anaesthesia procedures, or to monitor or remove cerebrospinal fluid for therapeutic or diagnostic purposes”. The connectors designed under this standard are intentionally incompatible with other connectors used in different organ systems to prevent dangerous wrong route connections.
- 2.2 In no circumstances shall the HSE, its servants and/or agents incur any liability or responsibility arising out of or in respect of the issue of this DPS Invitation. Any costs associated with the submission of an Application in response to this DPS Invitation are the sole responsibility of the economic operator submitting the Application and will not be reimbursable.
- 2.3 The purpose of this DPS Invitation is to provide interested economic operators with the information that they need to decide whether to participate in this Process.
- 2.4 All reasonable care was taken to ensure that the material set out in this DPS Invitation is true and accurate in all material respects as at the time of publication. However, no warranty or representation is given as to the accuracy or completeness of this material. Neither the HSE, nor any of its professional advisors accept any liability or responsibility for the accuracy, adequacy or completeness of the information set out herein.
- 2.5 Neither the HSE nor any of its advisors will be liable or responsible for any opinion, statement, or conclusion contained in, or any omission from this DPS Invitation or for any other written or oral communication made available during the course of this process. No representation or warranty is made in respect of such statements, opinions or conclusions.
- 2.6 The HSE reserves the right to amend this DPS Invitation and any information contained herein. Any such changes shall be notified via the e-Tenders postbox at www.etenders.gov.ie.
- 2.7 None of the information set out herein will constitute a contract, or part of a contract, or an offer to enter into a contract, between the HSE or a DPS Purchaser and any DPS Appointee. Nothing in this DPS Invitation is, nor shall be relied upon as, a promise or representation as to the HSE’s ultimate decision in relation to the establishment of a DPS or the award of any Contract(s) pursuant to the DPS.
- 2.8 The HSE reserves the right to take such steps as it considers appropriate, including but not limited to: changing the timetable relating to this process; rejecting any, or all, of the applications received; abandoning this process (or any part of it) at any time or; procuring the Goods by alternative means.
- 2.9 The HSE Tender Competition Rules V14, which forms part of the DPS Document Pack, is applicable to this process. The Applicant agrees that, by the submission of an Application for this process, the Applicant shall be bound by the terms contained in the HSE Tender Competition Rules V14.



- 2.10 No legal relationship or other obligation shall arise between any DPS Appointee and any DPS Purchaser unless and until a Contract Agreement has been executed between said DPS Appointee and DPS Purchaser following a DPS Tender conducted by or on behalf of the DPS Purchaser.
- 2.11 The laws of the Republic of Ireland are applicable to this process and any subsequent DPS Tender pursuant to this DPS. The courts of the Republic of Ireland shall have exclusive jurisdiction in relation to any disputes arising from this process and any subsequent DPS Tender pursuant to this DPS.
- 2.12 If there is any part of this DPS Invitation that is unclear or where the Applicant feels that it puts them at an unfair disadvantage, the Applicant should immediately contact the HSE via the electronic messaging system on www.etenders.gov.ie.
- 2.13 Applications may be accepted from a consortium¹ or joint venture, provided that the Application clearly states which economic operators are proposed to be members of the consortium, which are to be sub-contractors. If the Application does comprise a consortium or joint venture, each consortium member must submit a fully completed ESPD and DPS Questionnaire as part of the Application.
- 2.14 It is imperative that all questions in the ESPD, DPS Questionnaire and the Compulsory Product Information (CPI) and Pricing Schedule are completed in the relevant response sections, as this will be used as the basis for evaluation. If all questions in the ESPD and DPS Questionnaire are not completed in the relevant response sections, the HSE reserves the right not to evaluate the Application any further. Information provided elsewhere (e.g. addendums etc), should be clearly cross-referenced to the response section to which it relates. Information that is not clearly cross-referenced may not be taken into consideration in the evaluation of the Application.
- 2.15 Any queries or problems encountered when completing this DPS Invitation should be notified to the HSE via the electronic messaging system on www.etenders.gov.ie.
- 2.16 For general information on HSE refer to <http://www.hse.ie/eng/>.
- 2.17 The HSE has occasionally encountered difficulties in respect of supply and service assurance for important medical devices equipment following disruption in relationships between Original Equipment Manufacturers (OEM) / Medical Device Manufacturers (MDM) and Value Added Resellers (VAR) or Distributors. In the context of mitigating the risks associated with such disruption to the provision of health services, the HSE requires the Supplier to confirm that a binding legal commitment between the OEM/MDM or VAR of the products falling within scope of a DPS Tender or other procedure and the Supplier of these products can be provided in advance of the award of the Contract. Please note that such a binding legal commitment shall be a condition precedent to the award of the Contract.

Please note that where there is a breach of the requirement to maintain a valid and binding legal commitment between the manufacturer and the distributor which ensures continuity of supply for the relevant term of the Contract, HSE shall be entitled, in its absolute discretion, to take whatever steps it considers appropriate which may include (without limitation):

- (a) to exclude a Supplier from a DPS Tender or other procedure;
- (b) to terminate any awarded Contract;
- (c) where the distributor is no longer available to supply the relevant product (for whatever reason)

¹ Please note that all participants of the consortium or joint venture will be jointly and severally liable to a DPS Purchaser for the fulfilment of the terms of any Contract in the event that the consortium or joint venture is successful in a DPS Tender pursuant to the DPS.



- to require the manufacturer either to (i) appoint a replacement distributor (of equivalent standing to the distributor that is not available) or (ii) supply the relevant product(s) directly to the HSE; or
- (d) take such other steps (whether it is the distributor or the manufacturer that is no longer available) as the HSE considers appropriate having regard to the relevant circumstances.

The successful tenderer will be requested to confirm and sign at DPS Tender or at other procedure stage.

2.18 On 26 May, 2021, the Medical Device Directive (MDD) was replaced by the new Medical Device Regulation. Article 27 of Regulation (EU) 2017/745 will now apply to all medical devices and, from this date, the provision of the Unique Device Identification (UDI) code is obligatory for distributors of medical devices. The obligation for placing the UDI code applies according to the following timelines:

- 2.18.1 From the 26th May 2021, ALL Class III medical devices must have a UDI code on the label of the device
- 2.18.2 From the 26th May 2023, ALL Class II (a) and Class (b) medical devices must have a UDI code on the label of the device.
- 2.18.3 From the 26th May 2025, ALL Class I medical devices must have a UDI code on the label of the device.

All Applicants are asked to confirm that at a minimum the products which are the subject matter of this DPS Qualification (NRFit™ Consumable Products) comply with the above Medical Device Regulation. Successful Applicants may be requested to provide details of proof of compliance with Article 27 including the following:

- 2.18.4 Evidence of UDIs on the labelling of medical devices.
- 2.18.5 Evidence of an effective system that is maintained to track and trace UDIs and address any issues/complaints with medical devices of any class that are distributed to HSE funded hospitals.

The following European Regulations are applicable

1. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices as amended, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Please note, Medical Devices Regulation (MDR) (EU) 2017/745 became fully applicable on 26 May 2021

2. REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices as amended and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Please note, In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 became fully applicable on 26 May 2022.

Evidence of compliance must be demonstrated as part of a tender (copy of the CE Mark certificate together with relevant declarations to be provided prior to award). The CE Mark certificate must be in-date and issued by a Competent Authority within the meaning of the above Directives and duly authorised to issue such a certificate. For proposed products evidence of compliance must be presented at the time of tendering in the form of a copy of the manufacturer's Declaration of Conformity to the relevant Directive.



NB: Suppliers are reminded that it is the responsibility of every supplier proposing products for supply, either as part of a tender evaluation process to ensure that every single product proposed that is defined as a Medical Device complies with the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) which ever is applicable to the proposed products. The responsibility is also on suppliers to demonstrate compliance with the applicable directive for every single product proposed. Suppliers are advised to review the MDR_IVDR HSE Compliance Document, as all Appointees to this DPS will be required to meet the requirements, and provide the requested information as set out in this document either in a DPS Tender Process or prior to any direct call off from a DPS purchaser.

- 2.19 As a result of Brexit, at DPS Tender or other tender procedure stage the successful tenderer may be requested to provide details of the following:

- 2.19.1 Details of notifying body including country for equipment/goods/services?
- 2.19.2 If UK, does the company intend to transfer to EU Notifying Body?
- 2.19.3 If Yes, please provide name of EU Notifying Body and timeline for same.
- 2.19.4 If No, please provide reasoning as to why & confirm that the company have been informed that post-Brexit, they will be unable to supply to HSE and the HSE will make alternative arrangements.

SECTION 3: DYNAMIC PURCHASING SYSTEM

- 3.1 The scope of the DPS will be for supply of the Goods to the HSE and to other DPS Purchasers as listed in Appendix 1 of this DPS Invitation. The duration of the DPS will be 60 months effective from the Initial Deadline, but the HSE reserves the right to extend the duration with the agreement of all DPS Appointees.
- 3.2 The HSE, on its own behalf and on behalf of the DPS Purchasers, wishes to establish a DPS to source the supply of the Goods
- 3.3 A DPS is a procurement process available for the procurement of Contracts for products and services commonly available in the marketplace. It is similar to a standard framework agreement, but with the important difference that new Applicants can join at any time and a DPS is conducted entirely through electronic means.
- 3.4 A DPS has a number of characteristics which are beneficial to both Applicants and contracting authorities:
 - 3.4.1 A DPS remains open throughout its period of validity, thereby enabling new economic operators in the market to join at any point during its term;
 - 3.4.2 The administrative burden for DPS Appointees is reduced when applying for DPS Tenders or other procedures advertised under a DPS;
 - 3.4.3 DPS Tenders conducted under a DPS can have shorter timescales to award of contract.
- 3.5 A DPS involves a two-stage process. In the initial stage, all Applicants who satisfy both the Exclusion Grounds and Selection Criteria are admitted to the DPS for the supply of all or some of the Goods to



DPS Purchasers. The number of Applicants who may be appointed to the DPS at any point during its lifetime is not limited.

- 3.6 Individual Contracts are awarded during the second stage. During this stage, DPS Purchaser(s) will invite all DPS Appointees to bid for a specific Contract by means of a DPS Tender or other procedure, which will be issued directly to the DPS Appointees via e-Tenders.
- 3.7 The scope of this DPS will comprise of the supply of the Goods, which will comprise the following products and/or services, including products and/or services that would be objectively defined as similar in characteristics to the Goods:
- Spinal NRFit™ Consumable Products, Epidural NRFit™ Consumable Products, Nerve Block NRFit™ Consumable Products, NRFit™ Procedure Packs, Combined Spinal and Epidural NRFit™ Consumables Products and NRFit™ Accessory Products, all of which comply with ISO 80369 Standard.
- 3.8 If the Applicant is not the manufacturer of the products proposed, the Applicant is required to submit a letter for the brand(s) proposed from the manufacturer confirming that the Applicant is authorised to submit ceiling Pricing for the manufacturer's products and that the manufacturer will guarantee supply of the products proposed under this DPS.
- 3.9 The estimated expenditure of the Goods, across the DPS Purchasers included in the scope of this DPS is €2,000,000 per annum.
- 3.10 Applicants should apply for admission to the DPS if they are a supplier of all or some of the products and/or services, whether in full or in part, included within the scope of the Goods.
- 3.11 Applicants are advised that detailed specifications, award criteria and weightings for award of Contracts will be provided in the Invitation to tender for each DPS Tender or other procedure, and are not published at the DPS application stage.
- 3.12 In order to demonstrate compliance with the requirements of this application process, an Applicant may rely on the capacities of other entities, regardless of the legal nature of the links between the Applicant and those other entities². Where an Applicant who wishes to rely on the capacities of other entities for appointment to the DPS is subsequently successful at DPS Tender or other procedure stage, the Applicant may be required prove to the DPS Purchaser that it will have at its disposal the resources necessary, including by producing a commitment by those entities to that effect. If applicable, the DPS Purchaser shall issue such a request to the Applicant at the DPS Tender or other procedure stage.
- 3.13 Where an Appointee includes the use of a sub-contractor as part of their tender at DPS Tender or other procedure stage, the DPS Purchaser may take appropriate measures by, amongst other things, verifying in accordance with the provisions of the Regulations, whether there are grounds for exclusion of the intended sub-contractor under Article 57 of the Regulations.
- 3.14 This application process supersedes and replaces all previous documentation, communications and correspondence between the HSE and Applicants in relation to this DPS and Applicants should place no reliance on such previous documentation and correspondence in submitting their Application.

² Please refer to Paragraph 4.1.1.1 of this document.



SECTION 4: APPLYING TO ENTER THE DYNAMIC PURCHASING SYSTEM

4.1 The Application

4.1.1 Applicants may apply to enter the DPS by submitting an Application via the e-tenders portal; which must comprise the following:

4.1.1.1 A completed ESPD (Part II, Part III and Part IV);

4.1.1.2 A completed Compulsory Product and Ceiling Pricing Information Document;

4.1.1.3 A completed DPS Questionnaire;

4.1.2 Where an Applicant is relying on the capacity of other entities for the purpose of fulfilling any of the Selection Criteria for appointment to the DPS, it must ensure that each such entity completes and submits a separate ESPD and DPS Questionnaire.

4.1.3 Applicants should study the content of this DPS Invitation and all of the other documents included in the DPS Document Pack carefully and complete all of the requirements set out therein. Failure to provide all the requested information may result in the Application being deemed non-compliant and the Application may be rejected.

4.1.4 It is the responsibility of Applicants to ensure that they fully understand the requirements for submitting an Application. Where an Applicant does not fully understand the requirements, a query should be submitted pursuant to Section 4.4 below.

4.2 Applying for admission at initial creation of the DPS³

4.2.1 The requirement for admission into the DPS at the initial creation of the DPS is the completion of an Application. Applicants are required to submit their Applications via the e-Tenders portal by the Initial Deadline.

4.2.2 Partial Applications will not be considered. However, Applicants that miss the Initial Deadline can later apply to join the DPS pursuant to Section 4.3 below.

4.2.3 During the period in which the Initial Creation of the DPS is advertised www.eTenders.gov.ie, Applications can be submitted through the e-Tenders portal and will be held in the secure post-box until the Initial Deadline has expired.

4.3 Applying for Admission into the DPS once established⁴

4.3.3 Applicants may continue to submit an Application to join the DPS via the e-Tenders portal at any time after the Initial Deadline has passed, for the remaining duration of the DPS.

4.3.4 Applications submitted after the Initial Deadline has passed will not be considered for the initial creation of the DPS, which shall be confined to those Applications, which have been submitted prior to the Initial Deadline. Applications may continue to be submitted for consideration after the initial creation of the

³ This is where the DPS is being established for the first time.

⁴ This is where the DPS has already been established and Applicants wish to apply to enter for the first time or to re-apply.



DPS, and such Applicants will have to complete and submit the same documentation as if joining at the Initial Creation of the DPS.

- 4.3.5 Applications received after the Initial Deadline shall be evaluated within 10 working days following receipt of the Application, this period may be extended to 15 days where justified by the awarding body.
- 4.3.6 Applicants joining the DPS after the initial creation of the DPS will not be invited to tender for any DPS Tenders which commence in the period prior to their admission into the DPS.

4.4 Queries

- 4.4.1 Applicants intending to submit an Application by the Initial Deadline may submit queries via the electronic messaging service on www.eTenders.gov.ie. Queries must be submitted no later than the Deadline for Queries. Queries received after this date may not be responded to prior to the initial creation of the DPS. Please note responses to queries will be automatically sent to the specific email address registered by the Applicant on www.etenders.gov.ie. The electronic messaging alerts will contain unique links to an Applicant's message archive on the site where they can be accessed and viewed.
- 4.4.2 Following the establishment of the DPS, no time limits will apply to the submission of queries thereafter from new Applicants. Queries being submitted after the establishment of the DPS must also be submitted via the electronic messaging facility on www.eTenders.gov.ie.
- 4.4.3 Where appropriate, queries may be amalgamated or paraphrased by the HSE. Applicants should note that subject to Section 4.4.7 below the HSE will not provide responses or clarifications to individual Applicants privately.
- 4.4.4 All queries must state that they relate to this DPS and must include the HSE reference number. No query of any kind in connection with this DPS should be made to any other person within, or associated with the HSE or any DPS Purchaser and any attempt to do so may, at the HSE's absolute discretion, result in the elimination of the Applicant from further consideration.
- 4.4.5 If an Applicant believes a query and/or its response is confidential or commercially sensitive it must mark the query as "**confidential**" or "**commercially sensitive**". If the HSE at its absolute discretion is satisfied that the queries and/or its responses should be properly regarded as confidential or commercially sensitive, the nature of the queries and their responses will be kept confidential (subject to the HSE's obligations under law).
- 4.4.6 If the HSE is of the opinion that it would be inappropriate to answer the query on a confidential basis, it will notify the Applicant accordingly and require the Applicant to either withdraw the query or to raise any objection within three (3) calendar days of such notification and to state the grounds for its objection.
- 4.4.7 If the Applicant does not withdraw the query or raise any objection within the specified period, or the HSE is of the opinion that, notwithstanding the objection of the Applicant, the query is not confidential or commercially sensitive, the HSE may issue the query and its response to all Applicants.

SECTION 5: EXCLUSION GROUNDS & SELECTION CRITERIA

5.1. EXCLUSION GROUNDS

5.1.1 Applicants must self-declare, by way of Part III of the ESPD, that no grounds (mandatory or discretionary) for exclusion of the Applicant pursuant to Article 57 of the Regulations apply to them.

ESPD		
Part III A	Mandatory	Grounds relating to Criminal Convictions
Part III B	Mandatory	Grounds relating to Payment of Taxes or Social Security Contributions
Part III C	Mandatory	Grounds relating to Insolvency, Conflicts of Interests or Professional Misconduct

5.1.2 The HSE intends to exclude any Applicant to whom any ground for exclusion pursuant to Part III of the ESPD -Article 57 of the Regulations applies

5.1.3 At any time during the term of the DPS, the HSE may require a DPS Appointee to provide evidence of its continued compliance with the self-declared Exclusion Grounds.

5.2 SELECTION CRITERIA

5.2.1 Applicants must self-declare, by way of their response that they satisfy the Selection Criteria in the table below.

5.2.2 The Selection Criteria for admission to the DPS are as follows:

Ref.	Selection Criteria	Mandatory Requirement Pass/Fail
DPS Questionnaire	Supplier Declaration	Sign and Return a copy of the Supplier Declaration section (Part E) of the DPS Questionnaire.
DPS Questionnaire	Children's First Act, 2015 Declaration	Confirm that the application has been submitted consistent with the requirements set out in the Children's First Act (2015) Declaration (Part F of the DPS Questionnaire)
DPS Questionnaire	Overall Turnover of the Applicant's Organisation	Meets or exceeds a minimum of €500,000 per annum in each of the last 3 years.
DPS Questionnaire	Insurance	Confirmation that the Applicant has in place, or commits to and has the ability to obtain ⁵ the Insurance levels outlined in the table at Section 5.2.5.
DPS Questionnaire	Tax Clearance	Applicants must initially declare that they hold or have applied for a Tax Clearance Certificate by providing a Tax Clearance Access Number and Tax Reference Number to facilitate online verification of tax status. <u>Verification of an</u>

⁵ Commits to and has the ability to obtain the required Insurance levels in the event of being awarded a Contract pursuant to a DPS Tender



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		<u>Applicants tax status shall take place if successful at DPS Tender stage.</u>
DPS Questionnaire	Integrated Financial Management System	Applicants must confirm their commitment to provide all relevant information as may be required (as per clause 5.2.8) if successful at DPS Tender or other procedure stage
DPS Questionnaire	Management Reporting	Applicants must confirm their willingness to provide upon request Sales Reports relating to ALL HSE sales activity whether procured under this DPS or not. Please note that failure to provide complete and accurate information or deliberate omission of some information will result in your company's being suspended from the HSE DPS pending receipt of the outstanding information.
DPS Questionnaire	Quality Assurance Procedures	Applicants must demonstrate satisfactory quality assurance procedures in place and in operation.
DPS Questionnaire	Data Protection	Applicants must demonstrate satisfactory policies and procedures in relation to maintaining data protection and security of information are in place
DPS Questionnaire	Staff Training and Vetting Procedures	Applicants must demonstrate that they have satisfactory staff training and vetting procedures in place and operation
DPS Questionnaire	Garda Clearance	Applicants must confirm their willingness to provide evidence of Garda clearance in respect of staff assigned to provide a service if requested to do so by the HSE.
DPS Questionnaire	Environmental Policies & Procedures	Applicants are required to provide details of the environmental management measures that it has in place and outline its environmental management policies, procedures and methodologies.
DPS Questionnaire	Manufacturer Authorisation	If the Applicant is not the Manufacturer of the Goods, the Applicant is required to submit a letter for the brand(s) proposed from the manufacturer confirming that the Applicant is authorised to submit ceiling Pricing for the manufacturer's products and that the manufacturer will guarantee supply of the products proposed under this DPS.
DPS Questionnaire	Ability to Upscale	Applicants are required to submit details of how their organisation would upscale their stock levels, including delivery lead-times of NRFit™ Consumable Products should there be an increase in demand from Acute Hospitals in the Republic of Ireland.
DPS Questionnaire	Experience & Knowledge in Supplying the Goods	Achieve a minimum score of 3/5 or higher for the response to the "Applicant Experience & Knowledge" question in the DPS Questionnaire.
DPS Questionnaire	Experience & Knowledge in hospital transition of Luer Lock to NRFit™ Products	Achieve a minimum score of 3/5 or higher for the response to the "Applicant Experience & Knowledge" question in the DPS Questionnaire.



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DPS Questionnaire	Experience & Knowledge of Proposed NRFit™ Transition Team	Achieve a minimum score of 3/5 or higher for the response to the “Applicant Experience & Knowledge” question in the DPS Questionnaire.
DPS/Compulsory Product and Ceiling Pricing Information Document	Tenderers must complete the mandatory Compulsory Product Information and Pricing Schedule with ceiling pricing, which will apply for the first two years from the date of notification of appointment to the DPS. Failure to complete the Compulsory Product and Pricing Information Document will result in the rejection of your application.	

5.2.3 At any time during the term of the DPS, where applicable the HSE may require a DPS Appointee to provide evidence of its continued compliance with the self-declared Selection Criteria. By submitting a self-declaration, Applicants are further declaring that they are able, upon request and without delay, to provide the relevant supporting documentation to the HSE.

5.1.2 Provision Addressing Obligations and Responsibilities under the Children’s First Act 2015 –
Where any of the successful Appointee’s Personnel and/or sub-contractors carry out any work or activity, a necessary and regular part of which consists mainly of the successful Appointee’s Personnel or sub-contractors having access to, or contact with children in any of the types of establishments listed in Schedule 1 of the Children’s First Act 2015 (which for the avoidance of doubt includes any hospital, hospice, health care centre or other centre which receives, treats or otherwise provides physical or mental health services to children), the services provided by the successful Tenderer shall be regarded as “Relevant Services” for the purposes of the Children First Act, 2015 (the “Children First Act”) and the successful Tenderer shall comply with all applicable obligations arising under the Children First Act and the Children First National Guidance for the Protection and Welfare of Children 2017.

5.1.3 Where Clause 5.1.2 is applicable, the successful Tenderer shall:

- carry out a Child Safeguarding Risk Assessment in accordance with Section 11 (1) and (2) of the Children First Act;
- ensure a Child Safeguarding Statement (reviewed in last 24 months) is in place, is displayed in a prominent place and is furnished to all staff, as per Section 11 (3-10) of the Children First Act;
- ensure that a procedure for maintaining a list of Mandated Persons (as per Schedule 2 of the Children First Act) is in place;
- ensure that Mandated Persons (as per Schedule 2 of the Children First Act) have been identified and informed of their role ;
- ensure that a Child Protection & Welfare Policy is in place;
- ensure that all staff and relevant volunteers have completed the HSE e-Learning Module “An Introduction to Children First”; and
- ensure that the HSE Children First Implementation and Compliance Self-Audit Checklist has been completed and is available on request.

5.1.4 Without prejudice to Clause 5.1.2 above, upon request from the HSE, the successful Appointee shall, irrespective of whether the Services it provides are regarded as “Relevant Services” within the meaning of the Children First Act, provide reasonable assistance to the HSE so that the HSE can undertake appropriate risk assessments and put in place appropriate controls to safeguard children from harm as part of the HSE’s Child Safeguarding Risk Assessment and Child Safeguarding Statement, which controls may include requiring the successful Tenderer’s Personnel and/or sub-contractors to be Garda Vetted in accordance with the relevant clause of the Contract Agreement, undertake assigned Children First training and adhere to applicable HSE Child Protection and Welfare policies (as applicable).



5.2.4 Applicants applying for admission to the DPS must meet or exceed a minimum of €500,000 per annum in each of the last 3 years.

5.2.5 The applicable Insurance types and levels that the Applicant must have in place (or confirms their commitment and ability to obtain, if required, at DPS Tender Stage) are:

Insurance Type	Insurance Level
Product Liability Insurance	€6.5m
Public Liability Insurance	€6.5m
Professional Indemnity Insurance (please see note below in 5.2.5.3)	€6.5m
Employer's Liability Insurance	€12.7m

The Applicant shall agree to maintain in force during the period of any Contract pursuant to a DPS Tender, full and comprehensive insurance policies in respect of all customary liabilities and risks undertaken by the Applicant in connection with the provision of the Goods, including but not limited to:

- 5.2.5.1 products liability insurance of €6,500,000 on an 'each and every claim' basis, to be maintained for a period of six years following complete delivery of the Goods and covering claims for civil liability as well as negligence;
- 5.2.5.2 employers liability insurance to a limit no less than €12,700,000;
- 5.2.5.3 professional indemnity insurance to a limit no less than €6,500,000 on an 'each and every claim' basis, to be maintained for a period of six years following complete delivery of the Goods and covering claims for civil liability as well as negligence. If professional indemnity insurance is not applicable to your application, please state the reason(s) why in D4, Part D of the DPS Questionnaire;
- 5.2.5.4 public liability insurance to a limit no less than €6,500,000 in respect of any one claim;
- 5.2.6 The Applicant shall ensure that its insurance policies are taken out with reputable insurers licenced to underwrite business in the European Union and acceptable to the HSE (acting reasonably).
- 5.2.7 Applicants must provide a current and valid Electronic Tax Clearance certificate number to facilitate the on-line verification of their tax status.
In the first instance, Applicants must initially declare that they hold or have applied for a Tax Clearance Certificate by providing a Tax Clearance Access Number and Tax Reference Number to facilitate online verification of tax status.
- 5.2.8 Irelands publicly funded health organisations, are working towards the implementation of a single integrated financial management system (IFMS) for health, using SAP software (S4 and Ariba). Accordingly, the way you interact with the HSE may be affected with this change, please refer to IFMS Project - HSE.ie for up to date information.
- 5.2.9 Applicants must confirm their willingness to provide upon request Sales Reports relating to ALL HSE sales activity whether procured under this DPS or not. Please note that failure to provide complete and accurate



information or deliberate omission of some information will result in your company being suspended from the HSE DPS pending receipt of the outstanding information.

- 5.2.10 Applicants must demonstrate satisfactory quality assurance procedures are in place and in operation. Please outline your internal quality assurance procedures or any suitable accreditation attained by your company and/or any other entity upon which your application is based e.g. QA procedures / Quality Manual / ISO Certification/ HPRA.
- 5.2.11 Applicants must demonstrate satisfactory policies and procedures are in place and operation in relation to maintaining data protection and security of information e.g. Data Protection Policy in your company and/or any other entity upon which your applicant was is based.
- 5.2.12 Applicants must demonstrate that they have satisfactory staff training and vetting procedures in place and in operation in your company and/or any other entity upon which your application is based.
- 5.2.13 Prior to engaging in relevant work for the HSE, Relevant Organisations as per the National Vetting Bureau (Children and Vulnerable Persons) Acts 2012 to 2016 are required to ensure that employees are appropriately vetted. The successful appointee shall ensure that all of its staff, potential staff or any persons performing any of the Services relevant to this DPS Qualification process who may reasonably be expected in the course of performing any of the Services to have access to or come into contact with children or other vulnerable persons and/or have access to or come into contact with Service Users are Garda Vetted. All employment agencies shall source vetting in their own right, directly through the National Vetting Bureau (NVB); all others requiring vetting (inc. contractors) shall source vetting through the HSE itself, via the HSE's Garda Vetting Liaison Office, only. For any queries on Garda vetting, please contact gardavetting@hse.ie
- 5.2.14 Applicants must demonstrate that they have in place an environmental management and waste disposal policy and procedure in compliance with ISO 14000 or equivalent. Applicants are required to provide details of the environmental management measures that it has in place and outline its environmental management policies, procedures and methodologies.
- 5.2.15 Applicants must details of how their organisation would upscale their stock levels, including delivery lead-times of NRFit™ Consumable Products should there be an increase in demand from Acute Hospitals in the Republic of Ireland.
- 5.2.16 Applicants must achieve a minimum score of 3/5 or higher for the response to the "Applicant Experience Knowledge" question in the DPS Questionnaire. Applicants must outline in not more than 800 words a summary of their organisation with particular reference to their experience and knowledge of supplying the Goods. The summary should include details confirming that at a minimum the NRFit™ Consumable Products which are the subject matter of this DPS Qualification comply with the relevant regulatory ISO80369 Standard, are CE marked and comply with the Medical Device Regulation as outlined at clause 2.18 of the DPS Invitation document. Evidence must be provided (as a cross-referenced addendum) by way of a comprehensive electronic product catalogue of the products which are included within the scope of this DPS Invitation.



- 5.2.17 Applicants must achieve a minimum score of 3/5 or higher for the response to the “Applicant Experience Knowledge” question in the DPS Questionnaire. Applicants must outline in not more than 800 words a summary of their organisation with particular reference to their experience and knowledge of implementing a transition from luer lock consumable products to NRFit™ consumable products in an acute hospital setting. The summary should include details about the scope, stakeholders, any training which was provided to clinical users, across all relevant areas within an acute hospital setting, communication of the transition, any adverse events and how these may be mitigated for future transitions.
- 5.2.18 Applicants must achieve a minimum score of 3/5 or higher for the response to the “Applicant Experience Knowledge” question in the DPS Questionnaire. Applicants must outline in not more than 800 words a summary of their proposed team that would liaise directly at acute hospital level with an acute hospital’s nominated transition team. Please provide details of each member of your proposed transition team, their role in the transition process and their individual experience and qualifications to carry out their particular role in this transition process. Please note your proposed team must be available on the island of Ireland from Monday – Friday 9am to 5pm during the transition period.
- 5.2.19 Applicants must provide as part of their application their current catalogue of NRFit™ compliant products by completing the attached Compulsory Pricing Information (CPI) and Pricing Schedule HSE 27385. The prices provided must be ceiling prices (the applicant shall not charge any hospital within the scope of this DPS a price above the ceiling price inserted in their CPI and Pricing Schedule HSE 27385) for an initial duration of 24 months from the date of their approved application to the DPS. Once an Applicant is appointed to this DPS, if throughout the lifetime of the DPS the Appointee’s range of NRFit™ compliant products increases then the Appointee must submit the specific product details and ceiling pricing for those new products by submitting a copy of the Compulsory Pricing Information (CPI) and Pricing Schedule HSE 27385 containing only those new products, via the E Tenders Messaging Portal for this DPS. Please note the HSE reserve the right to extend this ceiling pricing for a further 24 months in consultation with the Appointee(s).



SECTION 6: EVALUATION OF APPLICATIONS FOR THE DPS

- 6.1 Each Application will be checked to ensure that the Applicant has submitted the required information and that the Application has been submitted on time within the deadline for submission set by this document and is complete. Applicants who do not comply with these requirements will be informed of their non-compliance and will be free to re-submit an amended Application for consideration by the HSE as part of a subsequent evaluation of new Applications.
- 6.2 The HSE will evaluate the Application to determine if it satisfies each of the Exclusion Grounds and Selection Criteria. The Applications will be evaluated on a **Pass or Fail** basis with the exception of the Selection Criteria: Applicant Experience & Knowledge (final three sections of DPS Questionnaire and (hereafter “**Experience & Knowledge**”).
- 6.3 In relation to the Experience & Knowledge, the Applications will be evaluated to determine the extent to which the Applicant has demonstrated sufficient experience and knowledge in the supply of the Goods, sufficient experience and knowledge in hospital transition of Luer Lock to NRFit™ Products and sufficient and experience of the proposed NRFit™ transition team to justify being appointed to the DPS. For Experience & Knowledge, the Applications will be scored in accordance with the following table:

Rating	Rating Mark	Description
Excellent	5	Demonstrates a more than sufficient level of experience and knowledge in all ways very little or no risk.
Very Good	4	Demonstrates a sufficient level of experience and knowledge and exceeds them in some ways; little risk.
Good	3	Demonstrates a sufficient level of experience and knowledge and is workable; acceptable risk.
Fair	2	Nearly demonstrates the level of experience and knowledge required, is workable but may be deficient or limited in some areas; unacceptable risk.
Poor	1	Insufficient information provided making Applicant’s suitability difficult to assess or insufficient level of experience and knowledge demonstrated; high risk.
No Response	0	Either no response or the level of experience and knowledge is not addressed; very high risk.

- 6.4 Applications **must achieve a minimum rating mark of 3/5 (Good) or higher** for the Applicant’s response to each of the three Experience & Knowledge Selection Criteria in order to be recommended for appointment to the DPS.
- 6.5 Applicants whose Application is deemed to have satisfied each of the Exclusion Grounds and Selection Criteria and which has achieved a minimum rating mark of 3/5 (Good) or higher for the Applicant’s response to each of the three Experience & Knowledge Selection Criteria will be recommended for appointment to the DPS.



- 6.6 Following approval of the recommendation, the HSE will then inform Applicants in writing via e-Tenders whether or not they have been admitted to the DPS.
- 6.7 In the event that an Application is rejected, the HSE will inform the Applicant of the reasons for rejection, and the Applicant will be free to re-submit an amended Application for consideration by the HSE as part of a subsequent evaluation of Applications.
- 6.8 The HSE shall maintain the list of DPS Appointees for electronic access by DPS Purchasers who wish to commence a DPS Tender to establish a specific Contract or, as an interim measure, during the initial (first time) transition from luer lock to NRFit™, call off NRFit™ products directly from one, some or each of the DPS Appointees.
- 6.9 Appointment to the DPS shall not:
- 6.9.1 act as a guarantee for any award of a Contract for the supply of Goods;
 - 6.9.2 create an obligation on the HSE or any DPS Purchaser to purchase any Goods via the DPS;
 - 6.9.3 provide any guarantee of business to DPS Appointees;
 - 6.9.4 constitute either a contract or the authorisation to supply the Goods to the HSE or any DPS Purchaser.

SECTION 7: DPS TENDERS

- 7.1 Any DPS Purchaser that wishes to award a Contract for the Goods, in total or in any part thereof, pursuant to the DPS, shall do so by means of a DPS Tender or one of the other procedures specified.
- 7.2 For Direct Drawdowns, this may be utilised in three specific circumstances:
- 7.2.1 for sole source products available from only one DPS appointee;
 - 7.2.2 for low value products under €5,000;
 - 7.2.3 on foot of a DPS Tender, Direct Drawdowns may be facilitated on the basis of a ranked list of approved suppliers.
- 7.3 For Requests for Quotations (RFQ's), this procedure may be utilised for low value products less than €50,000. In this instance the DPS purchaser will invite all DPS appointees to participate, or may choose to contact all DPS appointees in advance, and only include those appointees that express an interest in participating in the RFQ.
- 7.4 A DPS Tender may be conducted by or for an individual DPS Purchaser on a local, regional or national basis. The scope of each DPS Tender will be set out in the relevant Invitation to Tender.
- 7.5 All DPS Appointees will be invited to participate in each DPS Tender by way of an Invitation to Tender which will be issued directly to the DPS Appointees, or alternatively the DPS purchaser may choose to contact all DPS appointees in advance, and only include those appointees that express an interest in participating in the DPS Tender.
- 7.6 The DPS Tender will not be advertised publicly and no supplier or organisation, other than the DPS Appointees, will be entitled to submit a tender.



- 7.7 Invitations to Tender will be issued electronically to each DPS Appointee. Each DPS Appointee can choose whether, or not, they wish to participate in the DPS Tender.
- 7.8 The nature and scale of the Goods being procured in the DPS Tender, which may include all or some of the Goods specified at Section 3.7 of this DPS Invitation, will be set out in the relevant Invitation to Tender .
- 7.9 The relevant Invitation to Tender will also set out the specification of requirements, mandatory and scorable award criteria and weightings to be applied to evaluate the Tenders submitted as part of the DPS Tender.
- 7.10 The specific award criteria and weightings will be outlined in the relevant Invitation to Tender, but will fall within the following ranges:

DPS Tender Criteria	Range of Weightings
Ultimate Cost	20 - 100%
Quality	0 - 80%
Total	100%

- 7.11 Each DPS Tender Criteria may be divided into sub-criteria, and the weightings for each sub-criteria will fall within the range of weightings above for the relevant DPS Tender Criteria.
- 7.12 The duration of any Contract awarded pursuant to a DPS Tender will vary depending on the requirements of the DPS Purchasers, and will be advised in the relevant Invitation to Tender, but shall not be limited by the term, or term remaining, of the DPS.
- 7.13 The DPS Tender Document Pack will include all documents relevant to the DPS Tender. Unless otherwise specified in the Invitation to Tender, it is anticipated that that DPS Tender Document Pack will include (where relevant):
- 7.13.1 DPS Tender Invitation to Tender;
 - 7.13.2 DPS Tender Response Document;
 - 7.13.3 HSE Tender Competition Rules;
 - 7.13.4 HSE Standard Terms for Supplies and Services;
 - 7.13.5 HSE Service Provider Data Processing Agreement;
 - 7.13.6 HSE Draft Contract Agreement;
 - 7.13.7 HSE MDR_IVDR Compliance Document.
- 7.14 Please note that DPS Purchasers, who do not fall under the governance of the HSE, may issue alternative or additional documents to DPS Appointees as a condition of participating in a DPS Tender or other procedure.
- 7.15 On the basis of the Tenders received, the DPS Purchaser will apply the specific award criteria and weightings specified in the Invitation to Tender for the purpose of awarding a Contract for the Goods included in the scope of the DPS Tender.



- 7.16 Each Contract shall constitute a separate agreement between the DPS Purchaser(s) and DPS Appointee(s) who are successful in the DPS Tender.
- 7.17 A Contract Agreement shall be executed between the relevant DPS Purchaser(s) and the DPS Appointee(s) successful in the DPS Tender. Operational management of the Contract Agreement shall be the responsibility of the DPS Purchaser(s), unless otherwise specified in the Contract Agreement.
- 7.18 The successful DPS Appointee(s) may be required, as a condition of the award of the Contract, to provide evidence to the DPS Purchaser that it continues to satisfy each of the Exclusion Grounds and Selection Criteria outlined at Section 5 of this DPS Invitation.
- 7.19 Contracts awarded pursuant to a DPS Tender under the DPS shall be based upon the documents included in the DPS Tender Document Pack. Further conditions may be incorporated within specific Contract Agreements. Where this is the case, details of those further conditions will be included with the relevant DPS Tender Document Pack.



APPENDIX 1 - DPS PURCHASERS

The following entities (each a “DPS Purchaser”) may award Call-Off Contracts under the DPS.

1. Ministers of the Government of Ireland, Central Government Departments, Offices and non-commercial Agencies and Organisations which have a formal reporting and legal relationship to Central Government Departments, including all local authorities in Ireland (themselves including regional assemblies, local enterprise boards and library bodies).
2. Contracting authorities in the Irish health sector including but not limited to the Health Service Executive (HSE); the Health Information and Quality Authority (HIQA) and HSE funded Agencies delivering health and personal social services funded by more than 50% from Exchequer fund. (A complete list of HSE funded Agencies can be found at www.hse.ie).
3. Contracting authorities which are Third Level Educational Institutions (including universities, institutes of technology and members of the Education Procurement Service).
4. Contracting authorities which are Education and Training Boards (ETBs) and ETB schools, and primary, post-primary, special and secondary schools as well as ETBs acting on behalf of schools.
5. An Garda Síochana (Police).
6. The Irish Prison Service.
7. The Defence Forces