NHS SUPPLY CHAIN FRAMEWORK AGREEMENT FOR THE SUPPLY OF GOODS

NHS Supply Chain	Supply Chain Coordination Limited (registered number 10881715) whose registered office is at Wellington House, 133-155 Waterloo Road, London, United Kingdom, SE1 8UG;
The Supplier	
Date	
Type of Goods	Supplies
Framework Agreement Name	Wound Closure
Framework Agreement Number	Project_1011
Lots	Lot 1 – Wound Closure

This Framework Agreement is made on the date set out above subject to the terms set out in the schedules listed below ("**Schedules**"). NHS Supply Chain (as agent of Supply Chain Coordination Limited) and the Supplier undertake to comply with the provisions of the Schedules in the performance of this Framework Agreement.

The Definitions in Schedule 4 apply to the use of all capitalised terms in this Framework Agreement.

Schedules

Schedule 1	Key Provisions
Schedule 2	General Terms and Conditions
Schedule 3	Information Governance Provisions
Schedule 4	Definitions and Interpretations
Schedule 5(a)	Specification
Schedule 5(b)	Tender Response Document
Schedule 6	Commercial Schedule
Schedule 7	Ordering Procedure and Order Form
Schedule 8	Service Levels
Schedule 9	Call-off Terms and Conditions for the Supply of Goods

Signed by an authorised representative of Supply Chain Coordination Limited

Name:	.....	Signature:	.....
Position:	.....		

Signed by an authorised representative of the Supplier

Name:	.....	Signature	…….
Position:	…….		

Schedule 1

Key Provisions

Standard Key Provisions

1 Application of the Key Provisions

1.1 The standard Key Provisions at Clauses 1 to 7 of this Schedule 1 shall apply to this Framework Agreement.

1.2 The optional Key Provisions at Clauses 8 to 10 of this Schedule 1 shall only apply to this Framework Agreement where they have been checked and information completed as applicable.

1.3 Extra Key Provisions shall only apply to this Framework Agreement where such provisions are set out at the end of this Schedule 1.

2 Term

2.1 The Term of this Framework Agreement shall be twenty-four months from the Commencement Date and may be extended in accordance with Clause 16.2 of Schedule 2 provided that the duration of this Framework Agreement shall be no longer than forty-eight months in total.

3 Contract Managers

3.1 The Contract Managers at the commencement of this Framework Agreement are:

3.1.1 for NHS Supply Chain:

Category Manager – Wound Closure

3.1.2 for the Supplier:

Contract Manager

4 Names and addresses for notices

4.1 Notices served under this Framework Agreement are to be delivered to:

4.1.1 for NHS Supply Chain:

Category Director – Medical and Surgical Consumables, Wellington House, 133-155 Waterloo Road, London, SE1 8UG

4.1.2 for the Supplier:
Director

5 Management levels for escalation and dispute resolution

5.1 The management levels at which a dispute will be dealt with are as follows:

Level	NHS Supply Chain representative	Supplier representative
1	Category Manager	Contract Manager or equivalent
2	Category Lead	Senior Contract Manager or equivalent
3	Head of Category	Assistant Director or equivalent
4	Category Director	Director or equivalent

6 Order of precedence

6.1 Subject always to Clause 1.10 of Schedule 4, should there be a conflict between any other parts of this Framework Agreement the order of priority for construction purposes shall be:

6.1.1 the provisions on the front page of this NHS Framework Agreement for the Supply of Goods;

6.1.2 Schedule 1: Key Provisions;

6.1.3 Schedule 5(a): Specification;

6.1.4 Schedule 2: General Terms and Conditions;

6.1.5 Schedule 6: Commercial Schedule;

6.1.6 Schedule 8: Service Levels;

6.1.7 Schedule 5(b): Tender Response Document;

6.1.8 Schedule 3: Information Governance Provisions;

6.1.9 Schedule 4: Definitions and Interpretations;

6.1.10 the order in which all subsequent schedules, if any, appear; and

6.1.11 any other documentation forming part of the Framework Agreement in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.

7 Participating Authorities

7.1 The following Contracting Authorities are entitled to place Orders:

7.1.1 in relation to a Direct Route of Supply: any NHS Trust; other NHS entities; any private sector entity which is active in the United Kingdom Healthcare Sector; or any government department, government agency or other statutory body; and

7.1.2 in relation to a Non-direct Route of Supply: NHS Supply Chain,

for the avoidance of doubt, any successor bodies of any of the entities described in this definition are included in this definition.

Optional Key Provisions

8 Quality assurance standards self-certification ☐ (only applicable to the Framework Agreement if this box is checked and the standards are listed)

8.1 The Supplier warrants that on the request of NHS Supply Chain it shall provide a written and signed self-certification in the form requested by NHS Supply Chain that it complies and will notify NHS Supply Chain immediately if it no longer complies throughout the Term of the Framework Agreement and all Contracts with all quality assurance standards applicable to the Goods and Services and that it shall evidence such compliance on request.

9 Different levels and/or types of insurance ☒ (only applicable to the Framework Agreement if this box is checked and the table sets out the requirements)

9.1 The Supplier shall put in place and maintain in force the following insurances with the following minimum cover:

Type of insurance required	**Minimum cover**
Product Liability	£5 Million Pounds in Aggregate
Employers Liability	As per Schedule 2 15.1 (Insurances)
Public Liability	As per Schedule 2 15.1 (Insurances)
Professional Indemnity Insurance	£5 Million Pounds in Aggregate

10 Guarantee ☐ (only applicable to the Framework Agreement if this box is checked)

10.1 Promptly following the execution of this Framework Agreement, the Supplier shall, if it has not already delivered an executed deed of guarantee to NHS Supply Chain, deliver the executed deed of guarantee to NHS Supply Chain as required by the procurement process followed by NHS Supply Chain. Failure to comply with this Key Provision shall be an irremediable breach of this Framework Agreement.

Extra Key Provisions

Schedule 2

General Terms and Conditions

Contents

1 Supplier's appointment

1.1 NHS Supply Chain appoints the Supplier as a potential supplier of the Goods and Services and the Supplier shall be eligible to be considered for the award of Orders during the Term.

1.2 In consideration of NHS Supply Chain agreeing to appoint the Supplier to this Framework Agreement in accordance with Clause 1.1 of this Schedule 2 and the mutual exchange of promises and obligations under this Framework Agreement, the Supplier undertakes to supply Goods and Services under Orders placed with the Supplier:

1.2.1 of the exact quality, type and as otherwise specified in the Specification and accepted by NHS Supply Chain in the Tender Response Document;

1.2.2 at the Contract Price calculated in accordance with the Commercial Schedule; and

1.2.3 in such quantities, at such times and to such locations as may be specified in an Order.

1.3 The Supplier agrees that the Call-Off Terms and Conditions for the Supply of Goods shall apply to all supplies of the Goods and any associated Services made by the Supplier to a Participating Authority pursuant to this Framework Agreement. The Supplier agrees that it will not in its dealings with a Participating Authority seek to impose or rely on any other contractual terms which in any way vary or contradict the relevant Contract.

1.4 The Supplier shall comply fully with its obligations set out in this Framework Agreement, the Specification and Tender Response Document, the Call-off Terms and Conditions for the Supply of Goods and any other provisions of Contracts entered into under and in accordance with this Framework Agreement (to include, without limitation, the KPIs and all obligations in relation to the quality, performance characteristics, supply and delivery in relation to use of the Goods and the provision of the Services).

1.5 Without limitation to any of the provisions of Clause 22 of this Schedule 2 and/or the Commercial Schedule:

1.5.1 The Supplier agrees to work with NHS Supply Chain during the Term of this Framework Agreement to achieve continuous and innovative improvements to the quality and value of the Goods and Services, including the way in which the Goods and Services are sourced, supplied, ordered and packaged, to achieve the most efficient and best value Goods and Services for the mutual benefit of the Supplier, NHS Supply Chain, the Authority and NHS.

1.5.2 The Supplier agrees to work with NHS Supply Chain during the Term of this Framework Agreement to explore ways in which commitment offered by Authorities in relation to specific Contracts can be reflected in more competitive pricing for the Authority.

1.6 If there are any quality, performance and/or safety related reports, notices, alerts or other communications issued by the Supplier or any regulatory or other body in relation to the Goods, the Supplier shall promptly (which in the case of any incidents which may have an effect on patient safety, shall mean within one (1) Business Day) provide NHS Supply Chain with a copy of any such reports, notices, alerts or other communications.

1.7 Upon receipt of any such reports, notices, alerts or other communications pursuant to Clause 1.6 of this Schedule 2, NHS Supply Chain shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall cooperate fully in all matters relating to any such request.

1.8 In complying with its obligations under this Framework Agreement, the Supplier shall, and shall procure that all Staff shall, act in accordance with the NHS values as set out in the NHS Constitution from time to time.

2 NHS Supply Chain commitments

2.1 Unless otherwise set out in the Commercial Schedule, the Supplier acknowledges that:

2.1.1 there is no obligation for NHS Supply Chain or for any other Participating Authority to purchase any Goods or Services from the Supplier during the Term;

2.1.2 no undertaking or any form of statement, promise, representation or obligation has been made by NHS Supply Chain and/or any other Participating Authority in respect of the total quantities or value of the Goods and/or Services to be ordered by them pursuant to this Framework Agreement and the Supplier acknowledges and agrees that it has not entered into this Framework Agreement on the basis of any such undertaking, statement, promise or representation;

2.1.3 in entering this Framework Agreement, no form of exclusivity has been granted by NHS Supply Chain and/or any other Participating Authority; and

2.1.4 NHS Supply Chain and/or other Participating Authorities are at all times entitled to enter into other contracts and agreements with other suppliers for the provision of any or all goods and services which are the same as or similar to the Goods and Services.

3 Ordering procedure

3.1 Any Participating Authority may enter into Contracts by placing an Order in accordance with the Ordering Procedure.

4 Reasonable assistance

4.1 Upon the written request of any Participating Authority, the Supplier shall provide such Participating Authority with any reasonable and proportionate information that it holds about the Goods and Services it supplies under this Framework Agreement including, without limitation, the compatibility and interoperability of the Goods with other products, to enable the Participating Authority to complete any necessary due diligence before purchasing such Goods and/or Services.

5 Supplier performance

5.1 The Supplier shall perform all Contracts entered into under this Framework Agreement by NHS Supply Chain or any other Participating Authority in accordance with:

5.1.1 the requirements of this Framework Agreement; and

5.1.2 the provisions of the respective Contracts.

6 Business continuity

6.1 Throughout the Term, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements that are reasonable and proportionate to:

6.1.1 the criticality of this Framework Agreement to the Participating Authorities; and

6.1.2 the size and scope of the Supplier's business operations,

regarding continuity of the supply of Goods and Services during and following a Business Continuity Event.

6.2 The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months or such other period as may be agreed between the Parties taking into account the criticality of this Framework Agreement to Participating Authorities and the size and scope of the Supplier's business operations. The Supplier shall promptly provide to NHS Supply Chain, at NHS Supply Chain's written request, copies of its Business Continuity Plan, reasonable and proportionate documentary evidence that the Supplier tests its Business Continuity Plan in accordance with the requirements of this Clause 6.2 of this Schedule 2 and reasonable and proportionate information regarding the outcome of such tests. The Supplier shall provide to NHS Supply Chain a copy of any updated or revised Business Continuity Plan within fourteen (14) Business Days of any material update or revision to the Business Continuity Plan.

6.3 NHS Supply Chain may suggest reasonable and proportionate amendments to the Supplier regarding the Business Continuity Plan at any time. Where the Supplier, acting reasonably, deems such suggestions made by NHS Supply Chain to be relevant and appropriate, the Supplier will incorporate into the Business Continuity Plan all such suggestions made by NHS Supply Chain in respect of such Business Continuity Plan. Should the Supplier not incorporate any suggestion made by NHS Supply Chain into such Business Continuity Plan it will explain the reasons for not doing so to NHS Supply Chain.

6.4 Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to NHS Supply Chain on such implementation.

6.5 During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to fulfil its obligations in accordance with this Framework Agreement.

7 NHS Supply Chain's obligations

7.1 NHS Supply Chain shall, provide reasonable cooperation to the Supplier as appropriate, provide copies of or give the Supplier access to such of the Policies that are relevant to the Supplier complying with its obligations under this Framework Agreement.

7.2 NHS Supply Chain shall comply with NHS Supply Chain's Obligations, if any.

8 Contract management

8.1 Each Party shall appoint and retain a Contract Manager who shall be the primary point of contact for the other Party in relation to matters arising from this Framework Agreement. Should the Contract Manager be replaced, the Party replacing the Contract Manager shall promptly inform the other Party in writing of the name and contact details for the new Contract Manager. Any Contract Manager appointed shall be of sufficient seniority and experience to be able to make decisions on the day to day operation of the Framework Agreement. The Supplier confirms and agrees that it will be expected to work closely and cooperate fully with NHS Supply Chain's Contract Manager.

8.2 Each Party shall ensure that its representatives (to include, without limitation, its Contract Manager) shall attend review meetings on a regular basis to review the performance of the Supplier under this Framework Agreement and to discuss matters arising generally under this Framework Agreement. Each Party shall ensure that those attending such meetings have the authority to make decisions regarding the day to day operation of the Framework Agreement. Review meetings shall take place at the frequency specified in the Specification. Should the Specification not state the frequency, then meetings shall take place at intervals as may otherwise be agreed in writing between the Parties.

8.3 Two weeks prior to each review meeting (or at such time and frequency as may be specified in the Specification) the Supplier shall provide a written contract management report to NHS Supply Chain regarding the supply of the Goods and Services and the operation of this Framework Agreement. Unless otherwise agreed by the Parties in writing, such contract management report shall contain:

8.3.1 details of the performance of the Supplier under this Framework Agreement and any Contracts when assessed in accordance with the KPIs, as relevant to the Framework Agreement and any Contracts, since the last such performance report;

8.3.2 details of any complaints by Participating Authorities in relation to the supply of Goods and Services, their nature and the way in which the Supplier has responded to such complaints since the last review meeting written report;

8.3.3 any information specified in the Specification as being relevant to the operation of this Framework Agreement;

8.3.4 a status report in relation to the implementation of any current Remedial Proposals and Action Plans; and

8.3.5 such other information as reasonably required by NHS Supply Chain.

8.4 Unless otherwise agreed between the Parties, NHS Supply Chain shall take minutes of each review meeting and shall circulate draft minutes to the Supplier within a reasonable time following such review meeting. The Supplier shall inform NHS Supply Chain in writing of any suggested amendments to the minutes within five (5) Business Days of receipt of the draft minutes. If the Supplier does not respond to NHS Supply Chain within such five (5) Business Days the minutes will be deemed to be approved. Where there are any differences in interpretation of the minutes, the Parties will use their reasonable endeavours to reach agreement. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the dispute resolution process set out in Clause 5 of the Key Provisions and Clause 23.2 of this Schedule 2.

8.5 The Supplier shall provide any management information required in accordance with the ORS (including, for the avoidance of doubt, monthly statements) and as NHS Supply Chain may request from time to time within seven (7) Business Days of the date of the request. The Supplier shall supply the management information to NHS Supply Chain in such form as may be specified by the ORS or NHS Supply Chain and, where requested to do so, the Supplier shall also provide such management information to another Contracting Authority whose role it is to analyse such management information in accordance with UK government policy (to include, without limitation, for the purposes of analysing public sector expenditure and planning future procurement activities) ("**Third Party Body"**). The Supplier confirms and agrees that NHS Supply Chain may itself provide the Third Party Body with management information relating to the Goods and Services ordered and any payments made under this Framework Agreement or any Contracts and any other information relevant to the operation of this Framework Agreement.

8.6 Upon receipt of management information supplied by the Supplier to NHS Supply Chain and/or the Third Party Body, or by NHS Supply Chain to the Third Party Body, the Parties hereby consent to the Third Party Body and NHS Supply Chain:

8.6.1 storing and analysing the management information and producing statistics; and

8.6.2 sharing the management information or any statistics produced using the management information with any other Contracting Authority.

8.7 If the Third Party Body and/or NHS Supply Chain shares the management information or any other information provided under Clause 8.6 of this Schedule 2, any Contracting Authority receiving the management information shall, where such management information is subject to obligations of confidence under this Framework Agreement and such management information is provided direct by NHS Supply Chain to such Contracting Authority, be informed of the confidential nature of that information by NHS Supply Chain and shall be requested by NHS Supply Chain not to disclose it to any body that is not a Contracting Authority (unless required to do so by Law).

8.8 NHS Supply Chain may make changes to the type of management information which the Supplier is required to supply and shall give the Supplier at least one (1) month's written notice of any changes.

9 Price and payment

Contract Price

9.1 The Contract Price for all Contracts shall be calculated as set out in the Commercial Schedule and the payment provisions for all Contracts shall be as set out in the Call-off Terms and Conditions for the Supply of Goods.

Management Fee

9.2 Where Goods and any incidental Services are ordered and delivered via a Direct Route of Supply the Supplier shall pay to NHS Supply Chain a management fee as a percentage of the total Order value at the rate set out in the Commercial Schedule (the "Management Fee").

9.3 Unless otherwise agreed, NHS Supply Chain will submit a quarterly reconciliation report detailing all Management Fee breakdowns. The Supplier shall then confirm if they agree with the eligible Management Fee charges. On receipt of the agreed Management Fee values, NHS Supply Chain will create a Management Fee Invoice.

9.4 NHS Supply Chain contacts the Supplier for valid copies of Trust Purchase Orders and Supplier Quotations for the relevant URN number.

9.5 NHS Supply Chain reconciliation will contain:

9.5.1 Order Reference

9.5.2 Trust Name

9.5.3 Actual Order Date

9.5.4 Customer PO Number

9.5.5 Supplier Quotation Number

9.5.6 Order Value (exc VAT) and Order Value minus shipping and handling

9.5.7 Management Fee % Inc VAT

9.6 On receipt of this request the supplier will agree the values of the Management Fee reconciliation, and NHS Supply Chain shall invoice the Supplier for the Management Fee. The Supplier shall pay the Management Fee within thirty (30) days from receipt of such invoice.

9.7 Where the Supplier raises a query with respect to an invoice for the Management Fee, or NHS Supply Chain raises a query with respect to the Management Fee Report, the Supplier and NHS Supply Chain shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the Parties shall refer to dispute resolution in accordance with Clause 23 of this Schedule 2.

Other Payments

9.8 Where any payments are to be made under this Framework Agreement by either Party in addition to any payments to be made by Participating Authorities under any Contracts and the Management Fee to be paid by the Supplier, the details of such payments and the invoicing arrangements shall be set out in the Commercial Schedule.

10 Warranties

10.1 The Supplier warrants and undertakes that:

10.1.1 it will comply with the terms of all Contracts entered into by Participating Authorities under this Framework Agreement;

10.1.2 it will comply with the KPIs set out in Schedule 8;

10.1.3 it will promptly respond to all requests for information regarding the Framework Agreement, the Goods and/or Services and any Contracts at the frequency and in the format that NHS Supply Chain may reasonably require;

10.1.4 all information included within the Supplier's response to any documents issued by the Authority as part of the procurement relating to the award of this Framework Agreement (to include, without limitation, as referred to in the Specification in the Tender Response Document and Commercial Schedule) and all accompanying materials is accurate;

10.1.5 it has the right and authority to enter into this Framework Agreement and that it has the capability and capacity to fulfil its obligations under this Framework Agreement;

10.1.6 it is a properly constituted entity and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Framework Agreement and the documents referred to in this Framework Agreement;

10.1.7 all necessary actions to authorise the execution of and performance of its obligations under this Framework Agreement have been taken before such execution;

10.1.8 there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier;

10.1.9 there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into or complying with this Framework Agreement;

10.1.10 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Framework Agreement; and

10.1.11 it has satisfied itself as to the nature and extent of the risks assumed by it under the Framework Agreement and has gathered all information necessary to perform its obligations under the Framework Agreement and all other obligations assumed by it.

10.1.12 it shall: (i) comply with all relevant Law and Guidance and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;

10.1.13 it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 10.1.13 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.

10.2 The Supplier warrants that all information, data and other records and documents required by NHS Supply Chain as set out in the Specification and Tender Response Document shall be submitted to NHS Supply Chain in the format and in accordance with any timescales set out in the Specification and Tender Response Document.

10.3 Unless the parties agree otherwise in writing, the Supplier warrants and undertakes to NHS Supply Chain that it shall comply with any E-Procurement Guidance as it may apply to the Supplier and shall carry out all reasonable acts required of the Supplier to enable NHS Supply Chain to comply with such E-Procurement Guidance.

10.4 The Supplier warrants and undertakes that at the Commencement Date it is not and throughout the term of the Framework Agreement and any Contracts it will not be, involved in any Occasion of Tax Non-compliance.

10.5 The Supplier further warrants and undertakes to NHS Supply Chain that it will inform NHS Supply Chain in writing immediately upon becoming aware that any of the warranties set out in Clause 10 of this Schedule 2 have been breached or there is a risk that any warranties may be breached.

10.6 Any warranties provided under this Framework Agreement are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

11 Intellectual Property

11.1 Unless otherwise agreed in writing between the Parties, the Supplier has no right to use the branding or logo(s) of NHS Supply Chain or NHS in the promotion or marketing of the Supplier's goods and services, nor to reference the approval, support, endorsement, authorisation, certification or similar of NHS Supply Chain or NHS in relation to the Supplier's goods and services.

12 Statutory compliance

12.1 The Supplier shall comply with all Law and Guidance relevant to its obligations under this Framework Agreement and any Contracts.

12.2 Without limitation to Clause 12.1 of this Schedule 2, the Supplier shall be responsible for obtaining any statutory licences, authorisations, consents or permits required in connection with its performance of its obligations under this Framework Agreement and any Contracts.

13 Independence of Participating Authorities

13.1 The Supplier acknowledges that each Participating Authority is independently responsible for the conduct of its award of Contracts under this Framework Agreement and that NHS Supply Chain is not responsible or accountable for and shall have no liability whatsoever in relation to:

13.1.1 the conduct of Participating Authorities other than NHS Supply Chain in relation to the operation of this Framework Agreement; or

13.1.2 the performance or non-performance of any Participating Authorities other than NHS Supply Chain under any Contracts between the Supplier and such other Participating Authorities entered into under this Framework Agreement.

14 Limitation of liability

14.1 Nothing in this Framework Agreement shall exclude or restrict the liability of either Party:

14.1.1 for death or personal injury resulting from its negligence;

14.1.2 for fraud or fraudulent misrepresentation;

14.1.3 in any other circumstances where liability may not be limited or excluded under any applicable law; or

14.1.4 to make any payments agreed in accordance with Clause 9 of this Schedule 2.

14.2 Subject to Clauses 14.1, 14.3 and 14.5 of this Schedule 2, the total liability of each Party to the other under or in connection with this Framework Agreement whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to five hundred thousand pounds (£500,000).

14.3 There shall be no right to claim losses, damages and/or other costs and expenses under or in connection with this Framework Agreement whether arising in contract (to include, without limitation, under any relevant indemnity), tort, negligence, breach of statutory duty or otherwise to the extent that any losses, damages and/or other costs and expenses claimed are in respect of loss of production, loss of business opportunity or are in respect of indirect loss of any nature suffered or alleged.

14.4 Each Party shall at all times take all reasonable steps to minimise and mitigate any loss for which one Party is entitled to bring a claim against the other pursuant to this Framework Agreement.

14.5 The liability of the Supplier and any Participating Authorities under any Contracts entered into pursuant to this Framework Agreement shall be as set out in the Call-off Terms and Conditions for the Supply of Goods forming part of such Contracts.

15 Insurance

15.1 Subject to Clauses 15.2 and 15.3 of this Schedule 2 and unless otherwise confirmed in writing by NHS Supply Chain, as a minimum level of protection, the Supplier shall

put in place and/or maintain in force at its own cost with a reputable commercial insurer, insurance arrangements in respect of employer's liability, public liability and product liability in accordance with Good Industry Practice with the minimum cover per claim being the greater of five million pounds (£5,000,000) or any sum as required by Law unless otherwise agreed with NHS Supply Chain in writing.

15.2 Without limitation to any insurance arrangements as required by Law, the Supplier shall put in place and/or maintain the different types and/or levels of indemnity arrangements explicitly required by NHS Supply Chain, if specified in the Key Provisions.

15.3 Provided that the Supplier maintains all indemnity arrangements required by Law, the Supplier may self insure in order to meet other relevant requirements referred to at Clauses 15.1 and 15.2 of this Schedule 2 on condition that such self insurance arrangements offer the appropriate levels of protection and are approved by NHS Supply Chain in writing prior to the Commencement Date.

15.4 The amount of any indemnity cover and/or self insurance arrangements shall not relieve the Supplier of any liabilities under this Framework Agreement. It shall be the responsibility of the Supplier to determine the amount of indemnity and/or self insurance cover that will be adequate to enable it to satisfy its potential liabilities under this Framework Agreement. Accordingly, the Supplier shall be liable to make good any deficiency if the proceeds of any indemnity cover and/or self insurance arrangement is insufficient to cover the settlement of any claim.

15.5 The Supplier warrants that it shall not take any action or fail to take any reasonable action or (in so far as it is reasonable and within its power) permit or allow others to take or fail to take any action, as a result of which its insurance cover may be rendered void, voidable, unenforceable, or be suspended or impaired in whole or in part, or which may otherwise render any sum paid out under such insurances repayable in whole or in part.

15.6 The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to NHS Supply Chain that insurance arrangements taken out by the Supplier pursuant to Clause 15 of this Schedule 2 and the Key Provisions are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.

15.7 Upon the expiry or earlier termination of this Framework Agreement, the Supplier shall ensure that any ongoing liability it has or may have arising out of this Framework Agreement shall continue to be the subject of appropriate indemnity arrangements for the period of twenty one (21) years from termination or expiry of this Framework Agreement or until such earlier date as that liability may reasonably be considered to have ceased to exist.

16 Term and termination

16.1 This Framework Agreement shall commence on the Commencement Date and, unless terminated earlier in accordance with the terms of this Framework Agreement or the general law, shall continue until the end of the Term.

16.2 NHS Supply Chain shall be entitled to extend the Term on one or more occasions by giving the Supplier written notice no less than three (3) months prior to the date on which this Framework Agreement would otherwise have expired, provided that the

duration of this Framework Agreement shall be no longer than the total term specified in the Key Provisions.

16.3 In the case of a breach of any of the terms of this Framework Agreement by either Party that is capable of remedy (including any failure to pay sums due under this Framework Agreement), the non-breaching Party shall, without prejudice to its other rights and remedies under this Framework Agreement, issue notice of the breach and allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach ("**Remedial Proposal**") before exercising any right to terminate this Framework Agreement in accordance with Clause 16.4.1(ii) of this Schedule 2. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:

16.3.1 put forward and agree a Remedial Proposal with the non-breaching Party in relation to the relevant default or breach within a period of ten (10) Business Days (or such other period as the non-breaching Party may agree in writing) from written notification of the relevant default or breach from the non-breaching Party;

16.3.2 comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); and/or

16.3.3 remedy the default or breach notwithstanding the implementation of such Remedial Proposal in accordance with the agreed timescales for implementation,

shall be deemed, for the purposes of Clause 16.4.1(ii) of this Schedule 2, a material breach of this Framework Agreement by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

16.4 Either Party may terminate this Framework Agreement forthwith by notice in writing to the other Party if such other Party:

16.4.1 commits a material breach of any of the terms of this Framework Agreement which is:

(i) not capable of remedy; or

(ii) in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal; or

16.4.2 has been served with at least two (2) previous breach notices as a result of any material breaches which are capable of remedy within any twelve (12) month rolling period whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal. The twelve (12) months rolling period is the twelve (12) months immediately preceding the date of the third breach notice.

16.5 NHS Supply Chain may terminate this Framework Agreement forthwith by notice in writing to the Supplier if:

16.5.1 the Supplier, or any third party guaranteeing the obligations of the Supplier under this Framework Agreement, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;

16.5.2 the Supplier undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control) without the prior written consent of NHS Supply Chain and NHS Supply Chain shall be entitled to withhold such consent if, in the reasonable opinion of NHS Supply Chain, the proposed change of control will have a material impact on the performance of this Framework Agreement or the reputation of NHS Supply Chain;

16.5.3 the Supplier purports to assign, Sub-contract, novate, create a trust in or otherwise transfer or dispose of this Framework Agreement in breach of Clause 29 of this Schedule 2;

16.5.4 pursuant to and in accordance with the Key Provisions and Clauses 16.6, 24.8; 26.2; 26.4 and 30.2 of this Schedule 2; or

16.5.5 the Supplier is in breach of Clause 10.4 of this Schedule 2.

16.6 If NHS Supply Chain, acting reasonably, has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Framework Agreement and/or any material Sub-contractor of the Supplier when compared to any information provided to and/or assessed by NHS Supply Chain as part of any procurement process or other due diligence leading to the award of this Framework Agreement to the Supplier or the entering into a Sub-contract by the Supplier, the following process shall apply:

16.6.1 NHS Supply Chain may (but shall not be obliged to) give notice to the Supplier requesting adequate financial or other security and/or assurances for due performance of its material obligations under this Framework Agreement on such reasonable and proportionate terms as NHS Supply Chain may require within a reasonable time period as specified in such notice;

16.6.2 a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with Clause 16.6 of this Schedule 2 in accordance with any reasonable timescales specified in any such notice issued by NHS Supply Chain shall be deemed a breach of this Framework Agreement by the Supplier and shall be referred to and resolved in accordance with the Dispute Resolution Procedure; and

16.6.3 a failure to resolve such breach in accordance with such Dispute Resolution Procedure by the end of the escalation stage of such process (as set out in Clause 23.2 of this Schedule 2) shall entitle, but shall not compel, NHS Supply Chain to terminate this Framework Agreement in accordance with Clause 16.4.1(i) of this Schedule 2.

16.6.4 In order that NHS Supply Chain may act reasonably in exercising its discretion in accordance with Clause 16.6 of this Schedule 2, the Supplier shall provide NHS Supply Chain with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

16.7 NHS Supply Chain may terminate this Framework Agreement forthwith by notice in writing to the Supplier where:

16.7.1 the Framework Agreement has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure;

16.7.2 the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 from the procurement procedure leading to the award of this Framework Agreement;

16.7.3 the Framework Agreement should not have been awarded to the Supplier in view of a serious infringement of obligations under European law declared by the Court of Justice of the European Union under Article 258 of the Treaty on the Functioning of the EU; or

16.7.4 there has been a failure by the Supplier and/or one its Sub-contractors to comply with legal obligations in the fields of environmental, social or labour Law. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Supplier's Sub-contractors, the Authority may request the replacement of such Sub-contractor and the Supplier shall comply with such request as an alternative to the Authority terminating this Framework Agreement under this Clause 16.7.4.

17 Consequences of expiry or earlier termination of this Framework Agreement

17.1 Upon expiry or earlier termination of this Framework Agreement, NHS Supply Chain and the Supplier agree that all Contracts entered into under this Framework Agreement

will continue in full force and effect unless otherwise terminated under the terms and conditions of such Contracts.

17.2 The Supplier agrees that where this Framework Agreement has been terminated properly in accordance with Clause 16 of this Schedule 2 it shall not be entitled to make a claim against NHS Supply Chain in relation to costs incurred in the provision of the Goods and/or Services which do not form part of the Contract Price paid or payable by an Authority.

17.3 The Supplier shall cooperate fully with NHS Supply Chain or, as the case may be, any replacement supplier during any re-procurement and handover period prior to and following the expiry or earlier termination of this Framework Agreement. This cooperation shall extend to providing access to all information relevant to the operation of this Framework Agreement, as reasonably required by NHS Supply Chain to achieve a fair and transparent re-procurement and/or an effective transition without disruption to routine operational requirements.

17.4 The expiry or earlier termination of this Framework Agreement for whatever reason shall not affect any rights or obligations of either Party which accrued prior to such expiry or earlier termination.

17.5 The expiry or earlier termination of this Framework Agreement shall not affect any obligations which expressly or by implication are intended to come into or continue in force on or after such expiry or earlier termination.

18 Suspension of Supplier's appointment

18.1 Without prejudice to NHS Supply Chain's rights to terminate this Framework Agreement, if a right for NHS Supply Chain to terminate this Framework Agreement arises (irrespective of whether the circumstances leading to such right are capable of remedy) in accordance with Clause 16 of this Schedule 2, NHS Supply Chain may suspend the Supplier's appointment to receive new Orders under this Framework Agreement by giving notice in writing to the Supplier and all Participating Authorities.

18.2 If NHS Supply Chain provides notice to the Supplier in accordance with Clause 18.1 of this Schedule 2, the Supplier's appointment shall be suspended for the period set out in the notice or such other period notified to the Supplier by NHS Supply Chain in writing from time to time provided that such suspension shall be lifted if:

18.2.1 the circumstances leading to NHS Supply Chain's right to terminate this Framework Agreement have been remedied;

18.2.2 NHS Supply Chain has satisfied itself that the risk and/or impact of the circumstances giving rise to NHS Supply Chain's right to terminate this Framework Agreement no longer requires such suspension; or

18.2.3 NHS Supply Chain exercises its rights to terminate this Framework Agreement in accordance with Clause 16 of this Schedule 2.

19 Complaints process

19.1 The Supplier shall notify NHS Supply Chain of any formal written complaints made by other Participating Authorities relating to the Supplier's noncompliance with any of its

obligations under any Contract within two (2) Business Days of the Supplier becoming aware of such complaints.

19.2 Without prejudice to any rights and remedies that the Participating Authority may have under the relevant Contract and/or NHS Supply Chain may have under this Framework Agreement, the Supplier shall use its reasonable endeavours to resolve such complaint within ten (10) Business Days and in so doing, shall deal with the complaint fully, expeditiously and fairly.

19.3 Within two (2) Business Days of a written request by NHS Supply Chain, the Supplier shall provide further reasonable details of the complaint to NHS Supply Chain, including details of the steps being taken to progress its resolution and, following its resolution, details of how and when the complaint was resolved.

20 Sustainable development

20.1 The Supplier shall comply in all material respects with applicable environmental and social Law requirements in force from time to time in relation to the Goods and Services. Where the provisions of any such Law are implemented by the use of voluntary agreements, the Supplier shall comply with such agreements as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification. Without prejudice to the generality of the foregoing, the Supplier shall:

20.1.1 comply with all Policies and/or procedures and requirements set out in the Specification in relation to any stated environmental and social requirements, characteristics and impacts of the Goods and Services and the Supplier's supply chain;

20.1.2 maintain relevant policy statements documenting the Supplier's significant social and environmental aspects as relevant to the Goods and Services being supplied and as proportionate to the nature and scale of the Supplier's business operations; and

20.1.3 maintain plans and procedures that support the commitments made as part of the Supplier's significant social and environmental policies, as referred to in Clause 20.1.2 of this Schedule 2.

20.2 The Supplier shall meet reasonable requests by NHS Supply Chain for information evidencing the Supplier's compliance with the provisions of Clause 20 of this Schedule 2.

21 Electronic product information

21.1 Where requested by NHS Supply Chain, the Supplier shall provide NHS Supply Chain with the Product Information in such manner and upon such media as agreed between the Supplier and NHS Supply Chain from time to time for the sole use by NHS Supply Chain.

21.2 The Supplier warrants that the Product Information is complete and accurate as at the date upon which it is delivered to NHS Supply Chain and that the Product Information shall not contain any data or statement which gives rise to any liability on the part of NHS Supply Chain following publication of the same in accordance with Clause 21 of this Schedule 2.

21.3 If the Product Information ceases to be complete and accurate, the Supplier shall promptly notify NHS Supply Chain in writing of any modification or addition to or any inaccuracy or omission in the Product Information.

21.4 The Supplier grants NHS Supply Chain a perpetual, non-exclusive, royalty free licence to use and exploit the Product Information and any Intellectual Property Rights in the Product Information for the purpose of illustrating the range of goods and services (including, without limitation, the Goods and Services) available in NHS Supply Chain's product catalogue in relation to any catalogues produced during the Term. Subject to Clause 21.5 of this Schedule 2, no right to illustrate or advertise the Product Information is granted to the Supplier by the Authority, as a consequence of the licence conferred by this Clause 21.4 of this Schedule 2.

21.5 NHS Supply Chain may reproduce for its sole use the Product Information provided by the Supplier in NHS Supply Chain's product catalogue from time to time which may be made available on any healthcare communications networks in electronic format and/or made available on NHS Supply Chain's external website and/or made available on other digital media from time to time.

21.6 For the avoidance of doubt the Supplier shall have no right to compel NHS Supply Chain to exhibit the Product Information in any product catalogue as a result of the approval given by it pursuant to this Clause 21.6 of this Schedule 2 or otherwise under the terms of this Framework Agreement.

21.7 NHS Supply Chain may approach the Supplier during the Term to offer the Supplier the opportunity to take part in specific promotions or to purchase additional advertising space in relation to the Goods and/or Services, the Framework Agreement and any Contract and the Parties shall agree an appropriate price for any such advertising. If any such opportunity is cancelled by NHS Supply Chain it shall refund the purchase price to the Supplier but for the avoidance of doubt, NHS Supply Chain shall not be liable for any incidental costs incurred by the Supplier, including costs associated with the development of an advert.

21.8 The Supplier agrees to indemnify and keep indemnified NHS Supply Chain against any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings arising out of or in connection with NHS Supply Chain's use of the Product Information, provided always that NHS Supply Chain has not materially misused the Product Information.

22 Change management

22.1 The Supplier acknowledges to NHS Supply Chain that the requirements for the Goods and Services may change during the Term and the Supplier shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Specification and Tender Response Document, as may be requested by NHS Supply Chain from time to time. Any change to the Goods and Services or other variation to this Framework Agreement shall only be binding once it has been agreed in writing and signed by an authorised representative of both Parties.

23 Dispute resolution

23.1 During any dispute, including a dispute as to the validity of this Framework Agreement, it is agreed that the Supplier shall continue its performance of the provisions of the Framework Agreement to the extent that such obligations are not the subject of the

dispute (unless NHS Supply Chain requests in writing that the Supplier does not do so).

23.2 In the case of a dispute arising out of or in connection with this Framework Agreement the Supplier and NHS Supply Chain shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the dispute and follow the procedure set out in Clause 23.2 of this Schedule 2 as the first stage in the Dispute Resolution Procedure.

23.3 If any dispute arises out of the Framework Agreement either Party may serve a notice on the other Party to commence formal resolution of the dispute. The Parties shall first seek to resolve the dispute by escalation in accordance with the management levels as set out in Clause 5 of the Key Provisions. Respective representatives, at each level as set out in Clause 5 of the Key Provisions, shall have five (5) Business Days at each level during which they will use their reasonable endeavours to resolve the dispute before escalating the matter to the next level as appropriate until all levels have been exhausted. Level 1 will commence on the date of service of the dispute notice. The final level of the escalation process shall be deemed exhausted on the expiry of five (5) Business Days following escalation to that level unless otherwise agreed by the Parties in writing.

23.4 If the procedure set out in Clause 23.2 of this Schedule 2 above has been exhausted and fails to resolve such dispute, as part of the Dispute Resolution Procedure, the Parties will attempt to settle it by mediation. The Parties shall, acting reasonably, attempt to agree upon a mediator. In the event that the Parties fail to agree a mediator within five (5) Business Days following the exhaustion of all levels of the escalation procedure at Clause 22.3 of this Schedule 2, the mediator shall be nominated and confirmed by the Centre for Effective Dispute Resolution, London.

23.5 The mediation shall commence within twenty eight (28) days of the conformation of the mediator in accordance with Clause 22.4 of this Schedule 2 or at such other time as may be agreed by the Parties in writing. Neither Party will terminate such mediation process until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one Party has failed to participate in the mediation process. After this time, either Party may terminate the mediation process by notice to the other Party (such notification may be verbal provided that it is followed up by written conformation). NHS Supply Chain and the Supplier will cooperate with any person appointed as mediator providing them with such information and other assistance as they shall require and will pay their costs, as they shall determine or in the absence of such determination such costs will be shared equally.

23.6 Nothing in this Framework Agreement shall prevent:

23.6.1 NHS Supply Chain taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with supply of the Goods and/or Services; or

23.6.2 either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party or that relates to the safety of patients or the security of Confidential Information, pending resolution of the relevant dispute in accordance with the Dispute Resolution Procedure.

23.7 Clause 23 of this Schedule 2 shall survive the expiry of or earlier termination of this Framework Agreement for any reason.

24 Force majeure

24.1 Subject to Clause 24.2 of this Schedule 2 neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Framework Agreement nor liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.

24.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 24 of this Schedule 2 and will not be considered to be in default or liable for breach of any obligations under this Framework Agreement if:

24.2.1 the Supplier has fulfilled its obligations pursuant to Clause 6 of this Schedule 2;

24.2.2 the Force Majeure Event does not arise directly or indirectly as a result of any wilful or negligent act or default of the Supplier; and

24.2.3 the Supplier has complied with the procedural requirements set out in Clause 24 of this Schedule 2.

24.3 Where a Party is (or claims to be) affected by a Force Majeure Event it shall use reasonable endeavours to mitigate the consequences of such a Force Majeure Event upon the performance of its obligations under this Framework Agreement and to resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.

24.4 Where the Force Majeure Event affects the Supplier's ability to perform part of its obligations under the Framework Agreement the Supplier shall fulfil all such contractual obligations that are not so affected and shall not be relieved from its liability to do so.

24.5 If either Party is prevented or delayed in the performance of its obligations under this Framework Agreement by a Force Majeure Event, that Party shall as soon as reasonably practicable serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.

24.6 Subject to service of such notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the Force Majeure Event only for so long as such circumstances continue and for such time after they cease as is necessary for that Party, using its best endeavours, to recommence its affected operations in order for it to perform its obligations.

24.7 The Party claiming relief shall notify the other in writing as soon as the consequences of the Force Majeure Event have ceased and of when performance of its affected obligations can be resumed.

24.8 If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, NHS Supply Chain may at any time if the Force Majeure Event subsists

for thirty (30) days or more, terminate this Framework Agreement on service of written notice on the Supplier.

24.9 Following such termination in accordance with Clause 24.8 of this Schedule 2 and subject to Clause 24.10 of this Schedule 2, neither Party shall have any liability to the other.

24.10 Any rights and liabilities of either Party which accrued prior to such termination in accordance with Clause 24.8 of this Schedule 2 shall continue in full force and effect unless otherwise specified in this Framework Agreement.

25 Records retention and right of audit

25.1 Subject to any statutory requirement and Clause 25.2 of this Schedule 2, the Supplier shall keep secure and maintain for the Term and six (6) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Framework Agreement.

25.2 Where any records could be relevant to a claim for personal injury such records shall be kept secure and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Framework Agreement.

25.3 NHS Supply Chain shall have the right to audit the Supplier's compliance with this Framework Agreement. The Supplier shall permit or procure permission for NHS Supply Chain or its authorised representative during normal business hours having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records reasonably required to audit the Supplier's compliance with its obligations under this Framework Agreement.

25.4 Should the Supplier Sub-contract any of its obligations under this Framework Agreement, NHS Supply Chain shall have the right to audit and inspect such third party. The Supplier shall procure permission for NHS Supply Chain or its authorised representative during normal business hours no more than once in any twelve (12) months, having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Framework Agreement that are Sub-contracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany NHS Supply Chain or its authorised representative if requested.

25.5 The Supplier shall grant to NHS Supply Chain or its authorised representative, such access to those records as they may reasonably require in order to check the Supplier's compliance with this Framework Agreement for the purposes of:

25.5.1 the examination and certification of NHS Supply Chain's accounts; or

25.5.2 any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which NHS Supply Chain has used its resources.

25.6 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to provide such oral and/or written explanations as they consider necessary. Clause 25 of this Schedule 2 does not constitute a

requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under section 6(3)(d) and 6(5) of the National Audit Act 1983.

25.7 The Supplier shall provide reasonable cooperation to NHS Supply Chain, its representatives and any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Framework Agreement.

25.8 The Supplier shall provide all reasonable information as may be reasonably requested by NHS Supply Chain to evidence the Supplier's compliance with the requirements of this Framework Agreement.

26 Conflicts of interest and the prevention of fraud

26.1 The Supplier shall take appropriate steps to ensure that neither the Supplier nor any Staff are placed in a position where, in the reasonable opinion of NHS Supply Chain, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to NHS Supply Chain under the provisions of this Framework Agreement. The Supplier will disclose to NHS Supply Chain full particulars of any such conflict of interest which may arise.

26.2 NHS Supply Chain reserves the right to terminate this Framework Agreement immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of NHS Supply Chain, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to NHS Supply Chain under the provisions of this Framework Agreement. The actions of NHS Supply Chain pursuant to this Clause 26.2 of this Schedule 2 shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to NHS Supply Chain.

26.3 The Supplier shall take all reasonable steps to prevent Fraud by Staff and the Supplier (including its owners, members and directors). The Supplier shall notify NHS Supply Chain immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.

26.4 If the Supplier or its Staff commits Fraud NHS Supply Chain may terminate this Framework Agreement and recover from the Supplier the amount of any direct loss suffered by NHS Supply Chain resulting from the termination.

27 Equality and human rights

27.1 The Supplier shall:

27.1.1 ensure that (a) it does not, whether as employer or as supplier of the Goods and Services, engage in any act or omission that would contravene the Equality Legislation, and (b) it complies with all its obligations as an employer or supplier of the Goods and Services as set out in the Equality Legislation and take reasonable endeavours to ensure its Staff do not unlawfully discriminate within the meaning of the Equality Legislation;

27.1.2 in the management of its affairs and the development of its equality and diversity policies, cooperate with NHS Supply Chain in light of NHS Supply Chain's obligations to comply with its statutory equality duties whether under the Equality Act 2010 or otherwise. The Supplier shall take such reasonable and proportionate steps as NHS Supply Chain considers appropriate to

promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age; and

27.1.3 the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 27 of this Schedule 2.

27.2 The Supplier shall meet reasonable requests by NHS Supply Chain for information evidencing the Supplier's compliance with the provisions of Clause 27 of this Schedule 2.

28 Notice

28.1 Subject to Clause 23.5 of this Schedule 2, any notice required to be given by either Party under this Framework Agreement shall be in writing quoting the date of the Framework Agreement and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the Key Provisions or such other person as one Party may inform the other Party in writing from time to time.

28.2 A notice shall be treated as having been received:

28.2.1 if delivered by hand within normal business hours when so delivered or, if delivered by hand outside normal business hours, at the next start of normal business hours; or

28.2.2 if sent by first class recorded delivery mail on a normal Business Day, at 9.00 am on the second Business Day subsequent to the day of posting, or, if the notice was not posted on a Business Day, at 9.00 am on the third Business Day subsequent to the day of posting; or

28.2.3 if sent by email, if sent within normal business hours when so sent or, if sent outside normal business hours, at the next start of normal business hours provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient to inform the recipient that the email has been sent.

29 Assignment, novation and Sub-contracting

29.1 Subject to Clause 29.2 of this Schedule 2, the Supplier shall not assign, Sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Framework Agreement without the prior consent in writing of NHS Supply Chain, such consent not to be unreasonably withheld or delayed. If the Supplier Sub-contracts any of its obligations under this Framework Agreement, every act or omission of the Sub-contractor shall for the purposes of this Framework Agreement be deemed to be the act or omission of the Supplier and the Supplier shall be liable to NHS Supply Chain as if such act or omission had been committed or omitted by the Supplier itself.

29.2 The Supplier may assign, Sub-contract or novate this Framework Agreement to a member of its Group, provided always that such Group member shall have been assessed by NHS Supply Chain and passed to the satisfaction of NHS Supply Chain all grounds for exclusion and shortlisting criteria to be awarded onto this Framework Agreement.

29.3 Any authority given by NHS Supply Chain for the Supplier to Sub-contract any of its obligations under this Framework Agreement shall not impose any duty on NHS Supply Chain to enquire as to the competency of any authorised Sub-contractor. The Supplier shall ensure that any authorised Sub-contractor has the appropriate capability and capacity to perform the relevant obligations and that the obligations carried out by such Sub-contractor are fully in accordance with this Framework Agreement.

29.4 Where the Authority considers that the grounds for exclusion under Regulation 57 of the Public Contracts Regulations 2015 apply to any Sub-contractor, then:

29.4.1 if the Authority finds there are compulsory grounds for exclusion, the Supplier shall ensure, or shall procure, that such Sub-contractor is replaced or not appointed; or

29.4.2 if the Authority finds there are non-compulsory grounds for exclusion, the Authority may require the Supplier to ensure, or to procure, that such Sub-contractor is replaced or not appointed and the Supplier shall comply with such a requirement.

29.5 NHS Supply Chain shall upon written request have the right to review any Sub-contract entered into by the Supplier in respect of the provision of the Goods and the Supplier shall provide a certified copy of any Sub-contract within five (5) Business Days of the date of a written request from NHS Supply Chain. For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of Sub-contracts.

29.6 NHS Supply Chain may at any time transfer, assign, novate, Sub-contract or otherwise dispose of its rights and obligations under this Framework Agreement or any part of this Framework Agreement and the Supplier warrants that it will carry out all such reasonable further acts required to effect such transfer, assignment, novation, Sub-contracting or disposal. If NHS Supply Chain novates this Framework Agreement to any body that is not a Contracting Authority, from the effective date of such novation, the party assuming the position of NHS Supply Chain shall not further transfer, assign, novate, Sub-contract or otherwise dispose of its rights and obligations under this Framework Agreement or any part of this Framework Agreement without the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier.

30 Prohibited Acts

30.1 The Supplier warrants and represents that:

30.1.1 it has not committed any offence under the Bribery Act 2010 or done any of the following ("**Prohibited Acts**"):

(i) offered, given or agreed to give any officer or employee of NHS Supply Chain any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with NHS Supply Chain or for showing or not

showing favour or disfavour to any person in relation to this or any other agreement with NHS Supply Chain; or

(ii) in connection with this Framework Agreement paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to NHS Supply Chain; and

30.1.2 it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.

30.2 If the Supplier or its Staff (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of the Supplier in relation to this or any other agreement with NHS Supply Chain:

30.2.1 NHS Supply Chain shall be entitled:

(i) to terminate this Framework Agreement and recover from the Supplier the amount of any loss resulting from the termination;

(ii) to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and

(iii) to recover from the Supplier any other loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence under the Bribery Act 2010;

30.2.2 any termination under Clause 30.2.1 of this Schedule 2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to NHS Supply Chain; and

30.2.3 notwithstanding Clause 23 of this Schedule 2, any dispute relating to:

(i) the interpretation of Clause 30 of this Schedule 2; or

(ii) the amount or value of any gift, consideration or commission,

shall be determined by NHS Supply Chain, acting reasonably, and the decision shall be final and conclusive.

31 General

31.1 Each of the Parties is independent of the other and nothing contained in this Framework Agreement shall be construed to imply that there is any relationship between the Parties of partnership or of principal/agent or of employer/employee nor are the Parties hereby engaging in a joint venture and accordingly neither of the Parties shall have any right or authority to act on behalf of the other nor to bind the other by agreement or otherwise, unless expressly permitted by the terms of this Framework Agreement.

31.2 Failure or delay by either Party to exercise an option or right conferred by this Framework Agreement shall not of itself constitute a waiver of such option or right.

31.3 The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Framework Agreement or to exercise any right or remedy consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.

31.4 Any provision of this Framework Agreement which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of this Framework Agreement and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

31.5 Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Framework Agreement and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Framework Agreement or unless such representation, undertaking or warranty was made fraudulently.

31.6 Each Party shall bear its own expenses in relation to the preparation and execution of this Framework Agreement including all costs, legal fees and other expenses so incurred.

31.7 The rights and remedies provided in this Framework Agreement are cumulative and not exclusive of any rights or remedies provided by general law, or by any other contract or document. In this Clause 31.7 of this Schedule 2, right includes any power, privilege, remedy, or proprietary or security interest.

31.8 No persons other than the parties to this Framework Agreement and any Participating Authorities shall have the right to enforce the terms of this Framework Agreement which confer a benefit on such person or be entitled to object to or be required to consent to any amendment to the provisions of this Framework Agreement.

31.9 This Framework Agreement, any variation in writing signed by an authorised representative of each Party and any document referred to explicitly in this Framework Agreement or any variation to this Framework Agreement, contain the entire understanding between the Supplier and NHS Supply Chain relating to the operation of this Framework Agreement to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Framework Agreement. Nothing in this Framework Agreement seeks to exclude either Party's liability for Fraud. Any tender conditions and/or disclaimers set out in the Authority's procurement documentation leading to the award of this Framework Agreement shall form part of this Framework Agreement.

31.10 This Framework Agreement, and any dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales.

31.11 Subject to Clause 23 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any dispute or

claim that arises out of or in connection with this Framework Agreement or its subject matter.

31.12 All written and oral communications and all written material referred to under this Framework Agreement shall be in English.

Schedule 3

Information Governance Provisions

1 Confidentiality

1.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("**Discloser**") and subject always to the remainder of Clause 1 of this Schedule 3, each Party ("**Recipient**") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent provided that:

1.1.1 the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Commencement Date;

1.1.2 the provisions of Clause 1 of this Schedule 3 shall not apply to any Confidential Information:

(i) which is in or enters the public domain other than by breach of this Framework Agreement or other act or omissions of the Recipient;

(ii) which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;

(iii) which is authorised for disclosure by the prior written consent of the Discloser;

(iv) which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the Confidential Information from the Discloser; or

(v) which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.

1.2 Nothing in Clause 1 of this Schedule 3 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law, including the Freedom of Information Act 2000 ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**") or the Environmental Information Regulations 2004 ("**Environmental Regulations**").

1.3 NHS Supply Chain may disclose the Supplier's Confidential Information:

1.3.1 on a confidential basis to, any Contracting Authority (the Parties agree that all Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority);

1.3.2 on a confidential basis, to any consultant, contractor or other person engaged by NHS Supply Chain and/or the Contracting Authority receiving such information;

1.3.3 to any relevant party for the purpose of the examination and certification of NHS Supply Chain's accounts;

1.3.4 to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which NHS Supply Chain has used its resources;

1.3.5 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or

1.3.6 on a confidential basis, to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Framework Agreement;

and for the purpose of this Framework Agreement, references to disclosure "on a confidential basis" shall mean NHS Supply Chain making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 1.3 of this Schedule 3.

1.4 The Supplier may only disclose NHS Supply Chain's Confidential Information, and any other information provided to the Supplier by NHS Supply Chain in relation to the operation of this Framework Agreement, to the Supplier's Staff or professional advisors who are directly involved in the performance of or advising on the Supplier's obligations under this Framework Agreement. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in Clause 1 of this Schedule 3 as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at NHS Supply Chain's written discretion, destroyed securely or returned to NHS Supply Chain when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of NHS Supply Chain's Confidential Information received otherwise than for the purposes of performing the Supplier's obligations in this Framework Agreement.

1.5 Nothing in this Clause 1 of this Schedule 3 shall prevent the Recipient from disclosing the Confidential Information to its Group companies, provided that the Recipient procures that such Group companies comply with this Clause 1 of this Schedule 3 as if each reference to the Recipient in this Clause 1 of this Schedule 3 is a reference to any such Group company receiving the Confidential Information.

1.6 For the avoidance of doubt, save as required by Law or as otherwise set out in this Schedule 3, the Supplier shall not, without the prior written consent of NHS Supply Chain (such consent not to be unreasonably withheld or delayed), announce that it has entered into this Framework Agreement and/or that it has been appointed as a Supplier to NHS Supply Chain and/or make any other announcements about this Framework Agreement.

1.7 Clause 1 of this Schedule 3 shall remain in force:

1.7.1 without limit in time in respect of Confidential Information which comprises Personal Data, Sensitive Personal Data or which relates to national security; and

1.7.2 for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Framework Agreement unless otherwise agreed in writing by the Parties.

2 Data protection

2.1 The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties.

2.2 Where the Supplier is Processing Personal Data under or in connection with this Framework Agreement, the Supplier must, in particular, but without limitation:

2.2.1 only Process such Personal Data as is necessary to perform its obligations under this Framework Agreement, and only in accordance with any instructions given by NHS Supply Chain under this Framework Agreement;

2.2.2 put in place appropriate technical and organisational measures against any unauthorised or unlawful Processing of that Personal Data, and against the accidental loss or destruction of or damage to such Personal Data having regard to the specific requirements of Clause 2 of this Schedule 3, the state of technical development and the level of harm that may be suffered by a Data Subject whose Personal Data is affected by unauthorised or unlawful Processing or by its loss, damage or destruction;

2.2.3 take reasonable steps to ensure the reliability of Staff who will have access to Personal Data, and ensure that those Staff are aware of and trained in the policies and procedures identified in Clause 2 of this Schedule 3; and

2.2.4 not cause or allow Personal Data to be transferred outside the European Economic Area without the prior consent of NHS Supply Chain.

2.3 The Supplier and NHS Supply Chain shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the purpose for which the transfer is conducted; and (b) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to NHS Supply Chain under any Law and Guidance (this includes, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).

2.4 For the avoidance of doubt, the Supplier must not process Sensitive Personal Data under or in connection with this Framework Agreement unless it has complied fully with:

2.4.1 the requirements in Clauses 2.1 to 2.4 of this Schedule 3 (inclusive); and

2.4.2 the requirements of and its obligations under the Data Protection Act 1998 and The Data Protection (Processing of Sensitive Personal Data) Order 2000 (as amended from time to time) or any successor legislation.

2.5 Where any Personal Data is Processed by any Sub-contractor of the Supplier in connection with this Framework Agreement, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 2 of this Schedule 3, as if such Sub-contractor were the Supplier.

2.6 The Supplier shall indemnify and keep NHS Supply Chain indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings whatsoever or howsoever arising from the Supplier's unlawful or unauthorised Processing, destruction and/or damage to Personal Data and/or Sensitive Personal Data in connection with this Framework Agreement.

3 Freedom of Information and Transparency

3.1 The Parties acknowledge the duties of Contracting Authorities under the FOIA, Codes of Practice and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties.

3.2 The Supplier shall assist and cooperate with NHS Supply Chain to enable it to comply with its disclosure obligations under the FOIA, Codes of Practice and Environmental Regulations. The Supplier agrees:

3.2.1 that this Framework Agreement and any recorded information held by the Supplier on NHS Supply Chain's behalf for the purposes of this Framework Agreement are subject to the obligations and commitments of NHS Supply Chain under the FOIA, Codes of Practice and Environmental Regulations;

3.2.2 that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for NHS Supply Chain;

3.2.3 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier itself is subject to the FOIA, Codes of Practice and Environmental Regulations it will liaise with NHS Supply Chain as to the contents of any response before a response to a request is issued and will promptly (and in any event within two (2) Business Days) provide a copy of the request and any response to NHS Supply Chain;

3.2.4 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier is not itself subject to the FOIA, Codes of Practice and Environmental Regulations, it will not respond to that request (unless directed to do so by NHS Supply Chain) and will promptly (and in any event within two (2) Business Days) transfer the request to NHS Supply Chain;

3.2.5 that NHS Supply Chain, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and

regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Framework Agreement; and

3.2.6 to assist NHS Supply Chain in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of all information requested by NHS Supply Chain within five (5) Business Days of that request and without charge.

3.3 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations, the content of this Framework Agreement is not Confidential Information.

3.4 Notwithstanding any other term of this Framework Agreement, the Supplier consents to the publication of this Framework Agreement in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations.

3.5 In preparing a copy of this Framework Agreement for publication under Clause 3.4 of this Schedule 3, NHS Supply Chain may consult with the Supplier to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at NHS Supply Chain's absolute discretion.

3.6 The Supplier shall assist and cooperate with NHS Supply Chain to enable NHS Supply Chain to publish this Framework Agreement.

3.7 Where any information is held by any Sub-contractor of the Supplier in connection with this Framework Agreement, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 3 of this Schedule 3, as if such Sub-contractor were the Supplier.

4 Information Security

4.1 Without limitation to any other information governance requirements set out in this Schedule 3, the Supplier shall:

4.1.1 notify NHS Supply Chain forthwith of any information security breaches or near misses (including without limitation any potential or actual breaches of confidentiality or actual information security breaches) in line with NHS Supply Chain's information governance Policies; and

4.1.2 fully cooperate with any audits or investigations relating to information security and any privacy impact assessments undertaken by NHS Supply Chain and shall provide full information as may be reasonably requested by NHS Supply Chain in relation to such audits, investigations and assessments.

Schedule 4

Definitions and Interpretations

1 Definitions

1.1 In this Framework Agreement the following words shall have the following meanings unless the context requires otherwise, other than in relation to the Call-off Terms and Conditions for the Supply of Goods at Schedule 9 of this Framework Agreement. The definitions and Interpretations that apply to the Call-off Terms and Conditions for the Supply of Goods are as set out at Schedule 9 of this Framework Agreement.

"Action Plan"	shall have the meaning given to it in Clause 6 of Schedule 8;
"Authority"	means the authority named on the Order Form;
"Business Continuity Event"	means any event or issue that could impact on the operations of the Supplier and its ability to fulfil its obligations under this Framework Agreement including an influenza pandemic and any Force Majeure Event;
"Business Continuity Plan"	means the Supplier's business continuity plan which includes its plans for continuity of the supply of the Goods and Services during a Business Continuity Event;
"Business Day"	means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales;
"Call-off Terms and Conditions for the Supply of Goods"	means the call-off terms and conditions for Contracts as set out at Schedule 9 of this Framework Agreement forming part of the Contracts placed under this Framework Agreement;
"Codes of Practice"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"Commencement Date"	19th January 2026;
"Commercial Schedule"	means the document set out at Schedule 6;
"Confidential Information"	means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Framework Agreement including any procurement process which is: (a) Personal Data or Sensitive Personal Data including without limitation which relates to any patient or other service user or his or her treatment or clinical or care history;

	(b) designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through NHS Supply Chain's intranet;
"Contract"	means any Contract entered into under this Framework Agreement with the Supplier by any Participating Authority as further defined in the Call-off Terms and Conditions for the Supply of Goods;
"Contracting Authority"	means any contracting authority as defined in regulation 2 of the Public Contracts Regulations 2015 (as amended) (2015/102), other than NHS Supply Chain;
"Contract Manager"	means for NHS Supply Chain and for the Supplier the individuals specified in the Key Provisions or such other person notified by a Party to the other Party from time to time in accordance with Clause 8.1 of Schedule 2;
"Contract Price"	means the price exclusive of VAT that is payable to the Supplier by a Participating Authority under any Contract for the full and proper performance by the Supplier of its obligations under such Contracts (as calculated in accordance with the provisions of the Commercial Schedule) and as confirmed in the relevant Order Form relating to the particular Contract;
"Data Protection Legislation"	means the Data Protection Act 1998 and any other Law relating to the protection of personal and sensitive personal data and the privacy of individuals, including where applicable guidance and codes of practice issued by the Information Commissioner;
"Data Subject"	shall have the same meaning as set out in the Data Protection Act 1998;
"Direct Route of Supply"	means a route of supply whereby the Authority (which is a Participating Authority who is not NHS Supply Chain) places an Order with the Supplier, which is delivered and invoiced directly to that Authority;
"Dispute Resolution Procedure"	means the process for resolving disputes as set out in Clause 23 of Schedule 2;
"DOTAS"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue & Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance

	Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
"Electronic Trading System(s)"	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as NHS Supply Chain may specify from time to time;
"E-direct"	means Goods and Services ordered by NHS Supply Chain as the Authority on behalf of an NHS Supply Chain customer which are delivered directly to the customer and invoiced to NHS Supply Chain;
"Environment"	means the air, water, and land in or on which people, animals, and plants live;
"Environmental Regulations"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"E-Procurement Guidance"	means the NHS E-Procurement Strategy available via: http://www.gov.uk/government/collections/nhs-procurement together with any further Guidance issued by the Department of Health in connection with it;
"Equality Legislation"	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998;
"Ex Works"	means Goods and Services ordered from the Supplier based on the Contract Price, excluding delivery and other associated delivery costs, it being the responsibility of the Authority to arrange for collection of such Goods and Services from the Supplier;
"FOIA"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Framework Agreement;

	(b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods and/or Services, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and (i) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties;
"Framework Agreement"	means the form of framework agreement at the front of this document and all schedules attached to the form of framework agreement;
"Fraud"	means any offence under any law in respect of fraud in relation to this Framework Agreement or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;
"General Anti-Abuse Rule"	means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;

"Good Industry Practice"	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the manufacture and/or supply of goods and/or services similar to the Goods and/or Services under the same or similar circumstances as those applicable to this Framework Agreement, including in accordance with any codes of practice published by relevant trade associations;
"Goods"	means all goods, materials or items that the Supplier is required to supply to Participating Authorities under Contracts placed under this Framework Agreement and/or made available for purchase under the Framework Agreement in accordance with Clause 22 of Schedule 2 and/or the Commercial Schedule, details of such Goods, materials or other items being set out in the Specification and Tender Response Document and any Order;
"Group"	means in relation to a Party, that Party, any subsidiary or holding company from time to time of that Party, and any subsidiary from time to time of a holding company of that Party and holding company and subsidiary company shall have the meaning given in Section 1159 of the Companies Act 2006;
"Guidance"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods and Services, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by NHS Supply Chain and/or have been published and/or notified to the Supplier by the Department of Health, Monitor, NHS England, the Medicines and Healthcare Products Regulatory Agency, the European Medicine Agency the European Commission, the Care Quality Commission and/or any other regulator or competent body;
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"Intellectual Property Rights"	means all patents, copyright, design rights, registered designs, trademarks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trademarks and registered designs;
"Key Provisions"	means the key provisions set out in Schedule 1;
"KPI"	means the key performance indicators as set out in Schedule 8;
"Law"	means any applicable legal requirements including, without limitation: (a) any applicable statute or proclamation or any delegated or subordinate legislation or regulation as applicable in England and Wales;

	(b) any applicable European Union directive, regulation, decision or law; (c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (e) requirements set by any regulatory body as applicable in England and Wales; and (f) any applicable code of practice as applicable in England and Wales, (g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above).
"Management Fee"	has the meaning given under Clause 9.2 of Schedule 2;
"Management Fee Report"	has the meaning given under Clause 9.3 of Schedule 2;
"Monthly Service Level"	has the meaning given under Clause 3 of Schedule 8;
"NHS"	means the National Health Service;
"NHS Supply Chain's Obligations"	means NHS Supply Chain's further obligations, if any, referred to in the Specification and Tender Response Document;
"Non-direct Route of Supply"	means all routes of supply through which NHS Supply Chain (as the Authority) places an Order with the Supplier for Goods and/or Services and the Supplier invoices NHS Supply Chain for the sum of the relevant Order, whether or not such Goods and/or Services are delivered to NHS Supply Chain or another authority and whether or not such Goods and/or Services are collected Ex Works. Non-direct routes of supply include E-Direct and Stock (and any other non-direct routes which NHS Supply Chain may notify to the Supplier from time to time);
"Occasion of Tax Non-Compliance"	means: (a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of: i. a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an

	effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; ii. the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or (b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion;
"Order Form"	means an order form on which Orders are to be placed, containing the details set out in Schedule 7;
"Ordering Procedure"	means the procedure enabling Participating Authorities to call-off Goods and Services and enter into Contracts under this Framework Agreement, as set out in Schedule 7;
"Orders"	means orders for Goods and Services placed under this Framework Agreement by Participating Authorities;
"Organisation"	means the Supplier company;
"Participating Authority"	means a Contracting Authority entitled to place Orders under this Framework Agreement including NHS Supply Chain and any other Contracting Authority as set out in the Key Provisions;
"Party"	means NHS Supply Chain or the Supplier as appropriate and Parties means both NHS Supply Chain and the Supplier;
"Personal Data"	means personal data as defined in the Data Protection Act 1998;
"Policies"	means the policies, rules and procedures of NHS Supply Chain as notified to the Supplier from time to time;
"Process"	has the meaning given to it under the Data Protection Legislation and, for the purposes of this Framework Agreement, it shall include both manual and automatic processing. Processing and Processed shall be construed accordingly;
"Product Information"	means information (including images) concerning the Goods and Services as may be reasonably requested by NHS Supply Chain and supplied by the Supplier to NHS Supply Chain in accordance with Clause 21 of Schedule 2 for inclusion in NHS Supply Chain's product catalogue from time to time;
"Prohibited Acts"	has the meaning given under Clause 30.1.1 of Schedule 2;

"Remedial Proposal"	has the meaning given under Clause 16.3 of Schedule 2;
"Sensitive Personal Data"	means sensitive personal data as defined in the Data Protection Act 1998;
"Services"	means any services which are ancillary to or associated with the Goods, which are purchased by Participating Authorities under Contracts placed under this Framework Agreement and/or made available for purchase under the Framework Agreement in accordance with Clause 22 of Schedule 2 and/or the Commercial Schedule, details of such Services being set out in the Specification and Tender Response Document and any Order;
"Specification"	means the document set out in Schedule 5(a) as amended and/or updated in accordance with this Framework Agreement;
"Staff"	means all persons employed or engaged by the Supplier to perform its obligations under this Framework Agreement including any Sub-contractors and person employed or engaged by such Sub-contractors;
"Stock"	means Goods purchased by NHS Supply Chain (as an Authority) which are delivered and invoiced to NHS Supply Chain to be held as stock until such time as NHS Supply Chain customers place an order for such goods with NHS Supply Chain;
"Sub-contract"	means a contract between two or more suppliers, at any stage of remoteness from the Supplier in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of the whole or any part of this Framework Agreement);
"Sub-contractor"	means a party to a Sub-contract other than the Supplier;
"Supplier"	means the supplier named on the form of Framework Agreement on the first page;
"Tender Response Document"	means the document set out in Schedule 5(b) as accepted by NHS Supply Chain;
"Term"	means the term as set out in the Key Provisions;
"Third Party Body"	has the meaning given under Clause 8.5 of Schedule 2; and
"VAT"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

1.2 References to any statute or order shall include any statutory extension, modification or re-enactment, and any order, regulation, bye-law or other subordinate legislation.

1.3 References to any legal entity shall include any body that takes over responsibility for the functions of such entity.

1.4 References in this Framework Agreement to a “Schedule”, “Appendix”, “Paragraph” or to a “Clause” are to schedules, appendices, paragraphs and clauses of this Framework Agreement.

1.5 References in this Framework Agreement to a day or to the calculation of time frames are references to a calendar day unless expressly specified as a Business Day.

1.6 Unless set out in the Commercial Schedule as a chargeable item and subject to Clause 31.6 of Schedule 2, the Supplier shall bear the cost of complying with its obligations under this Framework Agreement.

1.7 The headings are for convenience only and shall not affect the interpretation of this Framework Agreement.

1.8 Words denoting the singular shall include the plural and vice versa.

1.9 Where a term of this Framework Agreement provides for a list of one or more items following the word “including” or “includes” then such list is not to be interpreted as an exhaustive list. Any such list shall not be treated as excluding any item that might have been included in such list having regard to the context of the contractual term in question. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.

1.10 Where there is a conflict between the Supplier’s responses to NHS Supply Chain’s requirements set out in the Specification in the Tender Response Document and any other part of this Framework Agreement, such other part of this Framework Agreement shall prevail.

1.11 Where a document is required under this Framework Agreement, the Parties may agree in writing that this shall be in electronic format only.

1.12 Any guidance notes in grey text do not form part of this Framework Agreement.

Schedule 5

5(a) Specification

FRAMEWORK AGREEMENT SPECIFICATION
WOUND CLOSURE

1. Introduction

1.1. The Framework Agreement is for the supply of Wound Closure Products including but not limited to Sterile Sutures and Needles, Haemostats, Tissue/Skin Adhesives, External Skins Staples and Staple Removers and Wound Closure Strips.

1.2. Full technical specifications of the product lines awarded to the Framework Agreement (each a "**Technical Specification**" and together the "**Technical Specifications**") must be made available to NHS Supply Chain on request during the term of the Framework Agreement.

1.2.1. Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.
1.2.2. If changes to the Technical Specification of any product line awarded to the Framework Agreement mean that the product line no longer meets the minimum requirements outlined in the Specification, NHS Supply Chain reserves the right to exclude that product line from the Framework Agreement.
1.2.3. NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement.

1.3. This Framework Agreement Specification refers to a number of standards and legislation. The list of standards and legislation is not intended to be exhaustive and any relevant standards and legislation which applies to the Framework Agreement (even if not stated) must be complied with by Applicants (together with those listed in this Framework Agreement Specification the "**Standards and Legislation**").

1.4. Product lines must comply with the Standards and Legislation (as amended, extended, or re-enacted from time to time).

1.5. Evidence of compliance to the Standards and Legislation must be provided by Applicants awarded to the Framework Agreement ("**Suppliers**") to NHS Supply Chain on request during the term of the Framework Agreement; if sufficient evidence is not provided by Suppliers NHS Supply Chain reserves the right to suspend product lines until such evidence is provided by Suppliers.

2. Criteria applicable across all product lines

2.1. Standards and Legislation

STANDARD AND LEGISLATION
Where products are classed as Medical Devices as per the definition under Medical Devices Regulation 2017/745 the following will apply: **Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)** All products must have their CE or UKCA marking evident on the product and/or packaging. **Or** **Medical Devices Regulation 2017/745 (as amended)** All products must have their CE or UKCA marking evident on the product and/or packaging. Where products are sterile, they must comply with either applicable standard below or equivalent international standard to designate device as sterile. **BS EN 556-1-2001** Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices. **BS EN556-2-2015** Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices. Where a product is sterilised an applicable validated sterilisation and routine control process must be applied, for example: **BS EN ISO 14937:2009** Sterilization of health care Sterilization of health care products. **BS EN ISO 11135:2014+A1:2019** Sterilization of health-care products. Ethylene oxide **BS EN ISO 11137-4:2015+A2:2019**. Sterilization of healthcare products. Radiation Requirements for the development, validation, and routine control of a sterilization process for medical devices **BS EN ISO 17665-1:2006** Sterilization of health care products. Moist heat. Requirements for the development, validation, and routine control of a sterilization process for medical devices

BS EN ISO 13485:2016 or Equivalent -Medical devices —Quality management systems

ISO 14971:2019 or Equivalent - Medical devices — Application of risk management to medical devices

United States Pharmacopeia (USP) / European Pharmacopeia / British Pharmacopeia

2.2. On request applicants must provide NHS Supply Chain with Safety Data Sheets (SDS) for all products that fall under REACH (Registration, Evaluation, Authorisation, and restriction of Chemicals) 2007 –more specifically, an SDS must be provided if a substance or a mixture supplied is classified as hazardous under the CLP Regulation (EC) No 1272/2008.

2.3. All products must not contain an active or preservative of concern as identified by Health and Safety Executive or UK Registration, Evaluation, Authorisation and Restriction of Chemicals (UK REACH) or be within their allowable limits. Where there are allowable limits, the ingredient name, Chemicals Abstract Service (CAS) number and concentration must appear on the label.

2.4. If a product line contains phthalates this must be indicated on the packaging of that product line in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).

2.5. All product lines and packaging should be latex free where possible. If a product line or any packaging contains latex this must be labelled on the product line or packaging (as applicable) to inform the user.

2.6. During the term of the Framework Agreement Applicants must make NHS Supply Chain aware of any awarded product line that is classed by the MHRA as a Medicinal Product.

2.7. The batch number and expiry date (if the product expires and has a required expiry date) must be present and legible on the individual product packaging, particularly when embossing is used rather than print. For clarity this must allow full traceability on finished products back to manufacturing source.

2.8. Instructions for use must be in English and include approved pictograms if the product falls within the Classification Labelling & Packaging (CLP) regulations. The instructions for use must be appropriate for the intended use of the product and provided within the unit of issue (UOI) or made available to NHS Supply Chain or end user on request.

2.9. For all products, all product labels must be in accordance with the relevant standard and/or regulation. Any shelf-life limits and/or specific storage conditions required before or after opening or reconstituting the product must be stated on

the product packaging. The usage period after opening must be detailed on either the product and/or product packaging and/or instructions for use made available to the end user.

2.10. All Products must be supplied, distributed, and labelled incompliance with Licenced Medical Products (LMP) where applicable. Regulations and instructions for storage need to be clearly described on the product / instructions for use made available to the end user (IFU).

2.11. If a product contains DEHP this must be stated on the individual product packaging or instructions for use (IFU) and/or made available to NHS Supply Chain or end user on request.

2.12. Any cautions / warnings / contraindications to use must be provided in IFU.

2.13. Must state details strictly necessary to identify the device for the user on the individual product packaging.

2.14. Lot number and expiry date must be stated on the individual product packaging.

2.15. For ordering purposes an identifier for example reference / manufacturing product code (MPC) must be stated on the individual product packaging and/or unit of issue packaging.

2.16. Where applicable, products must be supplied sterile and individually wrapped.

2.17. When the product is sterile, the product packaging must include a non-adherent tab which allows product packaging to be opened at one end maintaining ANTT.

2.18. All sterile products must have a transparent side to allow visualisation of the product through the individual product packaging.

2.19. Where a product is single use, the word single use and / or symbol must be depicted on the individual product packaging to inform the user of the products single use status in line with labelling (ISO 15223).

2.20. Individual packaging must be of durable construction preventing product being pushed through, tampered with, and must not tear or rip apart during transportation and storage, to avoid damage to the product and/or breaches of product sterility and to reduce risk of plastic packaging being a foreign body when device being used.

2.21. Individual product packaging must be of durable construction preventing tampering and must not tear or rip under normal working conditions.

2.22. Product must be robust enough to resist breakage when used as directed by manufacture.

2.23. All products must have their CE or UKCA marking evident on the product and/or packaging.

2.24. Where the product is to be used only in a specific part of the body, instructions/guidance must be provided with the individual product in English and on the product where possible, including diagrams if feasible.

2.25. Information on the product constituent's raw material/s must be made available to NHS Supply Chain or end user on request to support with customer recycling requirements.

2.26. Where applicable, must be stated if external product packaging is made of recyclable material and /or recyclable.

2.27. Information on Country of origin must be made available to NHS Supply Chain or end user on request.

2.28. Information on weight of product must be made available to NHS Supply Chain or end user on request.

2.29. Training and implementation must be provided on request and in accordance with trust requirements through mutual agreement. This could be for example, providing ongoing support including pre-implementation education, supplier support and implementation guidance, bespoke clinical training, eLearning, and post-implementation support.

2.30. Training material must be made available upon request Upon NHS Trust conversion, where required free of charge training must be provided.

2.31. All product line(s) must be supplied with a minimum 6-month shelf life.

2.32. All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer.

2.33. The sterilisation process for the supply of sterile product lines must be certified by a Notified Body.

2.34. The production of stainless-steel instrumentation must be from certified steel feed stock (i.e. SAE International/AISI (American Iron and Steel) standard formulation) and a Certification of Analysis must be obtained with every feed stock purchase. NHS Supply Chain reserves the right to request copies of the certification during the term of the Framework Agreement

2.35. Product lines awarded to the Framework Agreement must be consistent with any samples supplied for testing and evaluation.

3. Sterile Sutures and Needles: absorbable and non-absorbable sutures and a range of needle sizes, Haemostats flowable, fabrics, gauze, sheets, sponges,

powders, gels, snows, sprays and sealants, Tissue Adhesives, External Skins Staples and Staple Removers and Wound Closure Strips

3.1. **Sterile Surgical Sutures and Needles -** Single use sterile sutures and needles intended for use in a wide range of medical and surgical procedures and across all patient groups that includes but shall not be limited to:

3.1.1. **Standards and Legislation**

STANDARD AND LEGISLATION
United States Pharmacopeia (USP) / European Pharmacopeia / British Pharmacopeia

3.1.2. A full range of suture to include sizes 10 - 12/0 these sutures gauges must be scope and compliant to the current United States/ European/British Pharmacopeia primary standards for ensuring suture gauge quality:

USP	USP/Metric	Diameter limits in mm non-absorbable	Diameter limits in mm Synthetic Absorbable
12/0	0.01	0.001-0.009	0.001-0.009
11/0	0.1	0.010-0.019	0.010-0.019
10/0	0.2	0.020-0.029	0.020-0.029
9/0	0.3	0.030-0.039	0.030-0.039
8/0	0.4	0.040-0.049	0.040-0.049
7/0	0.5	0.050-0.069	0.050-0.069
6/0	0.7	0.070–0.099	0.070–0.099
5/0	1	0.10–0.149	0.10-0.149
4/0	1.5	0.15-0.199	0.15-0.199
3/0	2	0.20-0.249	0.20-0.249
2/0	3	0.30-0.339	0.30-0.339
0	3.5	0.35-0.399	0.35-0.399
1	4	0.40-0.499	0.40-0.499
2	5	0.50–0.599	0.50–0.599
3	6	0.60–0.699	0.60–0.699
4	6	0.60–0.699	0.60–0.699
5	7	0.70-0.799	0.70-0.799

6	8	0.80-0.899	
7	9	0.90-0.999	
8	10	1.00-1.099	
9	11	1.100-1.199	
10	12	1.200-1.299	

USP	USP/Metric	Diameter limits in mm Absorbable (Collagen)
9/0	0.4	0.040–0.049
8/0	0.5	0.050–0.069
7/0	0.7	0.070–0.099
6/0	1	0.10–0.149
5/0	1.5	0.15–0.199
4/0	2	0.20-0.249
3/0	3	0.30–0.339
2/0	3.5	0.35–0.399
0	4	0.40–0.499
1	5	0.50-0.599

3.2. **Sutures non-absorbable**

3.2.1. **Barbed polyolefin / polyamide suture** -A single-strand (monofilament), synthetic, non-bioabsorbable thread made from a polyolefin (e.g., polypropylene) or polyamide intended to approximate the edges of a soft-tissue wound or incision by stitching. It is designed with barbs along its length intended to facilitate tissue approximation by adding tension, a fixation feature (e.g., tab, loop, bidirectional barbs) to eliminate the need to tie a knot, and may include disposable suture application devices (e.g., needle, passer)

3.2.2. **Cotton suture -** A multiple-strand (multifilament), natural, non-bioabsorbable thread made from cotton fibres intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application.

3.2.3. **Linen suture**-A multiple-strand (multifilament), natural, non-bioabsorbable thread made from long textile (usually flax) fibres intended to join (approximate) the edges of a soft-tissue wound or incision (especially gastrointestinal) by stitching, or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application.

3.2.4. **Metallic suture, monofilament**-A single-strand (monofilament), non-bioabsorbable wire made of metal (e.g., surgical steel, titanium) intended to join (approximate) the edges of a soft-tissue wound or incision by stitching (e.g., for abdominal wound closure, intestinal anastomosis, hernia repair), or transosseous (through bone) stitching (e.g., sternal closure); it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application.

3.2.5. **Metallic suture, multifilament-**A multiple-strand (multifilament), non-bioabsorbable wire made of metal (e.g., surgical steel, titanium) intended to join (approximate) the edges of a soft-tissue wound or incision by stitching (e.g., for abdominal wound closure, intestinal anastomosis, hernia repair), or transosseous (through bone) stitching (e.g., sternal closure); it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application

3.2.6. **Nylon suture, non-bioabsorbable, monofilament**-A single-strand (monofilament), synthetic, non-bioabsorbable thread made of nylon (a polyamide polymer) intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application.

3.2.7. **Nylon suture, non-bioabsorbable, multifilament-**A multiple-strand (multifilament), synthetic, non-bioabsorbable thread made of nylon (a polyamide polymer) intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application

3.2.8. **Polyester suture, non-bioabsorbable, monofilament**-A single-strand (monofilament), synthetic thread made from a non-bioabsorbable polyester (e.g., polybutester) intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application.

3.2.9. **Polyolefin/fluoropolymer suture, monofilament** -A single-strand (monofilament), synthetic, non-bioabsorbable thread made of a polyolefin (e.g., polypropylene, polyethylene) or fluoropolymer (e.g., polytetrafluoroethylene, polyvinylidene fluoride) intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application.

3.2.10. **Polyolefin/fluoropolymer suture, multifilament -** A multiple-strand (multifilament), synthetic, non-bioabsorbable thread made of a polyolefin (e.g., polypropylene, polyethylene) or fluoropolymer (e.g., polytetrafluoroethylene, polyvinylidene fluoride) intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application**.**

3.2.11. **Silicone suture** A single-strand (monofilament), synthetic, non-bioabsorbable thread made of silicone intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching, or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application.

3.2.12. **Silk suture** -A natural, non-bioabsorbable thread made from raw silk spun by silkworms (typically coated with beeswax or silicone) intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application.

3.2.13. **Pacing lead Suture** -A flexible wire with an electrode, insulated with non-conductive material except at its ends, that serves as an electrical conductor between the heart and an external temporary pacing/defibrillation device used to treat postoperative cardiac arrhythmias/cardiac arrests. The electrode end is attached to the myocardium. The other end initially is typically attached to a removable needle used to perforate the chest wall from the inside out, after which it is connected to a pulse generator, typically via an adaptor.

3.2.14. **Surgical Tape** -A band or cord intended to be used during surgery for the approximation, cerclage, fixation, retraction, ligation, and/or suspension of internal anatomical structures; some types may be used for connecting and supporting bone and/or ligaments and tendons. The device is typically made of a synthetic material (e.g., polyester, nylon, silicone) or cotton, is available in a variety of lengths and widths, and may be left in situ. This is a device that cannot be chemically degraded or absorbed via natural body processes.

3.2.15. Products in this lot must meet the above and the following points:

3.2.16. Are flexible strands that may be either monofilament or multifilament in structure and that will not be absorbed by a living mammal. Sterile needles are usually a part of the construction of the suture systems, but it is possible for sutures to be non-needled.

3.2.17. A multifilament strand is used the individual filaments are a combination of spinning weaving braiding of the suture material or combination.

3.2.18. Product can be treated to resist absorption to provide longer wound support.

3.2.19. Additives can be used to give colour to the filament/s.

3.2.20. All suture products must be sterile and individually wrapped in a pack designed to ensure that sterility is maintained until the packing is open in the clinical area.

3.2.21. The suture length, when strand is laid out flat and is without tension, must not be less than 95% of the length stated on the label.

3.3. **Sterile Absorbable Sutures**

3.3.1. **Barbed polyester suture, antimicrobial** - A single-strand (monofilament), synthetic, bioabsorbable thread made from a polyester i.e. Polidioxanone, Polyglicolide, and containing an agent to locally inhibit bacterial growth, intended to approximate the edges of a soft-tissue wound or incision by stitching. It is designed with barbs along its length intended to facilitate tissue approximation by adding tension, a fixation feature (e.g., tab, loop, bidirectional barbs) intended to eliminate the need to tie a knot, and may include disposable suture application devices [e.g., needle, passer].

3.3.2. **Barbed polyester suture, non-antimicrobial** - A single-strand (monofilament), synthetic, bioabsorbable thread made from a polyester i.e. Polidioxanone, Polyglicolide intended to approximate the edges of a soft-tissue wound or incision by stitching. It is designed with barbs along its length intended to facilitate tissue approximation by adding tension, a fixation feature (e.g., tab, loop, bidirectional barbs) intended to eliminate the need to tie a knot, and may include disposable suture application devices [e.g., needle, passer]

3.3.3. **Collagen-polymer suture** - A multiple-strand (multifilament) thread made from strands of both a natural, bioabsorbable collagen derived from animals (e.g., sheep or bovine intestines) and non-bioabsorbable polymer [e.g., polyethylene (PE)], intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues (includes use in orthopaedic surgeries).

3.3.4. **Composite-polymer suture** - A multiple-strand (multifilament), synthetic thread made from strands of both a bioabsorbable polyester polymer (e.g., polydioxanone) and non-bioabsorbable polymer [e.g., polyethylene (PE)], intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues (includes use in orthopaedic surgeries). It is coated with a copolymer and may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application.

3.3.5. **Nylon suture, bioabsorbable, antimicrobial** - A multiple-strand (multifilament), synthetic, bioabsorbable thread made of modified nylon (a polyamide polymer) and containing an agent to locally inhibit bacterial growth, intended to join (i.e., approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application

3.3.6. **Polyester suture, bioabsorbable, monofilament, antimicrobial** - A single-strand (monofilament), synthetic, bioabsorbable thread made from a polyester and containing an agent to locally inhibit bacterial

growth, intended to join (approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues.

3.3.7. **Polyester suture, bioabsorbable, monofilament, non-antimicrobial** - A single-strand (monofilament), synthetic, bioabsorbable thread made from a polyester (e.g., polydioxanone, poliglecaprone, polycaprolactone, polyglyconate, polyhydroxybutyrate) intended to join (approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues.

3.3.8. **Polyester suture, bioabsorbable, multifilament, antimicrobial** - A multiple-strand (multifilament), synthetic, bioabsorbable thread made from a polyester and containing an agent to locally inhibit bacterial growth, intended to join (approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues. The thread provides extended temporary wound support, until the wound sufficiently heals to withstand normal stress, and is subsequently absorbed by hydrolysis; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application. It is not a barbed suture.

3.3.9. **Polyester suture, bioabsorbable, multifilament, non-antimicrobial** - A multiple-strand (multifilament), synthetic, bioabsorbable thread made from a polyester [e.g., polyglycolic acid, polyglactin] intended to join (approximate) the edges of a soft-tissue wound or incision by stitching or to ligate soft tissues. The thread provides extended temporary wound support, until the wound sufficiently heals to withstand normal stress, and is subsequently absorbed by hydrolysis; it may include an attached disposable device(s) [e.g., needle, passer] intended to facilitate suture application. It is not a barbed suture and does not include antimicrobial agents/materials.

3.3.10. Products in this lot must meet the above and the following points:

3.3.11. A range of materials / products including but not limited to:
- 3.3.11.1. Synthetic Absorbable Sutures
- 3.3.11.2. Natural Absorbable Sutures
- 3.3.11.3. Braided / non-braided
- 3.3.11.4. Monofilament / Braided / Knotless systems/ Barbed systems
- 3.3.11.5. Non-needled sutures
- 3.3.11.6. Suture sets
- 3.3.11.7. Antibacterial sutures
- 3.3.11.8. Needle shapes (Point type)
- 3.3.11.9. Needle curvatures
- 3.3.11.10. Ligatures
- 3.3.11.11. Endo ligatures
- 3.3.11.12. Stainless steel
- 3.3.11.13. Chrome alloys
- 3.3.11.14. Vessel loops

3.3.12. Are flexible strands prepared from synthetic polymers that may be in either monofilament or multifilament form and are capable of being absorbed by a living mammal. Sterile needles are usually a part of the construction of the suture system, but it is possible for sutures to be non-needled.

3.3.13. Where a multifilament strand is used the individual filaments are a combination of spinning weaving braiding of the suture material or combination.

3.3.14. Product can be treated to resist absorption to provide longer wound support.

3.3.15. Additives can be used to give colour to the filament/s.

3.3.16. All suture products must be sterile and individually wrapped in a pack designed to ensure that sterility is maintained until the packing is open in the clinical area.

3.3.17. The suture length, when strand is laid out flat and is without tension, must not be less than 95% of the length stated on the label.

3.3.18. **Needles Types and Shapes –** All needles (unless otherwise stated) are integrated into the construction of the sterile suture system. A full range of needle types and shapes including but not limited to:

3.3.19. **Needle Types**

- Conventional Cutting
- Taper Point
- Precision point
- Blunt needles
- Coloured Needles
- Ski needles
- Reverse Cutting
- Taper Cutting
- Micro needles cutting/spatula
- Spatula needles
- Specialist Needles Cosmetic / Ophthalmic /Cardiac

3.3.20. **Needle Shapes**

- 1/4 Circle
- 1/2 Circle
- Straight
- J needle
- 3/8 Circle
- 5/8 Circle
- 1/8 Circle

- Straight 1/2 Curved
- Straight cutting

3.3.21. Needle Sizing in Millimetres (mm) including but not limited to between 0.1m to 100mm.

3.3.22. Needle Material Types suture needles manufacture from, including but not limited to, stainless-steel, stainless-steel alloys, AISI 420 Stainless Steel & AISI 302 Stainless Steel, 455 stainless steel, 300 Stainless Steel, Nickel, Titanium Chromium Alloy Grades, Tungsten Rhenium Alloys

3.3.23. Thread Lengths in Centimetres (cm) including but not limited to between 5cm to 100cm.

3.3.24. Thread Material Types for thread material construction either braided or monofilament coloured/non-coloured, including, but not limited to:

- Stainless Steel
- Polyglactin 910 coated/uncoated
- Surgical Gut / plain/chromic
- Polyester
- Nylon fibre suture
- Natural Silk
- Polydioxanone
- Poliglecaprone
- Hexafluoropropylene
- Nylon
- Polyester fibre suture
- Polypropylene

3.3.25. Size: Suture Size which is currently designated by the metric size gauge number and within the corresponding USP (Untied States Pharmacopeia) or EP (European Pharmacopeia) BP (British Pharmacopeia) primary standards

- Length of the suture
- Type of Suture
- Material Type
- Number of Strands
- Number of Needles
- Batch/Lot number and name of manufacture or distributor.

3.3.26. Evidence of compliance to the below must be provided on request.

- Laboratory Thread Breakage strength tests across all suture ranges
- Laboratory Needle Strength Breakage strength tests across all suture ranges
- Laboratory Needle penetration tests
- Laboratory Needle detachment tests

3.4. **Haemostats -** Haemostatic products (woven / non-woven / re-absorbable gelatine) are used to effectively control bleeding, especially when the body's normal clotting responses are insufficient to accomplish satisfactory haemostasis (i.e., the reduction or stoppage of blood flow etc.). This is achieved through the assessment of need which will either correct or reduce a medical condition and may prevent deterioration of medical conditions. Various materials including but not limited.

3.4.1. **Bone haemostatic agent** - A sterile, implantable, bioabsorbable material consisting primarily of polysaccharides intended to facilitate haemostasis exclusively in bone. It is typically in the form of a flat sheet comprised of polysaccharide fibres (e.g. poly-N-acetyl glucosamine) intended to be applied directly to the bone surface. It may be used as an alternative to bone wax. Disposable devices dedicated to implantation may be included.

3.4.2. **Bone wax, natural** - An implantable device in the form of a sterile wax-like, putty-like, or paste material designed to stop bone bleeding by the creation of a physical barrier along the edges of bone that has been damaged by trauma or cut during a surgical procedure. When placed on the bone under moderate pressure it plugs the vascular openings in the bone and prevents further bleeding. It is made from natural purified beeswax (a yellowish or dark-brown wax secreted by honeybees for constructing honeycombs).

3.4.3. **Bone wax, synthetic -** A sterile, implantable device in the form of a sterile wax-like, putty-like, or paste material designed to stop bone bleeding by the creation of a physical barrier along the edges of bone that has been damaged by trauma or cut during a surgical procedure. When placed on the bone under moderate pressure it plugs the vascular openings in the bone and prevents further bleeding. It is typically made from biocompatible/bioabsorbable synthetic substances (e.g., water-soluble copolymers); its stickiness may be increased by warming and by additional handling and manipulation.

3.4.4. **Chitosan haemostatic agent, professional** - A non-bioabsorbable device that includes chitosan (a polysaccharide derived from chitin, the structural element in the exoskeleton of crustaceans) as a principal component, intended to be applied exclusively by healthcare professionals in a clinical setting to traumatic wounds in emergency situations (e.g., road accidents, combat, emergency rescue) or during surgical intervention to produce a rapid haemostasis by forming a robust plug of gel which is removed after use. The chitosan may be intended to provide antibacterial activity and is available in a variety of forms (e.g., fine particles in a pouch, coated on gauze).

3.4.5. **Collagen haemostatic agent, antimicrobial** - A bioabsorbable, implantable device derived from animal collagen (e.g., equine collagen),

and containing an antimicrobial agent, that is intended to be applied directly to a wound during surgery to facilitate local haemostasis primarily in body cavities at high-risk of infection (e.g., sacral cavity after rectum amputation). It produces haemostasis primarily through activation of platelets. The device is typically available in the form of a pad/sponge intended to remain in the wound to be absorbed by the body; it may be applied in combination with fibrin adhesives.

3.4.6. **Collagen haemostatic agent, non-antimicrobial** - A bioabsorbable device derived from animal collagen (e.g., bovine, or porcine collagen) designed to produce a rapid haemostasis through platelet activation/aggregation (which initiates the haemostatic cascade leading to a fibrin clot) during a surgical procedure. It is applied directly to the wound where it remains to be absorbed by the body; it is not dedicated to a specific anatomy/application and does not contain an antimicrobial agent. It may be supplied as a fibrillar or soft, pliable pad/sponge or loose fibres; it may be applied in combination with fibrin adhesives.

3.4.7. **Fatty acid haemostatic agent** - A non-bioabsorbable device primarily comprised of animal-derived fatty acids intended for external application to a bleeding cutaneous and/or mucosal wound to facilitate local haemostasis by creating a physical barrier to bleeding. It typically consists of an ointment supplied in a tube and does not contain an antimicrobial agent. It is intended for use in the home or healthcare facility.

3.4.8. **Gelatin haemostatic agent** - A sterile, bioabsorbable device derived from animal gelatin (typically pork skin gelatin) that is intended to be applied to surgical and traumatic wounds to facilitate local haemostasis through its high blood-absorbing capacity; it does not contain an antimicrobial agent. It is typically in the form of a pad/sponge and has no intrinsic haemostatic action but induces haemostasis through its intensely porous structure which enables it to absorb many times its weight in blood; the device is intended to remain in the wound to be absorbed by the body.

3.4.9. **Gelatin/inorganic composite haemostatic agent** - A bioabsorbable device made of animal gelatin (typically pork skin gelatin) and synthetic polymer materials that is intended to be applied to surgical and traumatic wounds to facilitate local haemostasis through its tamponade effect and formation of a mechanical barrier; it does not contain an antimicrobial agent. It is typically in the form of a pad/sponge/patch and has no intrinsic haemostatic action but induces haemostasis by facilitating the coagulation process by creating a matrix for platelet aggregation and fibrin formation; the device is intended to remain in the wound to be absorbed by the body.

3.4.10. **Non-organic haemostatic agent** - A non-bioabsorbable device made of mineral and/or synthetic polymer components (e.g., smectite, potassium ferrate/hydrophilic polymer) intended for application to a bleeding external epithelial wound [i.e., skin wound or gastrointestinal (GI) mucosa wound] to facilitate local haemostasis through formation of a sealant and/or clot acceleration; it might additionally be intended to absorb bodily fluids. It is available in various forms (e.g., powder, gel, impregnated gauze) intended to be applied directly or endoscopically to the wound temporarily; it does not contain an antimicrobial agent. Disposable manual or electronic devices for application may be included.

3.4.11. **Plant polysaccharide haemostatic agent, bioabsorbable** - A bioabsorbable device derived from plant polysaccharides (e.g., starch, agar derivative, cellulose-derived) intended for topical application to a traumatic wound (e.g., abrasion, laceration, cut), ulcer, and/or surgical wound to facilitate local haemostasis; it is not dedicated to bone haemostasis. It is available in various forms (e.g., liquid, spray, foam, particles, foam pad/sponge, bandage strip, gauze pad) that can be applied directly to the wound where it remains to be absorbed by the body; it does not contain an antimicrobial agent. It may be used in combination with supplemental agents (e.g., vitamin K-dependent coagulation factors).

3.4.12. **Plant polysaccharide haemostatic agent, non-bioabsorbable, antimicrobial** - A non-bioabsorbable device derived from plant polysaccharides [e.g., micro-dispersed oxidized cellulose (M-Doc), oxidized regenerated cellulose (ORC)] that contains an antimicrobial agent to help prevent infection, intended for topical application to a traumatic wound (e.g., abrasion, laceration, cut), ulcer, and/or surgical wound, to facilitate local haemostasis. It is available in various forms (e.g., gel, spray, ointment) that can be applied directly to the wound where it forms a seal until removed.

3.4.13. **Plant polysaccharide haemostatic agent, non-bioabsorbable, non-antimicrobial** - A non-bioabsorbable device derived from plant polysaccharides [e.g., micro-dispersed oxidized cellulose (M-Doc), oxidized regenerated cellulose (ORC), calcium alginate] intended for topical application to a traumatic wound (e.g., abrasion, laceration, cut), ulcer, and/or surgical wound, to facilitate local haemostasis; it does not contain an antimicrobial agent. It is available in various forms (e.g., gel, spray, powder, ointment, plaster/gauze pad, fibre/wool) that can be applied directly to the wound where it forms a seal until removed. The device is intended for use in the home or healthcare facility.

3.4.14. **Plant polysaccharide/inorganic composite haemostatic agent** - A bioabsorbable device consisting of a combination of both: 1) plant polysaccharide-based; and 2) inorganic (i.e., not derived from living matter) synthetic polymer-based [e.g., polyethylene glycol (PEG)]

haemostatic agents, intended to be used to achieve haemostasis during an open and/or endoscopic surgical procedure. It is available in various forms (e.g., powder, gel, impregnated gauze); it does not contain an antimicrobial agent. Disposable devices to assist application may also be included.

3.4.15. **Surgical haemostatic agent/anti-adhesion material** - A bioabsorbable membrane comprised of polysaccharides [at least one animal-derived (e.g., chitin)] intended to be topically applied to superficial surgical wounds or optionally implanted around internal surgical wounds to facilitate local haemostasis, and to function internally as a barrier to reduce the incidence of adhesions between adjacent anatomical structures. It is in the form of a paper-like membrane applied directly to the wound where it takes the form of a gel upon wound adherence and eventually biodegrades; neither antimicrobials nor pharmaceuticals are included.

3.4.16. **Synthetic peptide haemostatic agent** -A sterile, bioabsorbable device containing synthetic peptides intended to be applied to a surgical site to rapidly facilitate local haemostasis primarily through formation of a peptide hydrogel; it does not contain an antimicrobial agent. It is typically available as an aqueous solution (e.g., prefilled syringe) that can be applied directly to the wound where it remains to be absorbed by the body.

3.4.17. **Thrombin haemostatic agent, antimicrobial**-A non-bioabsorbable device containing human/animal-derived thrombin and an antimicrobial agent (e.g., silver) intended to be used by a healthcare professional for topical application to a surgical wound (e.g., during percutaneous vascular access), to facilitate local haemostasis primarily through thrombin activation of blood clotting mechanisms. It is typically available in the form of bandage, pad, sponge, flowable and or flowable with applicator that can be applied directly to the wound.

3.4.18. **Thrombin haemostatic agent, non-antimicrobial**-A non-bioabsorbable device containing human/animal-derived thrombin, without an antimicrobial agent, intended to be used by a healthcare professional for topical application to a surgical wound (e.g., during percutaneous vascular access), to facilitate local haemostasis primarily through thrombin activation of blood clotting mechanisms. It is typically available in the form of bandage, pad, sponge, flowable and or flowable with applicator that can be applied directly to the wound.

3.4.19. **Fibrin sealant biochemical preparation/application kit, open surgery**- A collection of sterile devices designed to be used for the biochemical preparation and subsequent delivery of autologous fibrin sealant to a site of intervention during open surgery (e.g., to achieve haemostasis, seal air leaks, adhere tissues). It typically consists of a

dedicated preparation unit (a cassette) with a collection of application devices including a spraypen applicator, needle, and tubing. Patient blood is contained within the preparation unit which is placed in a production unit (processor) which controls the biochemical processes and centrifugation to produce the fibrin sealant.

3.4.20. **Fibrin sealant biochemical preparation/application kit, endoscopic**-A collection of sterile devices designed to be used for the biochemical preparation and subsequent delivery of autologous fibrin sealant to a site of intervention during an endoscopic surgical procedure (e.g., to achieve haemostasis, seal air leaks, adhere tissues). It typically consists of a dedicated preparation unit (a cassette) with a collection of application devices including an endoscopic applicator, needle, and tubing. Patient blood is contained within the preparation unit which is placed in a production unit (processor) which controls the biochemical processes and centrifugation to produce the fibrin sealant.

3.4.21. Surgical adhesive/sealant, synthetic polymer - A biodegradable synthetic polymer material [e.g., cyanoacrylate, poly glycerol sebacate arylate (PGSA)] , bioabsorbable substance containing animal-derived material and [e.g., bovine serum albumin (BSA)/cross-linking agent] intended to be used for internal surgical applications to bond a wide range of tissue types (e.g., bowel, liver, lung, vascular, urological) and might in addition be intended to achieve haemostasis through tissue sealing. It is applied using a disposable applicator (which may be included) and is intended to be fast-setting (self- or light-induced) to form a thin elastic film.

3.4.22. Products in this lot must meet the above and the following points:

3.4.22.1. Where applicable Haemostat product must be provided sterile, including their contents, and must conform to the appropriate UK sterilisation standards. Haemostat products must clearly be labelled, with either wording or symbols, as sterile.

3.5. **Tissue / Skin Adhesives** are substances that, when applied to skin, undergo polymerisation to form a superficial film that enables tissue beneath the surface to be approximated together.

3.5.1. **Dura mater sealant** - An implanted bioabsorbable material (e.g., solution, gel, spray, patch, adhesive) intended to be applied to a defect in the dura mater, possibly as an adjunct to standard methods of closure (e.g., suturing), to prevent cerebrospinal fluid (CSF) leakage during healing. The material consists of either synthetic polymers or animal derived materials that subsequently form adhesive bonds with the dura mater and eventually degrade and are absorbed.

3.5.2. **Skin-approximation adhesive** - A sterile biodegradable glue made of synthetic polymer (e.g., cyanoacrylate) intended for topical closure of surgical incisions and simple traumatic lacerations that have easily approximated skin edges; it is not intended for internal surgical applications.

3.5.3. **Surgical internal adhesive/sealant, animal-derived** - A bioabsorbable substance containing animal-derived material [e.g., bovine serum albumin (BSA)/cross-linking agent] intended to be used for internal surgical applications to bond or seal cut, incised, or resected body tissues (e.g., for vascular anastomosis) typically as an adjunct to standard methods of closure, to seal leaks, and might in addition be intended to achieve haemostasis through tissue sealing. Disposable mixing devices/applicators may be included for preparation and application to anatomical sites.

3.5.4. **Surgical internal adhesive/sealant, human-derived** - A bioabsorbable substance containing human-derived material [e.g., human serum albumin (HSA)] intended to be used for internal surgical applications to bond or seal cut, incised, or resected body tissues typically as an adjunct to standard methods of closure, to seal leaks, and might in addition be intended to achieve haemostasis through tissue sealing. Disposable mixing devices/applicators may be included for preparation and application to anatomical sites.

3.5.5. **Surgical internal adhesive/sealant, microbe-derived** - A bioabsorbable substance containing microbe-derived material [e.g., recombinant human albumin (rHA)] intended to be used for internal surgical applications to bond or seal cut, incised, or resected body tissues typically as an adjunct to standard methods of closure, to seal leaks, and might in addition be intended to achieve haemostasis through tissue sealing. Disposable mixing devices/applicators may be included for preparation and application to anatomical sites

3.5.6. **Surgical internal adhesive/sealant, synthetic polymer** -A biodegradable synthetic polymer material [e.g., cyanoacrylate, poly glycerol sebacate arylate (PGSA)] intended to be used for internal surgical applications to bond a wide range of tissue types (e.g., bowel, liver, lung, vascular, urological) and might in addition be intended to achieve haemostasis through tissue sealing. It is applied using a disposable applicator (which may be included) and is intended to be fast-setting (self- or light-induced) to form a thin elastic film.

3.5.7. **Wound Closure Set Topical** - A collection of sterile devices used to topically close easily approximated skin edges of wounds. It typically includes a pressure-sensitive adhesive tape or mesh and a liquid adhesive, each contained within a dispensing applicator. The tape/mesh is first applied to temporarily approximate the skin edges followed by

application of the liquid adhesive, over the tape/mesh, which polymerizes to affect wound closure. This set may be used to treat surgical incisions, simple lacerations, and may also be used in conjunction with deep dermal stitches.

3.5.8. **Surgical Skin Microbial Sealant** - A sterile synthetic substance (e.g., cyanoacrylate) intended to be applied to the skin of a patient prior to surgical incision (typically over commonly used preoperative skin preparation and with or without standard surgical draping) to, upon polymerization, bond to the skin and fix microbes, reducing the risk of skin flora contamination during the surgical procedure. It is typically contained within a disposable, ready-to-use applicator.

3.5.9. Where applicable **3.6.1 to 3.6.8** must be flowable and or flowable with applicator

3.5.10. Products in this lot must meet the above and the following points:

3.5.10.1. A range of products with various properties including but not limited to:
3.5.10.1.1. Quick set times
3.5.10.1.2. Medium set times
3.5.10.1.3. Slow set times
3.5.10.1.4. Suitable for various skin types
3.5.10.1.5. Various types of applicators (Shapes)
3.5.10.1.6. High viscosities
3.5.10.1.7. Low
3.5.10.1.8. Anti-microbial
3.5.10.1.9. Flow rate control.
3.5.10.1.10. Single use

3.5.11. Products must be manufactured from medical grade adhesive including but not limited to butyl cyanoacrylate or octyl blend cyanoacrylate or monomeric n-butyl-2-cyanoacrylate. Also, it must clearly indicate the intended use of the tissue or skin adhesives for example for minor injuries use in Emergency Departments or Theatre Departments etc.

3.6. **External Skin Staplers and Staple Removers** – Surgical staples are specialized staples used in surgery in place of sutures to approximate wounds edges together. Skin Staple Removers are a single-use devices for removing skin staples from wound after they have healed and are not designed to cause any further trauma to the wound surface.

3.6.1. **Circumcision stapler/staple -** A sterile, hand-held, manual surgical instrument preloaded with non-bioabsorbable skin staples intended to be used to perform a circumcision. It is designed to cut the foreskin and apply a circular row(s) of staples proximal to the cut line. The stapler

portion typically consists of a dome intended to be inserted under the foreskin over the glans penis, and a circular cutting stapler mechanism with a manual lever intended to connect over the outside of the foreskin.

3.6.2. **Nasal septum stapler/staple** - A hand-held manual surgical instrument, preloaded with bioabsorbable preformed staples, designed to apply the staples across the nasal septum to close flaps and the separation of the septal layers during septoplasty. The staples are made of material(s) that are gradually degraded and absorbed by the body (typically biodegradable polymer).

3.6.3. **Skin staple** - A non-bioabsorbable, adjustable, U-shaped metallic device intended to be used to approximate the edges of a skin wound; it is not intended to be applied to internal tissues. It is typically provided in multiples in a single use loading unit (SULU) designed to be loaded into a skin stapler (not included).

3.6.4. **Skin stapler/staple, bioabsorbable** - A hand-held manual surgical instrument, preloaded with bioabsorbable skin staples, designed to apply the staples to approximate the free skin edges of an incision or wound. The staples (which may be clip-like) are made of material(s) that are gradually degraded and absorbed by the body (typically biodegradable polymer).

3.6.5. **Skin stapler/staple, non-bioabsorbable** - A hand-held manual, surgical instrument preloaded with non-bioabsorbable skin staples designed to apply the staples to approximate the free skin edges of an incision or wound. The staples (which may be clip-like) are made of metal [e.g., stainless steel or titanium (Ti)] and intended to be removed once the wound has sufficiently healed.

3.6.6. **Surgical staple loading unit, cutting** - A unit containing non-bioabsorbable surgical staples (implantable and typically U-shaped lengths of wire made of implant grade metal) and an internal cutting blade designed to be used with a surgical stapler (not included) during endoscopic or open-surgery (e.g., bowel resection to create anastomoses). The unit is designed to deploy the staples (e.g., in a straight or circular row) while the blade cuts the adjacent tissue.

3.6.7. **Surgical staple loading unit, non-cutting** - A unit containing non-bioabsorbable surgical staples (implantable and typically U-shaped lengths of wire made of implant grade metal) designed to be used with a surgical stapler (not included) to mechanically fasten internal tissues together (e.g., the subcuticular closure of skin or the approximation of the ends of bowel) to facilitate healing typically in abdominal, thoracic, gynaecologic, orthopaedic, or plastic and reconstructive surgery. The unit is designed to deploy the staples in multiples (e.g., as a row of staples) and is often referred to as a single use loading unit (SULU) or reload.

3.6.8. **Skin staple remover** -A hand-held manual surgical instrument intended to be used to remove skin staples after the healing process has progressed sufficiently to permit the borders of the wound or incision to remain together without assistance. It is a tweezers-like device made of metallic or synthetic polymer materials with blades at the distal end activated by lever action designed for grasping, opening, and removing surgical staples.

3.6.9. Products in this lot must meet the above and the following points:

3.6.9.1. A range of products with various properties including but not limited to:

3.6.9.1.1. Single use stapling systems
3.6.9.1.2. Multi use stapling systems
3.6.9.1.3. Single / multi use Fascia stapling systems
3.6.9.1.4. Loading units
3.6.9.1.5. Staple extractor/remover systems
3.6.9.1.6. Fixed Head Staples
3.6.9.1.7. Rotating Head
3.6.9.1.8. Various types of staples e.g. stainless steel, titanium etc.
3.6.9.1.9. Various number of staples that can be delivered by associated devices.

3.6.10. full range of stapler and staple sizes (Crown & length etc.).

3.6.11. The stapler must be disposable and single use.

3.6.12. Each stapler must be sterile, and the packing must maintain its sterility until it is opened.

3.6.13. Staplers can either be constructed in plastic or steel and must be designed for one handed operation.

3.6.14. All stapler systems must be preloaded with either staples that non-absorbable or absorbable. Constructed from stainless steel, titanium, or biological materials.

3.6.15. All products must be designed to ensure visibility of wound.

3.6.16. Staplers must have a pre-fire mechanism.

3.6.17. Staplers must have quick release mechanism.

3.6.18. All stapler handles must return to the resting position when discharged.

3.6.19. All product packaging must display number of staples within the stapler product.

3.6.20. Staplers must be presented in either regular 4.00mm>6.00mm or wide versions 6.01mm>8.00mm sizes.

3.6.21. All staplers must be suitable for all patient in all age groups.

3.7. **Wound Closure Strips** are of a porous, non-woven materials with a backing coated with a pressure-sensitive, hypoallergenic adhesive and reinforced with polyester filaments for added strength. They provide general wound support for increased tensile strength and finer wound edge approximation.

3.7.1. **Butterfly skin-closure adhesive strip** - A small, narrow piece of flexible material covered on one side with a pressure-sensitive adhesive, and with broad, wing-shaped ends that function to approximate the edges of a superficial wound. The device may be hypoallergenic and/or waterproof.

3.7.2. **Skin-closure adhesive strip -** A small, narrow flexible band (of fabric, plastic, paper, or other material) coated on one side with a pressure-sensitive adhesive, used to approximate the edges of superficial wounds. The device may be hypoallergenic and/or waterproof.

3.7.3. **Skin-cover adhesive strip, antimicrobial** - A small, narrow, flexible band (of fabric, plastic, paper, or other material) intended to cover a superficial wound, that is coated on one side with a pressure-sensitive adhesive and that has an absorbent pad prefilled (soaked) with an antiseptic to inhibit the growth of microorganisms. It may also be hypoallergenic and/or waterproof. Commonly referred to as a sticking plaster, it is intended for use in the home or a clinical setting. Must be a single-use device.

3.7.4. **Skin-cover adhesive strip, non-antimicrobial** - A small, narrow, flexible band (of fabric, plastic, paper, or other material) coated on one side with a pressure-sensitive adhesive and possibly with an absorbent pad, typically intended to cover a superficial wound or fix a dressing to skin. It may be hypoallergenic and/or waterproof; however it does not include antimicrobial agents/properties. Commonly referred to as a sticking plaster, it is intended for use in the home or a clinical setting.

3.7.5. Products in this lot must meet the above and the following points:

3.7.5.1. The product must be provided in a sterile packaging.
3.7.5.2. They must be supplied on a backing card which holds the product prior to clinical use.

3.7.5.3. Each wound closure strip system must be supplied sterile and be wrapped in a packet designed to maintain sterility until the package is opened.

3.7.5.4. The packaging must clearly identify the number of wound closure strips and the dimensions of each individual strip.

3.7.5.5. Wound Closure Strip of various sizes:

3.7.6. Wound closure strips must detach cleanly from their backing system without compromising their adhesiveness.

3.7.7. All wound closure strips must have the ability to effectively secure a wound by approximating the edges without causing further trauma to the wound.

3.7.8. Wound Closure Strips must have consistent adhesion strength and must be constant across the product range.

3.7.9. Product adhesive of wound closure strips must not cause irritation to patients' skin, and it must be clearly detail in what circumstance that wound closure strips cannot be used in the clinical environment.

5(b) Tender Response Document

Non-Financial Questions (Technical Envelope)
See Attachment 1a

Awarded Lines
See Attachment 1b

Awarded Additional Lines
See Attachment 1c

Discounts & Savings
See Attachment 1d

Schedule 6

Commercial Schedule

Part 1

1. The Parties acknowledge that the Contract Price is the basis upon which the Framework Agreement is awarded and unless amended in accordance with this Schedule 6 and/or Schedule 7 (as the case may be) the Contract Price shall remain fixed during the Term. For the avoidance of doubt the Supplier shall not be entitled to unilaterally adjust the Contract Price.

2. Management Fee – The Management Fee does not apply to all Orders for Goods placed pursuant to this Agreement in accordance with Clause 9 of Schedule 2.

3. During the Term of the Framework Agreement each Party may approach the other to discuss special offers, discounts, value added offerings and commitment or bulk buy deals. Neither Party shall be obliged to accept any offer made by the other.

4. The Supplier agrees to work with NHS Supply Chain during the Term of the Framework Agreement to identify cost saving opportunities, including the way in which Goods are sourced, supplied, ordered and packaged, which can be reflected in a more competitive Contract Price.

5. If the Supplier requests an increase to the Contract Price it must provide justification to NHS Supply Chain for such increase and NHS Supply Chain may in its absolute discretion consent to such increase.

6. To drive greater transparency and stability in contract pricing NHS Supply Chain reserves the right to review various cost price mechanisms throughout the Term of the Framework Agreement. In the event that there is a fluctuation in commodity costs used in the production of related finished goods that could impact the contracted price, NHS Supply Chain reserves the right to review the Contract Price in conjunction with the Supplier if evidenced through a commodity index tracker mechanism agreed with both parties.

7. Once a price variation has been agreed by both Parties pursuant to this Schedule 6 the new Contract Price shall take effect on the date agreed by the Parties in writing.

Part 2

1. Additional and Associated Goods and Services

1.1. Without limitation to the provisions of Clause 22.1 of Schedule 2, the Supplier acknowledges to NHS Supply Chain that over the Term, additional goods and services may be made available for purchase under the Framework Agreement. Such additional goods and services may also include the provision of associated goods, materials or items associated with those additional goods and services (which together shall be “the Additional and Associated Goods and Services”).

1.2. Additional and Associated Goods and Services to NHS Supply Chain will be made available for purchase under the Framework Agreement at the sole discretion of NHS Supply Chain. In order to determine whether the Additional and Associated Goods

and Services will be made available for purchase under the Framework Agreement NHS Supply Chain shall consider a number of different factors, including (but not limited to) whether the proposed Additional Solutions and Associated Goods are deemed to be within scope of the procurement exercise under which the Framework Agreement was awarded.

1.3. The Supplier acknowledges and agrees that, to the extent relevant, any Additional and Associated Goods and Services must comply with the standards set out in the Specification and the Tender Response Document.

1.4. Without prejudice to any of the other provisions set out in Schedule 2, NHS Supply Chain reserves the right to undertake at its absolute discretion a review of the Goods and Services which are supplied under the Framework Agreement. Following such review, NHS Supply Chain may change supply routes for any of the Goods and Services and/or remove certain Goods and Services and/or Additional and Associated Goods and Services from the Framework Agreement.

2. Price Saving Initiatives

2.1. NHS Supply Chain reserves the right to share savings information in order to assist Authorities with making informed procurement decisions.

2.2. Such savings initiatives shall include (but shall not be limited to):

2.2.1. The publication of price ranking sheets showing the Supplier's ranking as to price for a particular Good(s);

2.2.2. Data arising from the Compare and Save Programme;

2.2.3. Re-opening of competition in accordance with Schedule 7 for the supply of certain Goods and/or listing in the NHS Supply Chain Catalogue through a particular route of supply for a specified period of time;

2.3. Notwithstanding the provisions of Schedule 7 NHS Supply Chain recognises that:

2.3.1. the pricing set out in Schedule 5(b) Discounts and Savings may be used where commitment can be gained from an Authority and without reopening competition;

2.3.2. during the lifetime of the Framework Agreement, the Supplier may want to offer additional savings to a Participating Authority (or group of Participating Authorities) through the provision of discounted pricing, value added offerings, commitment, bulk buy initiatives, direct rebates (i.e. payments which are agreed directly between the Supplier and a Participating Authority or groups of Participating Authorities for Orders which are placed under the Framework Agreement) occasional special offers, (for instance in relation to new product introductions) NHS year-end spend and market growth incentives.

2.3.3. NHS Supply Chain may request pricing on behalf of a Participating Authority or group of Participating Authorities in return for commitment by NHS Supply Chain or a Participating Authority or group of Participating Authorities to

purchase an agreed value and/or volume of Goods that may or may not be for an agreed period of time. In these instances NHS Supply Chain may request and agree improved or different terms from those which are set out in the Framework Agreement (and pass these to the Participating Authority or group of Participating Authorities (as the case may be) for their consideration), including terms in relation to the matters set out below:

i. the Contract Price in respect of some or all of the Goods;

ii. the quantity of Goods which shall be ordered and whether the Goods subject to any Order shall be delivered in a single or multiple instalments;

iii. whether the Goods subject to an Order shall be delivered to NHS Supply Chain, or delivered directly to the relevant Participating Authority;

iv. whether the Supplier shall be required to monitor the volume of Goods stored at any Participating Authority's premises and to deliver further Goods in accordance with any instructions agreed with or given by NHS Supply Chain or the relevant Participating Authority;

v. the time at which the Supplier may issue its invoice in respect of any Goods subject to an Order, and whether such invoice shall be paid by NHS Supply Chain or the relevant Participating Authority;

vi. the transfer of risk in and title to any Goods subject to an Order.

3. Compare and Save Programme

3.1. NHS Supply Chain may, during the lifetime of the Framework Agreement, undertake a 'Compare & Save' (or similar) programme aimed at updating an alternative database for goods which have been awarded across this Framework Agreement.

3.2. Alternatives may include both like for like products and products which require a change of practice, training or switch of existing equipment by the Authority but which ultimately offer the same output. There may also be the option for the Supplier to add comments regarding specific information about the product i.e. training required, additional products required, only compatible with a certain machine. Suggested comparable products will be reviewed by NHS Supply Chain before they are made available to an Authority. Where the Supplier updates an alternative with another supplier's product NHS Supply Chain will automatically reverse this so that the other product is also detailed as an alternative.

3.3. In order to ensure this comparable database contains accurate like for like goods, NHS Supply Chain may from time to time request support from the Supplier in order to verify and update the data which is stored on this database.

3.4. The comparable products will be:

3.4.1. Used to suggest alternatives to Authorities in the event of a stock out situation;

3.4.2. Used to record savings from Authorities who are switching products to achieve savings – this information will then be reported to Supply Chain Coordination Limited; and

3.4.3. accessed by NHS Supply Chain staff and shared with Authorities at the Authorities' request.

3.5. Without prejudice to the provisions of paragraph 3.1 above, NHS Supply Chain reserves the right, in order to support Authorities on their savings initiatives, to actively market the information and inform Authorities of the savings opportunities through the Compare and Save programme

4. Supply Chain Simplification

4.1. NHS Supply Chain reserves the right to engage with the Supplier with regard to implementing supply chain simplification initiatives in order to assist in reducing the cost of Goods throughout the lifetime of the Framework Agreement. The supply chain simplification initiatives will aim to remove complexity and cost from the inbound supply chain from the point of manufacture through to delivery to NHS Supply Chain warehouses. Examples of such initiatives include, but are not exclusive to:

4.2. Packaging optimisation (i.e. cubic volume reduction, component elimination, material Specification reduction, etc.);

4.3. Logistics/transport optimisation (i.e. pallet fill increase, vehicle/container fill increase, etc.);

4.4. Direct inbound delivery (i.e. supply of product into NHS Supply Chain Distribution Centres on a containerised basis directly from overseas manufacturing facilities, bypassing UK / EU warehousing).

5. Incoterms

5.1. In addition to the provisions mentioned at paragraph 4 above (Supply Chain Simplification) NHS Supply Chain reserves the right to engage with the Supplier on various Incoterms (as more particularly set out in the ORS) throughout the lifetime of the Framework Agreement.

6. Samples

6.1. From time to time, NHS Supply Chain may request samples of the Goods to be provided to such location (as may be reasonably required by NHS Supply Chain) to a Participating Authority. Such samples shall be provided Free of Charge and may be used to inform a Participating Authority's purchasing decision under the Framework Agreement.

6.2. Without prejudice to the provisions set out in paragraph 6.1 above NHS Supply Chain may (on behalf of the Clinical Evaluation Team ("CET")) request samples to be provided by the Supplier (on a free of charge basis) over the lifetime of the Framework Agreement. Such samples shall be assessed by CET in order to determine whether such Goods shall be included in the reopening of competition in accordance with the terms of this Framework Agreement.

6.3. Where such samples are requested in accordance with paragraph 5.2 above, they must be provided to a “Ward Ready Standard” and which shall mean that such samples shall be provided in the packaging, box and Unit of Issue as a Participating Authority would expect to see at ward level. Failure to provide samples to a Ward Ready Standard or in accordance with the timescales which may reasonably be required by NHS Supply Chain may result in the Supplier being excluded from any reopening of competition in accordance with is held in accordance with the terms of the Framework Agreement.

Schedule 7

Ordering Procedure and Order Form

1. Contracts based on Framework Agreement without amendments

1.1. NHS Supply Chain may elect to purchase Goods and/or Services from such supplier(s) on the Framework Agreement as it may at its discretion choose, on the terms and at the Contract Price as calculated in accordance with Schedule 6.

1.2. As set out at paragraph 1.1 above, NHS Supply Chain may place an Order for Goods and/or Services on the supplier(s) based on the terms of this Framework Agreement, including the Call-off Terms and Conditions for the Supply of Goods, at any time during the Term. Such Order(s) shall form a Contract between the supplier(s) and NHS Supply Chain which shall comprise the following documents:

1.2.1. the Call-off Terms and Conditions for the Supply of Goods;

1.2.2. a completed Order Form;

1.2.3. the applicable parts of the Specification and Tender Response Document set out at Schedule 5 of this Framework Agreement, as may be supplemented by information set out and/or referred to in the Order Form; and

1.2.4. any relevant provisions applicable to the Contract as set out in the Framework Agreement.

2. Contracts based on Framework Agreement with amendments

2.1. Alternatively, where the Tender Response Document in relation to the Framework Agreement has insufficient detail to be able to price up bespoke requirements and award a Contract without further information, NHS Supply Chain may invite either: (i) one capable supplier; or (ii) some capable suppliers; or (iii) all capable suppliers (which in each case may not include the supplier) to submit an offer in relation to (a) a specific requirement of a Participating Authority. NHS Supply Chain reserves the right to reopen competition using any of (1) an eAuction; (2) threshold pricing; and (3) target pricing or other methodologies advised to suppliers.

2.2. Where more than one supplier is invited to submit an offer, the offers shall be evaluated using such criteria as a Participating Authority shall determine (including (i) price only; (ii) quality only; or (iii) a combination of quality and price) and in each case, the terms of the resulting Contract (including the Contract Price and Specification of the relevant Goods) may differ from those set out in the Framework Agreement and Call-Off Terms and Conditions.

2.3. As set out at paragraphs 2.1 - 2.2 above, NHS Supply Chain may at the request of one or more Participating Authorities re-open competition between the supplier(s) referred to at paragraph 2.1 above based on the award criteria referred to at paragraph 2.2 above. Once a competition has been concluded Orders may be placed by NHS Supply Chain under the Call-off Terms and Conditions for the Supply of Goods (as amended in accordance with the competition). A Contract concluded following a re-opening of competition is made up of the following components:

2.3.1. the bespoke requirements referred to in paragraph 2.1 above;

2.3.2. the Call-off Terms and Conditions for the Supply of Goods (as amended in accordance with the competition);

2.3.3. a completed Order Form;

2.3.4. the applicable parts of the Specification and Tender Response Document set out at Schedule 5 of this Framework Agreement, as may be supplemented by information used to conduct the competition; and

2.3.5. any relevant provisions applicable to the Contract as set out in the Framework Agreement.

2.4. For the avoidance of doubt, any competition pursuant to this Framework Agreement shall be carried out by NHS Supply Chain only on behalf of one or more Participating Authorities. No Participating Authority (other than NHS Supply Chain) shall be entitled to carry out a competition under this Framework Agreement without the express consent of NHS Supply Chain.

3. General

In relation to either or both of paragraphs 1 and 2 above, NHS Supply Chain may request pricing on the basis of a commitment by a Participating Authority to purchase a specified volume or value of Goods during an agreed period of time, for which NHS Supply Chain may pay the supplier in advance.

Schedule 8

Service Levels

1. The Supplier agrees to conform to the following KPIs during the Term of this Framework Agreement:

On time Deliveries on time subject to a tolerance of +/- thirty (30) minutes (for the avoidance of doubt, deliveries which arrive on time but are not unloaded due to the driver's decision, deliveries which do not arrive and deliveries which arrive at the wrong delivery location shall also be considered late)	98%
Quantity Quantity of delivery correct against the relevant Order (including deliveries in excess and shortfall of the Order quantity)	98%
Quality Quality of delivery in accordance with the Framework Agreement and Contracts (including delivery presentation in accordance with the Framework Agreement and Contracts (the delivery must be presented in such a way that it can be unloaded safely and in a ready for use condition taking into consideration the Framework Agreement and Contract requirements) and damaged Goods (the Goods must be in a condition that is new and ready to use))	95%
Administration Timely and accurate administration (including booking/amending delivery times and Orders and invoices, delivery advice notes and labels being in accordance with the requirements of the Framework Agreement and Contracts)	99%

2. Any KPI discrepancy attributable to an act or omission of NHS Supply Chain (or another Participating Authority) shall not be used to calculate the Supplier's sub-standard performance level.

3. A service level shall be generated for each of the KPIs in relation all Orders placed on the Supplier within each calendar month during the Term of the Framework Agreement and a monthly average service level for each KPI shall be calculated ("**Monthly Service Level**").

4. The Supplier's performance shall be measured:

   4.1. in relation to Orders placed pursuant to a Non-direct Route of Supply by NHS Supply Chain; and

   4.2. in relation to Orders placed pursuant to a Direct Route of Supply by the Authority and the Supplier.

5. In relation to Orders placed pursuant to a Direct Route of Supply the Supplier shall submit monthly reports to NHS Supply Chain outlining its performance in relation to the KPIs for the preceding month. Such report shall be submitted to NHS Supply Chain not later than the 14th day of the month following the month to which the report relates. NHS Supply Chain may verify the information provided by the Supplier with the Authority and reserves

the right to amend the Supplier's monthly service level report in accordance with the findings of such verification exercise.

6. Should the Monthly Service Level of the Supplier fall below the relevant KPI:

   6.1. on two (2) or more occasions in any six (6) month period in relation to On time and/or Quantity; and

   6.2. on three (3) or more occasions in any six (6) month period in relation to Quality and/or Administration,

   NHS Supply Chain may serve a performance notice on the Supplier. The Supplier shall present to NHS Supply Chain within thirty (30) days of receipt of such performance notice an action plan to improve the Supplier's Monthly Service Level ("**Action Plan**"). The Parties shall, within ten (10) Business Days of NHS Supply Chain receiving the Action Plan meet to discuss and agree the Action Plan. NHS Supply Chain may make reasonable amendments to the Action Plan to improve the Supplier's performance. The Action Plan must include a timetable for improvement of the Supplier's performance to, as a minimum, the level required by Clause 1 of this Schedule 8 in relation to the relevant KPI. Such timetable shall be agreed by the Parties but shall in any event be no longer than six (6) months.

7. In the event that the Supplier:

   7.1. fails to produce an Action Plan in accordance with Clause 6 of this Schedule 8; or

   7.2. fails to improve its Monthly Service Level to the minimum level required by Clause 1 of this Schedule 8 within the timetable set out in the Action Plan in accordance with Clause 6 of this Schedule 8,

   the Supplier shall be considered to have committed a material breach capable of remedy for the purpose of Clause 16.3 of Schedule 2.

8. Notwithstanding Clauses 6 and 7 of this Schedule 8, where the Monthly Service Level in relation to Quantity, Quality or On time of Goods delivered against the relevant Order(s) falls below the relevant KPI, NHS Supply Chain shall (without prejudice to its rights to claim for any other categories of loss arising from such failure to meet the relevant KPI) be entitled to raise a debit note to the Supplier for a sum equal to the loss NHS Supply Chain has incurred or suffered in relation to lost margin and the cost, if any, of purchasing alternative goods and/or services (and any related administrative costs) as a result of the shortfall in ready to use delivery quantity against the relevant Orders. The Parties agree this is a true and fair assessment of loss suffered through lost margin and the cost of purchasing alternative goods and/or services (and any related administrative costs). Where NHS Supply Chain does not elect to raise a debit note in the manor detailed in this paragraph, then it shall remain entitled to claim damages.

9. If the Supplier disputes NHS Supply Chain's Monthly Service Level as applicable to the Supplier, the Supplier shall provide evidence to NHS Supply Chain that the Monthly Service Level is incorrect within seven (7) days of disputing such Monthly Service Level and the Parties shall meet to discuss any necessary amendment to the Monthly Service Level. If the Parties cannot agree the Monthly Service Level the matter shall be referred to the dispute resolution procedure set out in Clause 23 of Schedule 2.

10. For the avoidance of doubt, nothing in this Schedule 8 shall limit in any way either Party's rights and remedies, including the right to claim damages and or termination rights which may arise, under this Framework Agreement or any Contract.

Schedule 9

Call-Off Terms and Conditions for the Supply of Goods

See Attachment 2