

	nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.		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 Contract.
18.6	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.	20.2	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 Contract.
18.7	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.	20.3	The Authority shall have the right to audit the Supplier's compliance with this Contract. The Supplier shall permit or procure permission for the Authority 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 Contract.
18.8	If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, the Authority may at any time if the Force Majeure Event subsists for thirty (30) days or more, terminate this Contract by issuing a Termination Notice to the Supplier.	20.4	Should the Supplier Sub-contract any of its obligations under this Contract, the Authority shall have the right to audit and inspect such third party. The Supplier shall procure permission for the Authority 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 Contract that are Sub-contracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested.
18.9	Following such termination in accordance with Clause 23 of this Schedule 2 and subject to Clause 18.10 of this Schedule 2, neither Party shall have any liability to the other.		
18.10	Any rights and liabilities of either Party which accrued prior to such termination in accordance with Clause 18.8 of this Schedule 2 shall continue in full force and effect unless otherwise specified in this Contract.	20.5	The Supplier shall grant to the Authority or its authorised representative, such access to those records as they may reasonably require in order to check the Supplier's compliance with this Contract for the purposes of:
19. <u>Contacts Data</u>			
19.1	The Parties each acknowledge and agree that they may need to undertake Processing of Personal Data relating to each Party's representatives (in their respective capacities as Controllers) in order to (as appropriate):	20.5.1	the examination and certification of the Authority's accounts; or
(a)	administer and provide the Goods;	20.5.2	any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the Authority has used its resources.
(b)	request and receive the Goods;		
(c)	compile, dispatch and manage the payment of invoices relating to the Goods;	20.6	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 20 of this Schedule 2 does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.
(d)	manage the Agreement and resolve any disputes relating to it;		
(e)	respond and/or raise general queries relating to the Goods; and	20.7	The Supplier shall provide reasonable cooperation to the Authority, 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 Contract.
(f)	comply with their respective regulatory obligations.		
19.2	Processing of Personal Data relating to each Party's representatives for the purposes set out in Clause 19.1 shall only be done by each Party in accordance with their respective privacy policies. The Parties acknowledge that they may be required to share Personal Data with their affiliates, group companies and other relevant parties, within or outside of the country of origin, in order to carry out the activities listed in Clause 19.1, and in doing so each Party will ensure that the sharing and use of this Personal Data complies with applicable Data Protection Laws.	20.8	The Supplier shall provide all reasonable information as may be reasonably requested by the Authority to evidence the Supplier's compliance with the requirements of this Contract.
		21. <u>Equality and human rights</u>	
20. <u>Records retention and rights of audit</u>		21.1	The Supplier shall:
20.1	Subject to any statutory requirement and Clause 20.2 of this Schedule 2, the Supplier shall keep secure and maintain for	21.1.1	ensure that (a) it does not, whether as employer or as supplier of the Goods and any associated 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 any associated 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;		as if such act or omission had been committed or omitted by the Supplier itself.
21.1.2	in the management of its affairs and the development of its equality and diversity policies, cooperate with the Authority in light of the Authority'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 the Authority 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	23.2	Notwithstanding Clause 23.1 of this Schedule 2, the Supplier may assign to a third party ("Assignee") the right to receive payment of any sums due and owing to the Supplier under this Contract for which an invoice has been issued. Any assignment under this Clause 23.2 of this Schedule 2 shall be subject to:
21.1.3	the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 21 of this Schedule 2.	23.2.1	the deduction of any sums in respect of which the Authority exercises its right of recovery under Clause 6.8 of this Schedule 2;
21.2	The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 21 of this Schedule 2.	23.2.2	all related rights of the Authority in relation to the recovery of sums due but unpaid;
22	Notice	23.2.3	the Authority receiving notification of the assignment and the date upon which the assignment becomes effective together with the Assignee's contact information and bank account details to which the Authority shall make payment;
22.1	Subject to Clause 15.5, of Schedule 2, any notice required to be given by either Party under this Contract shall be in writing quoting the date of the Contract 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.	23.2.4	the provisions of Clause 6 of this Schedule 2 continuing to apply in all other respects after the assignment which shall not be amended without the prior written approval of the Authority; and
22.2	A notice shall be treated as having been received:	23.2.5	payment to the Assignee being full and complete satisfaction of the Authority's obligation to pay the relevant sums in accordance with this Contract.
22.2.1	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	23.3	Any authority given by the Authority for the Supplier to Sub-contract any of its obligations under this Contract shall not impose any duty on the Authority 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 Contract.
22.2.2	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	23.4	Where the Supplier enters into a Sub-contract in respect of any of its obligations under this Contract relating to the manufacture, supply, delivery or installation of or training in relation to the Goods, the Supplier shall include provisions in each such Sub-contract, unless otherwise agreed with the Authority in writing, which:
22.2.3	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.	23.4.1	contain at least equivalent obligations as set out in this Contract in relation to such manufacture, supply, delivery or installation of or training in relation to the Goods to the extent relevant to such Sub-contracting;
23	Assignment, novation and Sub-contracting	23.4.2	contain at least equivalent obligations as set out in this Contract in respect of confidentiality, information security, data protection, Intellectual Property Rights, compliance with Law and Guidance and record keeping;
23.1	The Supplier shall not, except where Clause 23.2 of this Schedule 2 applies, assign, Sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Contract without the prior consent in writing of the Authority, such consent not to be unreasonably withheld or delayed. If the Supplier Sub-contracts any of its obligations under this Contract, every act or omission of the Sub-contractor shall for the purposes of this Contract be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority	23.4.3	contain a prohibition on the Sub-contractor Sub-contracting, assigning or novating any of its rights or obligations under such Sub-contract without the prior written approval of the Authority (such approval not to be unreasonably withheld or delayed);
		23.4.4	contain a right for the Authority to take an assignment or novation of the Sub-contract

	(or part of it) upon expiry or earlier termination of this Contract;		this or any other agreement with the Authority; or
23.4.5	requires the Supplier or other party to pay any undisputed sums which are due from it to the Sub-contractor within a specified period not exceeding thirty (30) days of verifying that the invoice is valid and undisputed;		(ii) in connection with this Contract 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 the Authority; and
23.5	Where the Authority considers that the grounds for exclusion under Regulation 57 of the Public Contracts Regulations 2015 apply to any Sub-contractor, then:	24.1.2	it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.
23.5.5	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	24.2	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 the Authority:
23.5.6	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.	24.2.1	the Authority shall be entitled:
23.6	The Supplier shall pay any undisputed sums which are due from it to a Sub-contractor within thirty (30) days of verifying that the invoice is valid and undisputed.	(i)	to terminate this Contract and recover from the Supplier the amount of any loss resulting from the termination;
23.7	The Authority 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 the Authority. 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.	(ii)	to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and
23.8	The Authority may at any time transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract 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 the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the party assuming the position of the Authority shall not further transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract without the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier.	(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;
24	<u>Prohibited Acts</u>	24.2.2	any termination under Clause 24.2.1 of this Schedule 2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and
24.1	The Supplier warrants and represents that:	24.2.3	notwithstanding the Dispute Resolution Procedure, any Dispute relating to:
24.1.1	it has not committed any offence under the Bribery Act 2010 or done any of the following ("Prohibited Acts"):	(i)	the interpretation of Clause 15 of this Schedule 2; or
	(i) offered, given or agreed to give any officer or employee of the Authority 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 the Authority or for showing or not showing favour or disfavour to any person in relation to	(ii)	the amount or value of any gift, consideration or commission,
			shall be determined by the Authority, acting reasonably, and the decision shall be final and conclusive.
25	<u>Conflicts of interest and the prevention of fraud</u>		
25.1	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 the Authority, 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 the Authority under the provisions of this Contract. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.		
25.2	The Authority reserves the right to terminate this Contract immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion		

	of the Authority, 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 the Authority under the provisions of this Contract. The actions of the Authority pursuant to this Clause 25.2 of this Schedule 2 shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.	26.5	Any provision of this Contract 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 Contract and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.
25.3	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 the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.	26.6	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 Contract 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 Contract or unless such representation, undertaking or warranty was made fraudulently.
25.4	If the Supplier or its Staff commits Fraud the Authority may terminate this Contract and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination.		
26	General		
26.1	The Supplier shall use reasonable endeavours to ensure its Business Continuity Plan operates effectively alongside the Authority's business continuity plan where relevant to the supply of the Goods. The Supplier shall also ensure that its Business Continuity Plan complies on an ongoing basis with any specific business continuity requirements, as may be set out in the Contract. 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:	26.7	Each Party shall bear its own expenses in relation to the preparation and execution of this Contract including all costs, legal fees and other expenses so incurred.
	26.1.1 the criticality of this Contract to the Authority; and	26.8	The rights and remedies provided in this Contract are independent, cumulative and not exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Contract or by any other contract or document. In this Clause 26.8 of this Schedule 2, right includes any power, privilege, remedy, or proprietary or security interest.
	26.1.2 the size and scope of the Supplier's business operations,	26.9	A person who is not a party to this Contract shall have no right to enforce any terms of it which confer a benefit on such person. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Contract.
	regarding continuity of the supply of Goods during and following a Business Continuity Event. 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 the Authority on such implementation. During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to supply the Goods in accordance with this Contract.	26.10	This Contract, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Contract or any variation to this Contract, contain the entire understanding between the Supplier and the Authority relating to the supply of the Goods 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 Contract. Nothing in this Contract 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 Contract shall form part of this Contract.
26.2	Each of the Parties is independent of the other and nothing contained in this Contract 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 Contract.	26.11	This Contract, 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.
26.3	Failure or delay by either Party to exercise an option or right conferred by this Contract shall not of itself constitute a waiver of such option or right.	26.12	Subject to Clause 15 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 Contract or its subject matter.
26.4	The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Contract 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.	26.13	All written and oral communications and all written material referred to under this Contract shall be in English.

Schedule 3

Definitions and Interpretations

1 Definitions

1.1 In this Contract the following words shall have the following meanings unless the context requires otherwise:

“ASN”	means advance shipping notice;
“Authority”	means the authority named on the form of Contract on the first page;
“Authority’s Obligations”	means the Authority’s further obligations, if any, referred to in the Key Provisions;
“Breach Notice”	means a written notice of breach given by one Party to the other, notifying the Party receiving the notice of its breach of this Contract;
“Business Continuity Event”	means any event or issue that could impact on the operations of the Supplier and its ability to supply the Goods 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 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;
“Commencement Date”	means the date of this Contract;
“Component Part”	means any constituent element or part of the Goods including any raw materials which when processed or combined become part of the Goods or which are used in the process of the production or assembly of the Goods; and “Component Parts” shall be construed accordingly;
“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 Contract including any procurement process which is: <ul style="list-style-type: none"> (a) Personal Data (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 the Authority’s intranet;
“Consigned Goods”	means Goods delivered by the Supplier in response to a Consignment Request prior to their use by the Authority;
“Consignment Request”	the Authority’s request for Goods to be delivered on a consignment basis;
“Contract”	means the form of contract at the front of this document and includes the Order Form, the Schedules and Annexes attached to the form of contract;
“Contracting Authority”	means any contracting authority as defined in regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;
“Controller”	shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);
“Charges”	means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract;
“cross-Government Decision Making Committee”	means the committee as referred to in the Guidance for new high volume manufacturers of COVID-19 Personal Protective Equipment, Office for Product Safety & Standards, April 2020;
“Data Protection Laws”	means (i) the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy;
“Defective Goods”	has the meaning given under Clause 4.6 of Schedule 2;
“Dispute(s)”	means any dispute, difference or question of interpretation or construction arising out of or in connection with this Contract, including any dispute, difference or question of interpretation relating to the Goods, any matters of contractual construction and interpretation relating to the Contract, or any matter where this Contract directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure;
“Dispute Notice”	means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute;

“Dispute Resolution Procedure”	means the process for resolving Disputes as set out in Clause 15 of Schedule 2. For the avoidance of doubt, the Dispute Resolution Procedure is subject to Clause 24.2.3 of Schedule 2;
“DOTAS”	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and 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;
“eProcurement Guidance”	means the NHS eProcurement 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;
“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 Contract; (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 applicable outside of England and Wales that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods, 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; but excluding, for the avoidance of doubt, the Covid 19 crisis and any related circumstances, events, changes or requirements;
“Fraud”	means any offence under any law in respect of fraud in relation to this Contract 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 similar to the Goods under the same or similar circumstances as those applicable to this Contract, including in accordance with any codes of practice published by relevant trade associations;
“Goods”	means all goods (including PPE Goods), materials or items that the Supplier is required to supply to the Authority under this Contract (including, without limitation, as stated in the Order Form which sets out the requirements of the Authority as issued to tenderers as part of the procurement process and the Supplier’s response to these

	requirements) and shall include parts of such Goods which have been repaired or replaced by or on behalf of the Supplier;
"Guidance"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, 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 the Authority and/or have been published and/or notified to the Supplier by the Department of Health and Social Care, Monitor, NHS England, NHS Improvement, the Medicines and Healthcare Products Regulatory Agency, the Health & Safety Executive, the Office for Product Safety & Standards, 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;
"Law"	means any applicable legal requirements including, without limitation: <ul style="list-style-type: none"> (a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales; (b) any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument); (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; (f) any relevant code of practice as applicable in England and Wales; and (g) any relevant collective agreement and/or international law provisions

	(to include, without limitation, as referred to in (a) to (f) above);
"NHS"	means the National Health Service;
"Occasion of Tax Non-Compliance"	means: <ul style="list-style-type: none"> (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: <ul style="list-style-type: none"> (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;
"Party"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
"Personal Data"	shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);
"Processing"	shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);
"PPE"	shall mean personal protective equipment as defined in the EU PPE Regulation 2016/425.
"PPE Goods"	means PPE products supplied to the Authority under this Contract, as further described in the Order Form
"Policies"	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
"Product Information"	means information concerning the Goods as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 for inclusion in the Authority's product catalogue from time to time;
"Purchase Order"	means the purchase order required by the Authority's financial systems, if a purchase order is referred to in the Key Provisions;

“Rejected Goods”	has the meaning given under Clause 4.2 of Schedule 2;
“Relevant Tax Authority”	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
“Remedial Proposal”	has the meaning given under Clause 12.3 of Schedule 2;
“Requirement to Recall”	has the meaning given under 4.9 of Schedule 2;
“Staff”	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any Sub-contractors and person employed or engaged by such Sub-contractors;
“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 Contract;
“Sub-contractor”	means a party to a Sub-contract other than the Supplier;
“Supplier”	means the supplier named on the form of Contract on the first page;
“Term”	means the term as set out in the Order Form;
“Termination Notice”	means a written notice of termination given by one Party to the other notifying the Party receiving the notice of the intention of the Party giving the notice to terminate this Contract on a specified date and setting out the grounds for termination;
“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 Law shall be deemed to include a reference to that Law as amended, extended, consolidated, re-enacted, restated, implemented or transposed from time to time.

- 1.3 References to any legal entity shall include anybody that takes over responsibility for the functions of such entity.
- 1.4 References in this Contract to a “Schedule”, “Annex”, or to a “Clause” are to schedules, annexes and clauses of this Contract.
- 1.5 References in this Contract 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 The headings are for convenience only and shall not affect the interpretation of this Contract.
- 1.7 Words denoting the singular shall include the plural and vice versa.
- 1.8 Where a term of this Contract 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.
- 1.9 Where there is a conflict between the Supplier’s responses to the Authority’s requirements (the Supplier’s responses being set out in the order form) and any other part of this Contract, such other part of this Contract shall prevail.
- 1.10 Where a document is required under this Contract, the Parties may agree in writing that this shall be in electronic format only.
- 1.11 Any guidance notes in grey text do not form part of this Contract.
- 1.12 Any Breach Notice issued by a Party in connection with this Contract shall not be invalid due to it containing insufficient information. A Party receiving a Breach Notice (“Receiving Party”) may ask the Party that issued the Breach Notice (“Issuing Party”) to provide any further information in relation to the subject matter of the Breach Notice that it may reasonably require to enable it to understand the Breach Notice and/or to remedy the breach. The Issuing Party shall not unreasonably withhold or delay the provision of such further information as referred to above as may be requested by the Receiving Party but no such withholding or delay shall invalidate the Breach Notice.
- 1.13 Any terms defined as part of a Schedule or other document forming part of this Contract shall have the meaning as defined in such Schedule or document.

Schedule 4
Additional Special Conditions

1 **Specific approval processes for medical devices that are not CE marked**

1.1 The provisions of this Clause 1 of Schedule 4 applies where Goods are in-vitro diagnostic medical devices or general medical devices to which CE marking is not currently applied pursuant to Regulations 36 (CE marking of in-vitro diagnostic medical devices) and Regulation 10 (CE marking of general medical devices) of the Medical Device Regulations 2002 (the "MDR"). It is recognised by the Parties that such Goods, having only recently been developed, may not necessarily meet the requirements that an in-vitro diagnostic medical device that bears CE marking in accordance with Regulation 36 and a general medical device that bears CE marking in accordance with Regulation 10 MDR would meet (and shall not in any event be labelled with Conformity Marking) and instead must receive an authorisation from the Secretary of State for Health and Social Care pursuant to Regulation 39(2) and/or 12(5) MDR to be placed on the market in the United Kingdom and supplied to the Authority for use in a healthcare environment ("**Product Authorisation**").

1.2 In relation to such Goods, the Supplier shall by dates agreed in writing with the Authority submit to the Authority:

1.2.1 such facilities that it will use for the manufacture and storage of the Goods in question for inspection by the Authority and any regulatory authority;

1.2.2 details of any manufacturing processes and controls that it will use in connection with the manufacture and supply of any such Goods in such detail that the Authority shall reasonably require;

1.2.3 for approval agreed quantities of pre-production samples of the Goods in question ("**Pre-Production Samples**"), such samples to be manufactured in conformance with the Specification; and

1.2.4 such quantities of the Goods for testing in a healthcare environment that the Authority may reasonably require ("**Testing Samples**").

1.3 Furthermore, the Supplier shall:

1.3.1 at the Authority's request, provide reasonable support, cooperation and information to the Authority to assist the Authority in obtaining and maintaining a Product Authorisation for the Goods in question; and

1.3.2 promptly notify the Authority if it experiences or anticipates that it may experience any difficulties or challenges with respect to manufacturing Pre-Production Samples or Testing Samples and the Authority shall provide such reasonable assistance to the Supplier as it is able (taking into account the exceptional circumstances described in Clause 2 of this Schedule 4).

1.4 It is a condition of this Contract that the Supplier shall not commence the manufacture and/or the supply of Goods for use generally by patients until the Supplier has:

1.4.1 obtained a relevant Product Authorisation and notified the Authority of the same; and

1.4.2 communicated its approval of the Pre-Production Samples to the Authority in writing (such approval not to be unreasonably withheld or delayed).

The Authority shall be entitled to waive the condition referred to in the preceding sentence by notice in writing to the Supplier subject to any requirements notified to the Supplier in writing by the Authority.

1.5 The Authority's approval of the Pre-Production Samples constitutes confirmation by the Supplier that the Goods shall be manufactured in conformity with those samples. The Supplier shall ensure that all such Goods manufactured include a type and serial number or batch number or other element allowing identification.

1.6 If the Supplier considers or has reason to believe at any stage that the Goods are no longer in conformity with the Product Authorisation it must immediately notify the Authority and take the corrective measures necessary to bring the Goods into conformity, to withdraw them or to recall them, as appropriate. Furthermore, where the Goods presents a risk, the Supplier shall immediately inform the enforcement authority in the UK to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

1.7 The Supplier shall following the grant of a Product Authorisation for Goods strictly adhere to any conditions applying to such Product Authorisation in manufacturing and supplying those Goods and otherwise complying with this Contract, and shall cease manufacture and supply if or once the Product Authorisation in question is withdrawn or expires unless the Authority otherwise requires in writing. Following the withdrawal or expiration of the Product Authorisation for the Goods, the Supplier shall provide reasonable assistance and cooperation to the Authority in recalling the Goods and the Authority shall meet the Supplier's reasonable costs of such assistance and cooperation save where the withdrawal of the Product Authorisation in question results from any breach by the Supplier of this Contract.

2 **Exceptional circumstances as a result of the Covid-19 pandemic**

2.1 The Parties recognise that the circumstances created as a result of the Covid-19 pandemic are exceptional and fast-moving. As a consequence, the Parties agree that they will act reasonably and in good faith together to seek to resolve any difficulties or challenges which may impact upon the manufacture and supply of Goods and in relation to the wider Covid-19 issues so as to ensure that public health is protected and preserved.

2.2 In this context:

2.2.1 the Supplier recognises that there may be a shortage of supply of Component Parts and accordingly, the Suppliers shall take all reasonable steps to safeguard and protect all stocks of Component Parts held by it and its Group from time to time which may be required to manufacture the Goods;

2.2.2 the Supplier recognises and agrees that the exceptional circumstances referred to above may mean that it is necessary for the Authority to involve itself in the Supplier's inbound supply chain for Component Parts. The Authority shall notify the Supplier in advance if it considers that this step is reasonably necessary and the Supplier shall provide all information and assistance as the Authority may require in order for it to take this step;

2.2.3 the Supplier agrees to provide transparency to the Authority to ensure that the Authority has sufficient visibility of the Supplier's manufacturing processes and timelines for the manufacture and

supply of Goods to allow it to plan and adjust order scheduling across the Authority's supply chain for products equivalent to or similar to the Goods;

- 2.2.4 the Supplier shall notify the Authority promptly of any exceptional events or circumstances which may impact upon the Supplier's ability to manufacture and supply Goods in accordance with this Contract and the Authority's requirements ("**Relevant Circumstances**"). If the Supplier is or is likely to be subject to delays in manufacturing and supplying any of the Goods to the Authority, the Authority shall be entitled by notice in writing to cancel all or part of an Order;
- 2.2.5 if the Relevant Circumstances apply or if any Pre-Production Samples of the Goods fail to gain approval in accordance with Clause 1.4.2 then the Authority shall be entitled: (a) to have the Goods manufactured by an alternative manufacturer (and shall upon reasonable commercial terms be granted a licence of any relevant Intellectual Property Rights owned or licensed to the Supplier which are necessary for the manufacture of the Goods and the Supplier shall provide the Authority, upon request, with all relevant information necessary for such manufacture) and; (b) to purchase from the Supplier the Supplier's stocks of Component Parts to the extent that such quantities of Component Parts are held in line with the quantities required to fulfil an Order. The purchase price of such Component Parts shall be an amount equal to the price paid by the Supplier for such Component Parts. In addition, the Authority shall be entitled to purchase from the Supplier any tooling used or to be used exclusively for the manufacture of the Goods at the price paid by the Supplier, subject to any depreciation which would ordinarily be applied to such tooling in line with usual accounting practice; and
- 2.2.6 if the Authority exercises its rights under Clause 2.2.5 of this Schedule, the Supplier will deliver up to the Authority the Component Parts and relevant tooling and title in such Component Parts and tooling shall immediately transfer to the Authority. The Supplier shall take all such steps and complete all such additional documentation as is necessary to transfer title in the Component Parts and tooling to the Authority.