DHSC Terms and Conditions for the Supply of Goods

The Authority	**Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU, UK
The Supplier	**Unispace Global Ltd** Devon House, St Katherine's Way, London E1W 1JP Company Registration No: 07719633
Date	**16/05/20**
Type of Goods	PPE - Nitirile Gloves manufactured by Mercator Medical in Thailand and Hartalega in Malaysia as per Section 6 - Deliverables.

This Contract is made on the date set out above subject to the terms set out in the Order Form and schedules ("**Schedules**") below. The Authority and the Supplier undertake to comply with the provisions of the Order Form and the Schedules in the performance of this Contract.

The Supplier shall supply to the Authority, and the Authority shall receive and pay for, the Goods on the terms of this Contract. For the avoidance of doubt, the Contract consists of the terms set out in the Order Form and the Schedules, together with the annexes as stated.

The Definitions in Schedule 3 apply to the use of all capitalised terms in this Contract.

Schedules

Schedule 1	Key Provisions
Schedule 2	General Terms and Conditions
Schedule 3	Definitions and Interpretations
Schedule 4	Additional Special Conditions

Order Form

1. Contract Reference	DHSC/Case 5154
2. Date	16/05/20
3. Buyer	**Department of Health and Social Care** 39 Victoria Street, London, SW1H 0EU UK
4. Supplier	**Unispace Global Ltd** Devon House, St Katherine's Way, London E1W 1JP UK Company Registration No: 07719633
5. The Contract	The Supplier shall supply the deliverable described below on the terms set out in this Order Form and the Schedules and any Annexes. Unless the Contract otherwise requires, capitalised expressed used in this Order Form have the same meanings as in Schedule 3. In the event of any conflict between this Order Form and the Schedules, this Order Form shall prevail. Please do not attach any supplier terms and conditions to this Order Form as they will not be accepted by the Buyer and may delay conclusion of the Contract.
6. Deliverables	

Item	Size	NPC (DHSC internal Use only)	Qty (Cartons of 1000 pieces)	Unit price / Carton	Price per Unit	Contrac Value in GBP
Item 1 - Examination Type Gloves - Nitrile - Premium Nitrile	[redacted]	GVNI0109	[redacted]	[redacted]	[redacted]	[redacted]

Long Cuff Glove, 5g Weight, break strength equal to or greater than 6n, manufactured by Mercator Medical in Thailand	[redacted]	GVNI0118				
	[redacted]	GVNI0119				
Item 2 - Examination Type Gloves Nitirle- Violet Blue Nitrile Glove, 3.2g Weight, break strength equal to or greater than 6n, manufactured by Hartalega in Malaysia	[redacted]	GVNI0110				
	[redacted]	GVNI0120	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	GVNI0121				
Item 3 - Examination Type Gloves Nitrile - Blue Nitrile Glove, 3.2g Weight, break strength equal to or greater than 6n, manufactured by Mercator Medical in Thailand	[redacted]	GVNI0111				
	[redacted]	GVNI0122	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	GVNI023				
TOTAL			[redacted]			**£103,684,000**

The Supplier warrants that it will carry out inspections of the Goods at the point of manufacture and in any case prior to delivery of the Goods at the delivery address. Such inspection shall be carried out by suitably training and qualified personnel of the Supplier or its representatives.

Delivered in accordance with the following instructions:

Delivery Address(es):
Delivery shall be Ex Works (EXW) at the following manufacturer premises:

Mercator Medical 88/8 Moo12, Tambon Kamphaeng Phet, Rattaphum District, Songkhla 90180, Thailand; and

Hartalega No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor, Malaysia.

In each case the Buyer authorises its Authority Collection Agent (Uniserve as described below) to collect the Goods at the locations above and in accordance with Clause 2.2 of Schedule 2. Collection shall be on the dates notified by the Supplier to the Authority Collection Agent provided that the Supplier has notified the Authority Collection Agent 14 days in advance that the Goods are available for collection. The Supplier shall ensure that the Goods are accompanied by the relevant paperwork required for their export from the relevant country. The Supplier shall liaise and co-operate with the

Authority Collection Agent (Uniserve) at all times. The contact details for Uniserve are as follows:

T: 01375 856 060 M: 07887 867 841 W: www.uniserve.co.uk
Uniserve Group, London Mega Terminal, Thurrock Park Way, Tilbury, Essex, RM18 7HD

[redacted] and covidairfreightDHSC@dhsc.gov.uk

Date(s) of Delivery:

Item ID	Quantity by Month [redacted]							
	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20
Item 1	[redacted]							
Item 2								
Item 3								
TOTAL								

Monthly delivery dates to be confirmed by Supplier. Where the Supplier is unable to deliver the Goods in accordance with the above table, including due to a Force Majeure Event, the Supplier will promptly notify the Buyer or its authorised representative. For the avoidance of doubt, the definition of Force Majeure Event in Schedule 3 is amended to include any viral outbreaks (including Covid 19) and any related circumstances.

Failure of the Supplier to make the Goods available for collection at all or to the schedule above shall not put the Supplier in breach of the Contract save that failure to do so will give either party the right to terminate this Contract in respect of the Goods which are unable to be collected by giving 48 hours written notice to the other unless the Supplier confirms in such 48 hour period that it can supply all or some of the Goods within a reasonable time to be determined by the Buyer (acting reasonably and in good faith), in which case this Contract shall only terminate in respect of those Goods which are unable to be supplied within a reasonable time to be determined by the Buyer (acting reasonably and in good faith) and the delivery dates shall be amended accordingly. Notwithstanding any other provision of this Contract, the above rights together with paragraph (c) of section 10 below shall be the parties sole remedy in relation to any delay in delivery of the Goods.

Within 24 hours of the Goods being available for Collection from the addresses above the Buyer or its authorised representative will visually inspect the Goods and notify the Supplier of any damaged Goods, packaging issues or discrepancies in the quantities as set out above. In the absence of such notification the Supplier will be deemed to have supplied the quantities required and the Goods (including their packaging) will be deemed to have been delivered in a satisfactory condition. For the avoidance of doubt if Goods are later found to be defective, including manufacturing defects, or otherwise not in accordance with this Contract clause 4.6 of Schedule 2 shall apply.

	In the event that the Authority Collection Agent fails to collect the Goods on the dates agreed or with a 24 hour period after such date and provided the Supplier has properly given 14 days of the Goods being available for collection, the Supplier shall be entitled to consider the Goods delivered for the purposes of this Contract. The Supplier shall be entitled to invoice the Buyer for the remaining payment due for such Goods provided always that the Supplier has provided dated visual evidence to the Buyer that the Goods were in fact available for collection on the agreed date. The Supplier shall store the Goods until such time as they are collected and charge the Buyer reasonable storage costs until such time as they are collected. Supplier to send ADVANCE SHIPPING NOTICES to the Uniserve points of contact above. The following detail needs to be included within the notice. o Supplier Name (and code) o Purchase Order No. o Part No. / NPC Code (NHS specific code) o Product Description (as complete as possible, ideally as NHS product listing) o Quantity (total) o Pack Qty / Packs per pallet o No. of pallets o Quality status (i.e. approved, certification status etc.) o Any product expiration dates o Any other contract reference In accordance with clause 2.2 of Schedule 2 delivery of each shipment is complete once collected by the Authority Collection Agent at the above relevant delivery address. The Buyer will be responsible for all aspects of onward transport from the above delivery addresses.
7. Specification	The specification of the Deliverables is as set out in Annex A. Evidence is required to demonstrate compliance with the required standard is an EC Declaration of Conformity and supporting Test Report.
8. Term	The Term shall commence on: 16/05/20 And the Expiry Date shall be upon delivery of the last batch of Goods described in the table at Section 6 above, unless it is otherwise extended or terminated in accordance with the terms and conditions of the Contract. The Buyer may extend the Contract for a period of up to 3 months by giving not less than 5 Business days' notice in writing to the Supplier prior to the Expiry Date. The terms and conditions of the Contract shall apply throughout any such extended period.

9. Charges

The Charges for the Deliverables shall be set out below:

Item	Size	NPC (DHSC internal Use only)	Qty (Cartons of 1000 pieces)	Unit price / Carton	Price per Unit	Contrac Value in GBP
Item 1 - Examination Type Gloves - Nitrile - Premium Nitrile Long Cuff Glove, 5g Weight, break strength equal to or greater than 6n, manufactured by Mercator Medical in Thailand	[redacted]	GVNI0109	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	GVNI0118				
	[redacted]	GVNI0119				
Item 2 - Examination Type Gloves Nitirle- Violet Blue Nitrile Glove, 3.2g Weight, break strength equal to or greater than 6n, manufactured by Hartalega in Malaysia	[redacted]	GVNI0110	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	GVNI0120				
	[redacted]	GVNI0121				
Item 3 - Examination Type Gloves Nitrile - Blue Nitrile Glove, 3.2g Weight, break strength equal to or greater than 6n, manufactured by Mercator Medical in Thailand	[redacted]	GVNI0111	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	GVNI0122				
	[redacted]	GVNI023				
TOTAL			[redacted]			**£103,684,000**

10. Payment

The parties agree that:

Payment Plan	Total	%
Pre-payment (20% of Total Contract Value)	[redacted]	[redacted]
Delivery Payment (80% of Total Contract Value based on actual delivery of Goods)	[redacted]	[redacted]
TOTAL	**£103,684,000**	**100%**

(a) The Supplier may issue an invoice for the pre-payment in the table above immediately on the signature of this Order Form and such invoice shall be paid immediately on signature of this Order Form;

	(b) The Supplier may issue further invoices upon each delivery of the Goods at the Delivery Address set out in Section 6 above. Such subsequent invoices shall represent the remaining 80% of the relevant Charges payable by the Authority for the Goods actually delivered and adjusted as necessary for Goods not delivered, including for Termination as set out in Section 6 above and such invoices shall be paid by the Authority on receipt and acceptance of the Goods in accordance with Section 6, provided always that such invoice is undisputed and validly issued in accordance with the invoicing requirements set out below and elsewhere in this Contract. The parties agree that the payment terms set out above shall apply only in respect of this Order Form, and that nothing set out herein shall relieve the Supplier of its obligations to comply with, or otherwise vary the remaining terms of this Order Form or any other provision of this Contract. The Supplier acknowledges and agrees that any advance payment of Charges as set out in this Order Form may be recovered by the Authority in accordance with the terms and conditions (including (without limitation) in the event that the Goods are not delivered or are rejected or otherwise in the event of the expiry or early termination of this Contract prior to the acceptance of any such Goods by the Authority). All invoices must be sent quoting a valid purchase order number to the following email address COVID-19FinanceOperations@dhsc.gov.uk. The Buyer will send you a unique Purchase Order number (the **"PO Number"**) prior to delivery of the Goods. You must in receipt of a valid PO Number before submitting an invoice for delivery payments. To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, PO item number (if applicable) and the details (name and telephone number) of your Buyer contact (i.e. Contract Manager). Non-compliant invoices will be sent back to you, which may lead to a delay in payment. If you have a query regarding an outstanding payment, please contact us by email, marking for the attention of our Accounts Payable section and send to the following email address COVID-19FinanceOperations@dhsc.gov.uk

11. Buyer Authorised Representative(s)	For general liaison your contact will continue to be ***Procurement.operations@dhsc.gov.uk*** or, in their absence, [redacted]	
12. Seller's Authorised Representative(s)	For general liaison your contact will continue to be [redacted] or, in their absence, [redacted]	
13. Address for notices	**Buyer:** **Department of Health & Social Care** Attention: [redacted] Email: [redacted]	Supplier: **Unispace Global Ltd** Devon House St Katherine's Way London E1W 1JP [redacted]
14. Key personnel	**Buyer:** **Department of Health & Social Care** [redacted] Email: [redacted]	Supplier: **Unispace Global Ltd** Devon House St Katherine's Way London E1W 1JP [redacted] Email: [redacted]
15. Procedures and Policies	The Buyer may require the Supplier to ensure that any person employed in the delivery of the Deliverables has undertaken a Disclose and Barring Service check. The supplier shall ensure that no person who discloses that he/she has a conviction that is relevant to the nature of the Contract, relevant to the work of the Buyer, or is of a type otherwise advised by the Buyer (each such conviction a "**Relevant conviction**"), or is found by the Supplier to have a Relevant Conviction (whether as a result of a police check, a Disclosure and Barring Service check or otherwise) is	

	employed or engaged in the provision of any part of the Deliverables.

Signed by the authorised representative of THE AUTHORITY

Name:	[redacted]	Signature:	[redacted]
Position:	Deputy Director	Date	16th May 2020

Signed by the authorised representative of THE SUPPLIER

Name:	[redacted]	Signature	[redacted]
Position:	Director	Date	13th May 2020

Schedule 1

Key Provisions

Standard Key Provisions

1 Application of the Key Provisions

1.1 The standard Key Provisions at Clauses 1 to 2 of this Schedule 1 shall apply to this Contract.

1.2 The optional Key Provisions at Clauses 3 to 12 of this Schedule 1 shall only apply to this Contract where they have been checked and information completed as applicable.

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

2 Order of precedence

2.1 Subject always to Clause 1.9 of Schedule 3 should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:

2.1.1 Order Form

2.1.2 Schedule 1: Key Provisions;

2.1.3 Schedule 2: General Terms and Conditions;

2.1.4 Schedule 3: Definitions and Interpretations;

2.1.5 any other documentation forming part of the Contract 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.

2.2 For the avoidance of doubt, the Order Form shall include, without limitation, the Authority's requirements in the form of its specification and other statements and requirements, the Supplier's responses, proposals and/or method statements to meet those requirements, and any clarifications to the Supplier's responses, proposals and/or method statements as included In these Terms and Conditions. Should there be a conflict between these parts of the Order Form, the order of priority for construction purposes shall be (1) the Authority's requirements; (2) any clarification to the Supplier's responses, proposals and/or method statements, and (3) the Supplier's responses, proposals and/or method statements.

3 Quality assurance standards ☒ (only applicable to the Contract if this box is checked and the standards are listed)

3.1 The following quality assurance standards shall apply, as appropriate, to the manufacture, supply, and/or installation of the Goods:

BS EN 455-1:2000,

BS EN 455-2:2015

4 Purchase Orders ☒ (only applicable to the Contract if this box is checked)

4.1 The Authority shall issue a Purchase Order to the Supplier in respect of any Goods to be supplied to the Authority under this Contract. The Supplier shall comply with the terms of such Purchase Order as a term of this Contract and shall ensure that any Purchase Order is clearly noted on each delivery. For the avoidance of doubt, any actions or work undertaken by the Supplier under this Contract prior to the receipt of a Purchase Order covering the relevant Goods shall be undertaken at the Supplier's risk and expense and the Supplier shall only be entitled to invoice for Goods covered by a valid Purchase Order.

5 Time of the essence ☐ (only applicable to the Contract if this box is checked)

5.1 Time is of the essence as to any delivery dates under this Contract and if the Supplier fails to meet any delivery date this shall be deemed to be a breach incapable of remedy for the purposes of Clause 12.4 (i) of **Error! Reference source not found.**.

6 Specific time periods for inspection ☒ (only applicable to the Contract if this box is checked and Clause 6.1 of this Schedule 1 is completed)

6.1 The Authority shall inspect the Goods within 90 days of the date of delivery of the relevant Goods to confirm that these are not defective, including manufacturing defects, or otherwise not in accordance with the requirement.

7 Specific time periods for rights and remedies under Clause 4.6 of Error! Reference source not found. ☐ **(only applicable to the Contract if this box is checked and Clause 7.1 of this Schedule 1 is completed)**

7.1 The Authority's rights and remedies under Clause 4.6 of **Error! Reference source not found.** shall cease **[*insert period – e.g. 12 months*]** from the date of delivery of the relevant Goods.

8 Termination for convenience ☐ (only applicable to the Contract if this box is checked and Clause 8.1 of this Schedule 1 is completed)

8.1 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier at any time on [**one (1)/three (3) months'**] written notice

9 Right to terminate ☐ (only applicable to the Contract if this box is checked)

9.1 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of this Contract in

circumstances where it is served with a valid Breach Notice having already been served with at least [two (2)] previous valid Breach Notices within the last twelve (12) calendar month rolling period as a result of any previous material breaches of this Contract which are capable of remedy (whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal). The twelve (12) month rolling period is the twelve (12) months immediately preceding the date of the [third] Breach Notice.

10 Consigned Goods ☐ (only applicable to the Contract if this box is checked)

10.1 Provided that such Consignment Request is consistent with the forecast requirement for the Goods (as set out in the Order Form and/or as calculated in accordance with any relevant processes set out in this document and/or as otherwise agreed by the Parties in writing), the Supplier shall deliver the Consigned Goods in accordance with Clause **Error! Reference source not found.** of **Error! Reference source not found.** in response to a Consignment Request for their eventual purchase and use by the Authority in accordance with the terms set out in this Contract.

10.2 For the avoidance of doubt, Clause 4 of **Error! Reference source not found.** shall apply to the inspection, rejection, return and recall of the Consigned Goods.

10.3 The Authority shall, or shall procure that its third party provider shall, maintain any storage facilities throughout the term of this Contract where the Consigned Goods are to be stored in such manner that such storage facilities remain suitable to store the Consigned Goods.

10.4 Prior to the Consigned Goods being taken into use by the Authority, the Authority shall ensure that:

10.4.1 the Consigned Goods are stored at the storage facilities in such a manner as to protect them from damage or deterioration;

10.4.2 the Consigned Goods in its possession remain readily identifiable as the Supplier's property;

10.4.3 any identifying marks or packaging on or relating to the Consigned Goods are not removed, defaced or obscured; and

10.4.4 the Consigned Goods are kept in satisfactory condition in accordance with any reasonable and necessary instructions from the Supplier from time to time.

10.5 The Authority shall keep accurate stock records in relation to any Consigned Goods and shall provide the Supplier with a sales report ("**Sales Report**") each [**week/month/quarter/other agreed period**] detailing current stock levels and the Consigned Goods taken into use by the Authority. For the avoidance of doubt, a sale will take place at the point any Consigned Goods are taken into use by the Authority.

10.6 On receipt of the Sales Report, the Supplier may invoice the Authority the Contract Price for all of the Consigned Goods taken into use by the Authority (as set out in that Sales Report).

10.7 Each [***week/month/quarter/other agreed period***] the Authority shall take into use and purchase at the Contract Price at least the minimum quantity of Consigned Goods specified in the Order Form for such period (if any) ("**Minimum Quantity**"). If the Supplier fails to supply the Authority with any Consigned Goods required by the Authority (including, without limitation, where the Authority obtains substitute goods from a third party as a result), the Minimum Quantity for the period in question shall be reduced by the quantity of the Consigned Goods that the Supplier fails to supply. Except to the extent that the Authority's failure to purchase the Minimum Quantity during any given period is caused by the Supplier's default or a Force Majeure Event, if the Authority purchases less than the Minimum Quantity for a given period, the Supplier may charge the Authority for any shortfall between:

10.7.1 the Contract Price of the Minimum Quantity in the relevant period; and

10.7.2 the Contract Price for Consigned Goods purchased by the Authority in that period.

10.8 The Authority (on a first in first out basis) may return to the Supplier any Consigned Goods that it is unable to use ("**Returned Goods**") by giving written notice to that effect ("**Returns Notice**"). Upon receipt of a Returns Notice, the Supplier shall collect the Returned Goods at the Supplier's risk and expense within ten (10) Business Days of the date of the Returns Notice. If the Supplier requests and the Authority accepts that the Returned Goods should be disposed of by the Authority rather than returned to the Supplier, the Authority may invoice the Supplier for the costs associated with the disposal of the Returned Goods and the Supplier shall pay any such costs.

10.9 Risk in respect of any Returned Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier; or (b) immediately following the expiry of ten (10) Business Days from the date of the Returns Notice related to such Returned Goods. If Returned Goods are not collected within ten (10) Business Days of the date of the relevant Returns Notice, the Authority may return the Returned Goods to the Supplier at the Supplier's risk and expense and/or charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of the relevant Returns Notice. The Authority may invoice the Supplier for such return expenses and/or storage costs and the Supplier shall pay any such expenses or costs.

10.10 The Consigned Goods shall at all times be subject to the direction and control of the Supplier, and the Supplier may (at the Supplier's risk and expense), upon (10) Business Days written notice to the Authority, collect (on a first in first out basis) any Consigned Goods that have not been taken into use by the Authority within [***insert period***] of their delivery to the Authority and/or which have a remaining shelf life of less than [***insert period***].

10.11 The Authority acknowledges that it holds Consigned Goods in its possession as bailee for the Consignor until such time as ownership passes in accordance with Clause 3.2 of **Error! Reference source not found.**.

10.12 On the termination or expiry of this Contract for whatever reason, all Consigned Goods not taken into use by Authority as at the point of such termination or expiry shall be deemed Returned Goods. Such Returned Goods shall be deemed the subject of a Returns Notice that shall be deemed to have been received by the Supplier with a notice date the same as the date of the expiry or earlier termination of this Contract. Clauses 10.8 and 10.9 of this Schedule 1 shall then apply

accordingly and this Clause, together with Clauses 10.8 and 10.9 of this Schedule 1, shall survive the expiry or earlier termination of this Contract for these purposes.

11 Electronic product information ☐ (only applicable to the Contract if this box is checked)

11.1 Where requested by the Authority, the Supplier shall provide the Authority the Product Information in such manner and upon such media as agreed between the Supplier and the Authority from time to time for the sole use by the Authority.

11.2 The Supplier warrants that the Product Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Product Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same.

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

11.4 The Supplier grants the Authority 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) available pursuant to the Authority's contracts from time to time.

11.5 Before any publication of the Product Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's product catalogue to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Product Information in any product catalogue as a result of the approval.

11.6 If requested in writing by the Authority, and to the extent not already agreed as part of writing, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System

12 Supply of PPE Goods ☒ (only applicable to the Contract if this box is checked)

Regulatory Requirements

12.1 The Supplier acknowledges and understands that when procuring PPE the Authority is required to ensure the PPE Goods are compliant with and meet applicable legal and regulatory requirements.

12.2 The Supplier shall supply the PPE Goods to Authority in accordance with the terms of this Contract and in accordance with the relevant requirements of applicable laws and regulations applicable to the supply of PPE, including, as applicable, the EU PPE Regulation 2016/425, the Personal Protective Equipment (Enforcement) Regulations 2018 and the Medical Device Regulations 2002 (together the "PPE Laws").

12.3 Save in relation to any PPE Goods for which the Supplier has approval in accordance with the cross-Government Decision Making Committee and without prejudice to the generality of clause 12.2, the Supplier shall ensure for PPE Goods supplied:

12.3.1 the appropriate conformity assessment procedure(s) applicable to the PPE Goods have been followed;

12.3.2 all declarations of conformity and approvals required by PPE Laws are in place prior to the delivery of any PPE Goods to the Authority;

12.3.3 where required by PPE Laws, there is a CE mark affixed to the PPE Goods in accordance with the PPE Laws; and

12.3.4 where, necessary current EC-type examinations certificates are in place for the PPE Goods.

12.4 If there are any PPE Goods supplied to the Authority hereunder that require a CE mark under more than one set of regulations, due to the nature of those PPE Goods, including and not limited to:

- PPE Laws;
- Control of Lead at Work Regulations 2002;
- Ionising Radiations Regulations 2017;
- Control of Asbestos Regulations 2012;
- Control of Substances Hazardous to Health Regulations 2002; and
- any other relevant regulations,

the Supplier shall ensure that the CE marking for any such PPE Goods is affixed in accordance with the relevant requirements and shall indicate that the PPE Goods also fulfils the provisions of that other regulation or regulations.

Goods bought to the market before 21 April 2019

12.5 The Supplier shall provide details, including any EC-type examination certificates and approval decisions issued under Directive 89/686/EEC and Directive 93/42/EEC (if applicable), and corresponding national implementing legislation, of any PPE Goods supplied under this Contract that have been placed on the market before 21 April 2019 and products already in the distribution chain by that date confirming that these can continue to be supplied as PPE to the Authority until 21 April 2023, unless their certificate or approval will expire before that date.

Annex A – Technical Specification for Examination Gloves.

This Annex sets out details of the technical specification that the Goods are required to meet.

Medical Device	Device Type	Medical Device Essential Technical Requirements for derogation applications to the MHRA	Relevant standards for design and performance Access to harmonised and other relevant standards from BSI are free of charge
	Examination glove - Single use/disposable - Sterile or Non- Sterile -Powder-free	Design and Performance: ● Must be made of well-established materials for this product area such as nitrile, vinyl or latex ● Should have long cuffs, reaching well above the wrist Label: See MDR Annex I – information to be supplied with the device and use of symbols in accordance internationally recognised symbols • Where applicable, must be labelled STERILE along with the method of sterilisation • Gloves containing latex must be labelled with the symbol for latex on at least the smallest packaging unit and caution placed in the instructions for use against its use where there is a known allergy to latex. • Must have an expiry date • Must specify the size	BS EN 455-1:2000 Requirements and testing for freedom from holes. or BS EN ISO 374-2 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. BS EN 455-2:2015 Requirements and testing for physical properties. BS EN 455-3:2015 Requirements and testing for biological evaluation. (In terms of sensitivity for the wearer e.g. latex protein) BS EN 455-4:2009 Requirements and testing for service life determination or ANSI/ISEA 105 or ASTM D6319 and BS EN 556-1:2001 for terminally sterilised medical devices for sterility aspect (where applicable) or equivalent technical solutions

Annex B – Declaration of Conformity

This Annex sets out details of the declarations of conformity for the goods to be supplied.

MERCATOR MEDICAL

EU DECLARATION OF CONFORMITY

Manufacturer' s Name	: Mercator Medical (Thailand) Ltd.
Manufacturer' s Address	: 88/8 Moo.12 Tambon Kampaengphet, Amphur Rattaphum, Songkhla 90180 Thailand Tel: +66 74 584 222 Fax: +66 74 584 223
Product	: Non-sterile Powder Free Nitrile Latex Examination Gloves

We Mercator Medical (Thailand) Ltd. declare and ensure with sole responsibility, that the abovementioned product(s) meet the provision of the Council Directive 93/42/EEC (Medical Device Directive) Class I, Non-sterile, which apply to them, and are in conformity with the latest version of all parts of EN 455. The obligations laid down in Annex VII. And are in conformity with the provision of the PPE Regulation (EU) 2016/425 as a Category III product, Type B where such is the case, with the latest version of EN ISO 374-1, EN 374-2, EN 374-4, EN ISO 374-5, EN 16523-1, EN 388 and EN 420.

This declaration is supported by the Quality System approval to ISO13485:2016/EN ISO13485:2016 and ISO 9001:2015 issued by SGS United Kingdom Ltd Systems & Services Certification. All supporting documentation is retained at the premises of the manufacturer.

We explicitly authorize Mercator Medical S.A. to act as our sole Authorized Representative in European Union for the above indicate product.

Authorized Representative for Mercator Medical (Thailand) Ltd. is
Mercator Medical S.A.
Address: ul. H. Modrzejewskiej 30
31-327 Krakow, Poland

Authorized Signature:

Mr. Dariusz Jan Krezymon

CEO

Mercator Medical (Thailand)., Ltd

Date: 17/2/2020

Mercator Medical (Thailand)Ltd.
88/8 Moo 12 Tambon Kampaengphet
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enquiry@mercator.co.th
www.mercator.co.th

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Hartalega

Innovation & Quality

DECLARATION OF CONFORMITY

MANUFACTURER:	Hartalega NGC Sdn. Bhd. No. 1, Persiaran Tanjung Kawasan Perindustrian Tanjung 43900 Sepang, Selangor, Malaysia Tel: (603) 3280 3888 Fax: (603) 3271 0135
EUROPEAN REPRESENTATIVE:	Medical Device Safety Service (MDSS) Schiffgraben 41 30175 Hannover, Germany
PRODUCT:	Nitrile Powder Free Examination Gloves
CLASSIFICATION:	Class I, according to Annex IX of Directive 93/42/EEC
CONFORMITY ASSESSMENT ROUTE:	Annex VII

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:	Refer to Attachment
START OF CE-MARKING:	November 15, 2014
PLACE, DATE OF ISSUE:	Hartalega NGC Sdn. Bhd., 09th May 2019

SIGNATURE: [redacted]

NAM[redacted]

POSITION: QUALITY MANAGEMENT REPRESENTATIVE

Rev 4

ATTACHMENT 1

Standard	Title
ISO 9001:2015	Quality Management System – Requirement
EN ISO 13485:2016	Medical Device – Quality Management System – Requirement for Regulatory Purpose
EN 455 – 1:2000	Medical Device for Single Use Part 1: Requirement and Testing for Freedom from Holes
EN 455 – 2:2015	Medical Device for Single Use Part 2: Requirement and Testing for Physical Properties
EN 455 – 3:2015	Medical Device for Single Use Part 3: Requirement and Testing for Biological Evaluation
EN 455 – 4:2009	Medical Device for Single Use Part 4: Requirement and Testing for Shelf Life Claim
BS EN 1041:2008 + A1:2013	Information Supplied by the Manufacturers with Medical Devices
ASTM D6319 – 10(2015)	Standard Specification for Nitrile Examination Gloves for Medical Application
BS EN ISO 14971:2012	Risk Management for Medical Devices
ISO 15223 – 1:2016	Medical devices – Symbol to be Used with Medical device Labels, Labeling and Information to be Supplied Part 1: General Requirement
ISO 10993 – 1:2018	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management System
ISO 10993 – 5:2009	Biological Evaluation of Medical Devices Part 5: Test for In Nitro Cytotoxicity
ISO 10993 – 10:2010	Biological Evaluation of Medical Devices Part 10: Test for Irritation and Delayed – Type Hypersensitivity
ISO 2859 – 1:1999/Amd.1:2011	Sampling Procedures and Tables for Inspection by Attributes

Annex C – Test Reports

This Annex sets out details of the test reports that have been provided for the goods to be supplied.

Mercator files:
- 2777(2)12470-03(2)E00-00 Nitrile Powder Free Glove mCare (ID 180547)
- EN 374 part 1 (1)
- EN 374 part 1 (1) (1)
- EN 374 part 2 and EN 420
- EN 374 part 5
- EN 455 Blue Nitrile size L
- Food Contact Test Report FC1800335
- GMP Codes Alimentarius SGS Certification
- GMP Codes Alimentarius SGS Certification (1)

Hartalega files:
- BS EN ISO 374-5 2016 SATRA CHM0260437 1730 EN
- EN 420 2003 & BS EN 374-3 2003 SATRA CHM0231968 1505 EN
- EN 420 2003 + A1:2009 SATRA CHM0268714 1811 EN A
- EN 420 2003 + A1:2009, PAHs & BS EN 16523-1 2015 SATRA CHM0264532 1746 EN A
- EN 455-1 2000 SGS CRSSA 11141 17
- EN 455-2 2015 SGS CRSSA 11144 17 (M)
- EN 455-3 2015 CRSSA 1148 17
- 001_HNGC-TF-MD-001(Rev4)