DHSC Terms and Conditions for the Supply of Goods

The Authority	**Department of Health and Social Care**
The Supplier	***Gemini Surgical UK Ltd***
Date	***1/5/2020***
Type of Goods	Surgical Gowns

This Contract is made on the date set out above subject to the terms set out in the Order Form and schedules ("**Schedules**") contained in the document (DHSC Contract for Goods - Terms and Conditions April 2020.pdf) 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

Schedules 2, 3 and 4 are contained in the document DHSC Contract for Goods - Terms and Conditions April 2020.pdf

Order Form

1. Contract Reference	DHSC/809
2. Date	1/5/2020
3. Buyer	Department of Health & Social Care, 39 Victoria Street, London, SW1H 0EU
4. Supplier	Gemini Surgical UK Ltd, Kemp House, 160 City Road, London, United Kingdom, EC1V 2NX, registration no:11241419
5. The Contract	The Supplier shall supply the deliverable described below on the terms set out in this Order Form as set out in Annex A.

	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	(Goods) As set out in the Purchase Order(s) in Annex A and described below: - Medical Safety Goggles - FFP2 Surgical Face Shields - IIR Surgical Masks Delivered in accordance with the following instructions: The supplier will contact the Authority's agent as set out in Annex D to arrange collection of the goods in accordance with Annex A from/to the following addresses in accordance with the below delivery schedule ((subject to change by Authority's agent): Collection Address (Manufacturers): - Medical Safety Goggles SHENZHEN CAS-ENVISION MEDICAL TECHNOLOGY CO. LTD 4F, Bldg 4, Tusincere Technology Park No. 333 Longfei Avenue, Longcheng Street Longgang District, Shenzhen China - FFP2 Surgical Face Shields SHENZHEN FITTOP HEALTH TECHNOLOGY CO LTD 5/F, BLDG4, HUALIAN INDUSTRIAL ESTATE HUA'NING ROAD, DALANG, LONGHUA DISTRICT SHENZHEN CHINA - IIR Surgical Masks CHAMFOND BIOTECH CO LTD 2/F, Building E, Sino-Danish Eco Life Science Park Hi-Tech Zone, Najing China 210032

	Delivery Address: **NHS Supply Chain c/o Clipper Logistics** Daventry Distribution Centre Danes Way DIRFT Daventry NN6 7GX [redacted]
7. Specification	The specification of the Deliverables is as set out in Annex B
8. Term	The Term shall commence on placement of the Purchase Order 001 at Annex A. And the Expiry Date shall be upon delivery of Purchase Orders, 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 **in Annex B.**
10. Payment	The Authority agrees to pay the Supplier the values of the Goods as set out in Lines 01 of the Purchase Order Form 001 at Annex A upon the commencement of this Contract and presentation of a valid invoice. Upon presentation of a valid invoice and accompanying collection confirmation from the Authority's agent; the Authority agrees to pay the remaining unit costs based on actual deliveries in accordance with the payment schedule as set out in Line 02 of Purchase Order 001 at Annex A. Within 10 Business Days of receipt of your countersigned copy of the Contract, we will send you a unique Purchase Order number (the **"PO Number"**). You must in receipt of a valid PO Number before submitting an invoice. 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 ***[Contract Manager name and contact details] TBC*** Department of Health & Social Care, 39 Victoria Street, London, SW1H 0EU or, in their absence, ***[secondary name and contact details] TBC.***	
12. Seller's Authorised Representative(s)	For general liaison your contact will continue to be [redacted] or, in their absence, ***[secondary name and contact details].***	
13. Address for notices	**Buyer:** Department of Health & Social Care, 39 Victoria Street, London, SW1H 0EU [redacted]	**Supplier:** **Gemini Surgical UK Ltd, Kemp House, 160 City Road, London, United Kingdom, EC1V 2NX** [redacted]
14. Key personnel	**Buyer:** Department of Health & Social Care, 39 Victoria Street, London, SW1H 0EU [redacted]	**Supplier:** **Gemini Surgical UK Ltd, Kemp House, 160 City Road, London, United Kingdom, EC1V 2NX** [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	1st May 2020

Signed by the authorised representative of THE SUPPLIER

Name:	[redacted]	Signature	[redacted]
Position:	Head Director	Date	23/4/20

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 **Error! Reference source not found.** 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 **Error! Reference source not found.**: 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:

EN166:2001
EN149:2001
EN14683:2019

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

3.2 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. 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.

4 Time of the essence ☒ (only applicable to the Contract if this box is checked)

4.1 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 **Error! Reference source not found.** of **Error! Reference source not found.**.

5 Specific time periods for inspection ☐ (only applicable to the Contract if this box is checked and Clause 5.1 of this Schedule 1 is completed)

5.1 The Authority shall visually inspect the Goods within **[*time period during which any inspection must be carried out*]** of the date of delivery of the relevant Goods.

6 Specific time periods for rights and remedies under Clause Error! Reference

source not found. **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)**

6.1 The Authority's rights and remedies under Clause **Error! Reference source not found.** of **Error! Reference source not found.** shall cease **[*12 months*]** from the date of delivery of the relevant Goods.

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

7.1 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier at any time on **[*one (1)/three (3)/six (6) months'*]** written notice. **[**Such notice shall not be served within [one (1)] year of the Commencement Date**]**.

7.2 Should the Authority terminate this Contract in accordance with Clause 8.1 of this Schedule 1, then the Authority shall pay to the Supplier the termination sum calculated in accordance with Schedule **[insert schedule number**.]

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

8.1 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.

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

9.1 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.

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

9.3 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.

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

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

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

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

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

9.5 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.

9.6 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).

9.7 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:

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

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

9.8 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.

9.9 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.

9.10 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 [***period***] of their delivery to the Authority and/or which have a remaining shelf life of less than [***period***].

9.11 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 **Error! Reference source not found.** of **Error! Reference source not found.**.

9.12 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 12.8 and 12.9 of this Schedule 1 shall then apply accordingly and this Clause, together with Clauses 12.8 and 12.9 **Error! Reference source not found.** of this Schedule 1, shall survive the expiry or earlier termination of this Contract for these purposes.

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

10.1 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.

10.2 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.

10.3 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.

10.4 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.

10.5 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.

10.6 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

11 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 Without prejudice to the generality of clause 12.2 the Supplier shall ensure for PEE 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; and

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.

Goods bought to the market before 21 April 2019

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.

Other Specific Requirements

12.6 The Supplier shall offer to the Authority spares and consumables required for any of the PPE Goods supplied to the Authority. The Supplier agrees any charging rate for the spares and consumables shall be inclusive of all packaging and standard delivery.

Annex A – Purchase Order Form

PURCHASE ORDER FORM No 001

Line Number	Specification	Delivery Schedule	Total Estimated Quantity	FIRM Price (£) Ex VAT	
				Per Item	Total
01	50% Upfront Payment - Medical Safety Goggles (Ventilation Valve) Anti-Fog	Contract start date	[redacted]		
02	50% Remaining Payment - Medical Safety Goggles (Ventilation Valve) Anti-Fog	TBC by Authority's courier			
03	50% Upfront Payment - FFP2 Surgical Face Mask	TBC by Authority's courier			
04	50% Remaining Payment - FFP2 Surgical Face Mask	TBC by Authority's courier			
05	50% Upfront Payment - IIR Surgical Mask	TBC by Authority's courier			
06	50% Remaining Payment - IIR Surgical Mask	TBC by Authority's courier			

Total Firm Price	£13,036,000

Annex B – Specification & Certificates

Medical Goggles

CE

Declaration of Conformity

Manufacturer:	Shenzhen CAS-Envision Medical Technology Co., Ltd.
Address:	4/F, Building#4, Qidixiexin Science Park, No.333 Longfei Avenue, Longcheng Street, Longgang District, Shenzhen City, China
Product.:	Medical Safety Goggle
Model :	GLYZ-Y
Classification:	I
Directive:	Regulation (EU) 2016/425 Personal Protective Equipment (PPE).
Standards applied:	EN 166:2001

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directive and Standards . All supporting documentations are retained under the premises of the manufacturer.

The manufacturer also declares that he has set up and maintains an appropriate procedure to guarantee the post-sales surveillance required by the same Directive.

Place, date of issue, Shenzhen, P.R. China, March 11, 2020

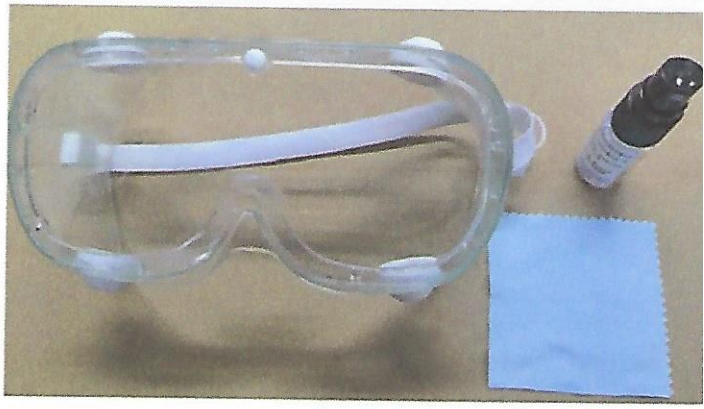
Signature of General Director

5. Production date: 20-Mar-2020

6. Expiry date: 19-Mar-2023

7. Product type: Medical type

8. Model:



9. Material:

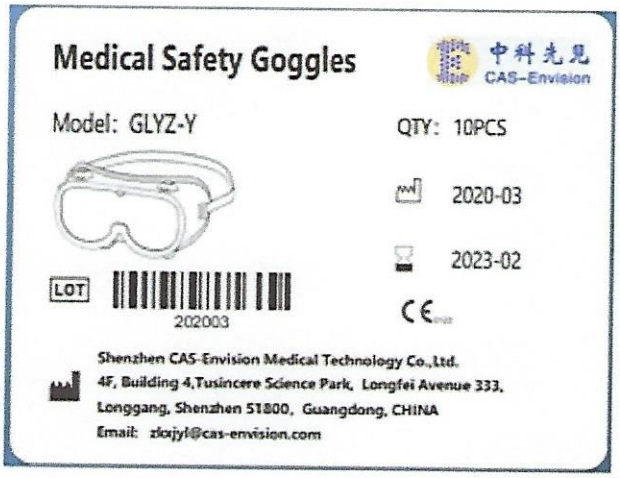
Picture frame material :PVC
Mirror material :PC
Vent valve material :PP
Tie material :polyester+latex

10. Colour: White

11. Class: Clinical

12. Certificate: CE ISO

13. Product label:



FFP2 Surgical Mask

ISTITUTO SERVIZI EUROPEI TECNOLOGICI

ISET S.r.l. Unipersonale

Sede Legale e Uffici
Via Donatori di sangue, 9 - 46024 Moglia (MN)
Tel. e fax +39 (0)376 598963
www.iset-italia.eu iset@iset-italia.com

Cap. soc. i.v. € 10.200,00
Cod. Fisc. e P.IVA Reg. Imprese 02 332 750 369
REA 02 332 750 369
Cap. soc. i.v. MN 0221098

CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

1) **APPLICANT:** (who finally puts the product on the market)
SHENZHEN FITTOP HEALTH TECHNOLOGY CO.,LTD.
5/F, BLDG 4, Hualian Industrial Estate, Huaning Road Dalang, Longhua District, Shenzhen, China
2) **CERTIFICATE NO.:** ISETC.000520200302
FILE REFERENCE: KMTCF0229-PPE
3) **ISET MARK:**

4) **CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):
The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.
5) **TYPE OF PRODUCT:** KN95 MASK
MODEL(S): FM80
6) **LIST OF DIRECTIVES / REGULATIONS /STANDARDS** (as declared by the manufacturer itself)
Personal Protective Equipment 2016/425
EN 149:2001+A1:2009
7) **NOTE:** The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website www.iset-italia.eu. This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.
8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.
9) **DATE OF ISSUE:** 02/03/2020 **EXPIRY DATE:** 01/03/2023
10) **SIGNATURE:** Li Zhang
(On behalf of the Legal representative)

ISTITUTO SERVIZI EUROPEI TECNOLOGICI
ISET S.R.L

Test Report
EN 149:2001+A1:2009

Respiratory protective devices — Filtering half masks to protect against particles —Requirements, testing, marking

Testing laboratory ..... :	Shenzhen Huawin Testing Certification Co., Ltd.
Address ..... :	7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao' an District,Shenzhen, China
Report body..... :	Shenzhen Huawin Testing Certification Co., Ltd.
Address ..... :	7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao' an District,Shenzhen, China
Applicant ..... :	SHENZHEN FITTOP HEALTH TECHNOLOGY CO.,LTD
Address ..... :	5/F, BLDG 4, Hualian Industrial Estate, Huaning Road Dalang, Longhua District, Shenzhen, China
Standard ..... :	EN 149: 2001+A1:2009
Test Result ..... :	Compliance with EN 149: 2001+A1:2009
Procedure deviation ..... :	N.A.
Non-standard test method ..... :	N.A.
Type of test object ..... :	KN95 MASK
Trademark ..... :	/
Model/type reference ..... :	FM80
Rating ..... :	FFP3
Manufacturer ..... :	SHENZHEN FITTOP HEALTH TECHNOLOGY CO.,LTD
Address ..... :	5/F, BLDG 4, Hualian Industrial Estate, Huaning Road Dalang, Longhua District, Shenzhen, China

Possible test case verdicts :	
test case does not apply to the test object ..... :	N/A
test object does meet the requirement ..... :	P(ass)
test object does not meet the requirement ..... :	F(ail)

Test by : **Shenzhen Huawin Testing Certification Co., Ltd. 7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao' an District,Shenzhen, China**

Reported by : Allen — Signature — 2020.03.01 Date

Allen / Project Engineer
Name and Title

Approved by : Robert — Signature — 2020.03.01 Date

HUAWIN TESTING TECHNOLOGY CO.,LTD ★ HUAWIN 华测检测技术有限公司 ★ Test Report ★

Robert / Manager
Name and Title

IIR Masks

ISTITUTO SERVIZI EUROPEI TECNOLOGICI

ISET S.r.l. Unipersonale

Sede Legale e Uffici
Via Donatori di sangue, 9 - 46024 Moglia (MN)
Tel. e fax +39 (0)376 598963
www.iset-italia.eu iset@iset-italia.com

Cap. soc. i.v. € 10.200,00
Cod. Fisc. e P.IVA/Reg. Imprese 02 332 750 369
REA 02 332 750 369
Cap. soc. i.v. MN 0221098

CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

1) **APPLICANT:** (who finally puts the product on the market)
Chamfond Biotech Co.,Ltd
2/F,Bldg E,Sion-Danish Eco life Science Park, Hi-tech Zone, 210032Nanjing, PEOPLE'S REPUBLIC OF CHINA
2) **CERTIFICATE NO.:** ISETC.000320200302
FILE REFERENCE: MTCF0229-MDD
3) **ISET MARK:**

4) **CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):

CE 0865

The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.

5) **TYPE OF PRODUCT:** Mask
MODEL(S): M-01 M-02 (Sterile environment for production and packaging)
6) **LIST OF DIRECTIVES / REGULATIONS /STANDARDS** (as declared by the manufacturer itself)
Personal Protective Equipment 2016/425
EN 14683:2019
7) **NOTE:** The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website www.iset-italia.eu. This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.
8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.
9) **DATE OF ISSUE:** 08/03/2020 **EXPIRY DATE:** 07/03/2023
10) **SIGNATURE:** Li Zhang
(On behalf of the Legal representative)

ISTITUTO SERVIZI EUROPEI TECNOLOGICI ISET S.R.L

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY

Name und Adresse des Herstellers: / Name and address of the manufacturer:	**Chamfond Biotech Co., Ltd 2/F, Bldg. E, Sino-Danish Eco Life Science Park, Hi-tech Zone, 210032 Nanjing, China**
Bevollmächtigter der EG: / EC Authorized Representative:	**Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124, Heidelberg, Germany**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

das Medizinprodukt: / the medical device:	**Maske / Mask Modell/ Model: M-01**
UMDNS-Code: / UMDNS code:	12447
Produktfotografie: / Product photograph:	
Grundlegende UDI-DI: / Basic UDI-DI:	/
Handelsname: / Trade name:	/
der Klasse: / of class:	**Class I** nach Anhang VIII der Verordnung EU 2017/745 (MDR) / according to annex VIII of Regulation EU 2017/745(MDR)

Erfüllt die Bestimmungen der Verordnung EU 2017/745 (MDR). Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". / Meets the provisions of the Regulation EU 2017/745(MDR). The declaration is valid in connection with the "final inspection report" of the device.

Konformitätsbewertungsverfahren: / Conformity assessment procedure:	**Arlicle 19,Annex IV of EU 2017/745**
Die Konformitätserklärung ist gültig bis: / Declaration of Conformity is valid until: /	**2021-03-12**

Nanjing, 2020-03-12
Ort, Datum / Place, date /

Chen Bohan, Management Representative.
Name und Funktion / Name and function

Annex C – Charges

As per quotes dated 22/04/2020.

GEMINI SURGICAL UK

QUOTATION

To: Ms. Eleanna Robinson-Dambalaki
Commercial Officer
Corporate Commercial Delivery Team
: MOD Abbey Wood
Bristol

Quote No: 0298
Date: 22nd April, 2020
Expiration Date: 25th April

MEDICAL SAFETY GOGGLES (ANTI-FOG)

Code	Qty	Description	Unit Price (£)	Total Price (£)
[redacted]				

4 WEEKS DELIVERY

[redacted] Medical Safety Goggles (Ventilation Valve) Anti-Fog [redacted]

Collection Address

SHENZHEN CAS-ENVISION MEDICAL TECHNOLOGY CO. LTD
4F, Bldg 4, Tusincere Technology Park
No. 333 Longfei Avenue, Longcheng Street
Longgang District, Shenzhen
China

GEMINI SURGICAL UK

QUOTATION

To: Ms. Eleanna Robinson-Dambalaki
Commercial Officer
Corporate Commercial Delivery Team
: MOD Abbey Wood
Bristol

Quote No: 0298
Date: 22nd April 2020
Expiration Date: 25th April

FFP2 SURGICAL MASKS

Code	Qty	Description	Unit Price (£)	Total Price (£)
FT	[redacted]	FFP2 Surgical Face Mask	[redacted]	

SHENZHEN FITTOP HEALTH TECHNOLOGY CO LTD

Collection Address

5/F, BLDG4, HUALIAN INDUSTRIAL ESTATE
HUA'NING ROAD, DALANG, LONGHUA DISTRICT
SHENZHEN
CHINA

Gemini Surgical UK 160 Kemp House, City Road, London EC1V 2NX
+44 203 368 8574 www. geminisurgical.co.uk alan@geminisurgical.co.uk

GEMINI SURGICAL UK

QUOTATION

To: Ms. Eleanna Robinson-Dambalaki
Commercial Officer
Corporate Commercial Delivery Team
: MOD Abbey Wood
Bristol

Quote No: 0298
Date: 22nd April, 2020
Expiration Date: 25th April

IIR SURGICAL MASKS

Code	Qty	Description	Unit Price (£)	Total Price (£)
M-01	[redacted]	IIR Surgical Mask	[redacted]	

CHAMFOND BIOTECH CO LTD

Collection Address

2/F, Building E, Sino-Danish Eco Life Science Park
Hi-Tech Zone, Najing
China 210032

Gemini Surgical UK 160 Kemp House, City Road, London EC1V 2NX
+44 203 368 8574 www. geminisurgical.co.uk alan@geminisurgical.co.uk

Annex D – The Authority's Delivery Agent

On-Time Shanghai DHSC Contacts

[redacted]

[redacted]

Shanghai Warehouse Address

先达国际货运(上海)有限公司

空运普货进仓地图

Gary Cobbing
Chief Commercial & Operations Officer
gc@ugroup.co.uk

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