ANNEX 2 TO CONTRACT FOR THE SUPPLY GOODS

ADDITIONAL REQUIREMENTS (2.2 – Variations to Call-off Terms and Conditions)

SCHEDULE 2 of the Call-off Terms and Conditions

Clause 1.7 (Supply of Goods) shall be amended by the replacement of the cross-reference with the correct cross-reference to Clause 1.6.

Clause 2.3 shall be deleted and replaced by the following:

- 2.3 "The following details shall be shown on the outside of every package and within a delivery note which must accompany each package:
 - 2.3.1 a description of the Goods which shall include, without limitation, the weight of the Goods where available and any order number allocated to the Goods by the Authority and/or Supplier;
 - 2.3.2 the quantity in the package, where available;
 - 2.3.3 any special directions for storage;
 - 2.3.4 the expiry date of the contents, where applicable;
 - 2.3.5 the batch number; and
 - 2.3.6 the name and address of the manufacturer of the Goods and Supplier.

In addition, all Goods that customarily bear any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality must be delivered with all the said marks, tabs, brands, labels, serial numbers or other devices intact. Without prejudice to the generality of the foregoing, the Supplier shall label all Goods supplied to the Authority, and the packaging of such Goods, to highlight environmental and safety information as required by applicable Law."

Clause 9 (Price and Payment) shall be amended by the addition of the following:

- "9.9 Where the Authority is entitled to receive any sums (including, without limitation, any costs, charges or expenses) from the Supplier under this Contract, the Authority may invoice the Supplier for such sums. Such invoices shall be paid by the Supplier within 30 days of the date of such invoice.
- 9.10 If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue amount at a rate of 4% above Bank of England base rate, accruing on a daily basis from the due date up to the date of actual payment, whether before or after judgment."

Clause 10 (Warranties) shall be amended by the addition of the following clauses, as follows:

- 10.1.31 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;
- 10.1.32 it shall at all times conduct its business in a manner that is consistent with any reasonable anti-slavery Policy of the Authority that is notified in writing to the Supplier 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 10.1.32 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.

Clause 15 (Term and Termination) shall be amended as follows:

At clause 15.2.1 substitute "three (3) months" with "1 (one) month"; and

After clause 15.5.5 insert new clause 15.5.6 as follows:

"15.5.6 Upon the occurrence of any of the events in regulations 73(1)(a)-(c) of the Public Contracts Regulations 2015 (SI 2015/102)."

- Clause 17 (Packaging, etc.) shall be amended by the addition of the following to amend/replace the current provision as indicated:
- 17.2 *[to be inserted after current provision]* "and in relation to Goods imported into the United Kingdom for the purposes of the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 and all applicable product and safety liability legislation in force in the United Kingdom from time to time, the Supplier shall assume all obligations for all activities performed outside the United Kingdom in relation to the Goods and the packaging, in addition to any other obligations the Supplier may have pursuant to such regulations and other legislation."
- 17,4 *[to replace the current provision] "*The Supplier shall ensure that all Goods that are required by Law or Guidance to bear any safety information, environmental information, any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality at the point such Goods are delivered shall comply with such requirements at the point of delivery."

Clause 18 (Coding requirements) shall be deleted and replaced by following:

18.1 Unless otherwise confirmed and/or agreed by the Authority in writing the Supplier shall ensure full compliance with any Guidance issued by the Department of Health in relation to the adoption of GS1 and PEPPOL standards

(to include, without limitation, any supplier compliance timeline and other policy requirements published by the Department of Health in relation to the adoption of GS1 and PEPPOL standards for master data provision and exchange, barcode labelling and purchase to pay transacting).

- 18.2 Once compliance with any published timelines has been achieved by the Supplier pursuant to the Order Form, the Supplier shall, during the Term, maintain the required level of compliance relating to the Goods in accordance with any such requirements and Guidance referred to as part of this Contract.
- 18.3 Once product information relating to Goods is placed by the Supplier into a GS1 certified data pool, the Supplier shall, during the Term, keep such information updated with any changes to the product data relating to the Goods.

Clause 28 (Assignment, novation and subcontracting) shall be amended by deleting the following:

28.5 "...use its reasonable endeavours to..."

SCHEDULE 3 of the Call-off Terms and Conditions

Clause 2 shall be deleted, and replaced with the following:

"2 Data Protection

- 2.1 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):
 - (a) administer and provide the Goods;
 - (b) request and receive the Goods;
 - (c) compile, dispatch and manage the payment of invoices relating to the Goods;
 - (d) manage the Contract and resolve any disputes relating to it;
 - (e) respond and/or raise general queries relating to the Goods; and
 - (f) comply with their respective regulatory obligations.
- 2.2 Processing of Personal Data relating to each Party's representatives for the purposes set out in Clause 2.1 of this Schedule 3 of these Call-off Terms and Conditions 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 2.1 of this Schedule 3 of these Call-off Terms and Conditions, and in doing so each Party will ensure that the sharing and use of this Personal Data complies with applicable Data Protection Laws."

SCHEDULE 4 of the Call-off Terms and Conditions

Clause 1.1 of Schedule 4 of the Call-off Terms and Conditions shall be deleted, and replaced with the following:

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

"Authority"	means the authority named on the Order Form;
"Authority's Obligations"	means the Authority's further obligations, if any, referred to in the Specification and Tender Response Document and/or the Order Form;
"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;
"Call-off Terms and Conditions"	means these Call-off Terms and Conditions for the Supply of Goods (comprising of the front page of the document and the Schedules);
"Codes of Practice"	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;
"Commencement Date"	means the date of the Order Form;
"Component Parts"	means the raw materials or any other constituent element of the Goods;

"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:
	 (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 the Authority's intranet;

"Contract"	means the Order Form, the provisions on the front page and all Schedules of these Call-off Terms and Conditions and the applicable provisions of the Framework Agreement;
"Contracting Authority"	means any contracting authority as defined in Regulation 2 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;
"Contract Manager"	means for the Authority and for the Supplier the individuals specified in the Order Form or as otherwise agreed between the Parties in writing 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 of these Call-off Terms and Conditions;
"Contract Price"	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 calculated in accordance with the provisions of the Framework Agreement and as confirmed in the Order Form;
"Controller"	shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);
"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 General Data Protection Regulation (Regulation (EU) 2016/679), 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 of these Call-off Terms and Conditions;
"Dispute Resolution Procedure"	means the process for resolving disputes as set out in Clause 22 of Schedule 2 of these Call-off Terms and Conditions;
"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;
"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 the Authority may specify from time to time;
"Environmental Regulations"	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;
"eProcurement Guidance"	means the NHS eProcurement Strategy available via: <u>http://www.gov.uk/government/collections/nhs-procurement</u> 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;
"FOIA"	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;

"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 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 subcontractor 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;
"Framework Agreement"	means the Framework Agreement referred to in the Order Form;
"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,
Flactice	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, 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);
"Group"	means entities (other than the Supplier) within its corporate structure;
"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, 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, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs;
"Key Provisions"	means the key provisions set out in Schedule 1 of these Call-off Terms and Conditions and/or as part of the Order Form;
"KPI"	means the key performance indicators as set out in the Specification and Tender Response Document and/or the Order Form, if any;

"Law"	means:
	(a) any applicable statute or proclamation or any delegated
	 (a) any applicable statute or proclamation or any delegated or subordinate legislation or regulation;
	(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; and
	(f) any applicable code of practice, in each case 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;
"Mediation Notice"	has the meaning given under Clause 22.5.1 of Schedule 2 of these Call-off Terms and Conditions;
"NHS"	means the National Health Service;
"Occasion of Tax Non-	means:
Compliance"	(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 the order form for the Goods, including its Annexes issued by the Authority and incorporated within the Contract;
"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);

"Policies"	
	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
"Processing"	
	shall have the same meaning as set out in the General Data Protection Regulation (Regulation (EU) 2016/679);
"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 of these Call-off Terms and Conditions for inclusion in the Authority's product catalogue from time to time;
"Rejected Goods"	has the meaning given under Clause 4.2 of Schedule 2 of these Call-off Terms and Conditions;
"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 15.3 of Schedule 2 of these Call-off Terms and Conditions;
"Requirement to Recall"	has the meaning given under 4.9 of Schedule 2 of these Call-off Terms and Conditions;
"Schedule"	means the relevant part of the Call-off Terms and Conditions as per the headings within that document;
"Sensitive Personal Data"	means special categories of personal data as defined in the Data Protection Laws;
"Specification and Tender Response Document"	means the Specification and Tender Response Document set out in the Framework Agreement as supplemented by any further information set out and/or referred to in the Order Form and as amended and/or updated in accordance with this Contract ;
"Staff"	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any subcontractors and person employed or engaged by such subcontractors;
"Supplier"	means the supplier named on the Order Form;
"Term"	means the term as referred to in the Key Provisions and more particularly provided for within the Order Form;
"Third Party Body"	has the meaning given under Clause 8.5 of Schedule 2 of these Call-off Terms and Conditions; and
"VAT"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

Clause 1.4 of Schedule 4 of the Call-off Terms and Conditions shall be amended by the addition of references to "Annex".