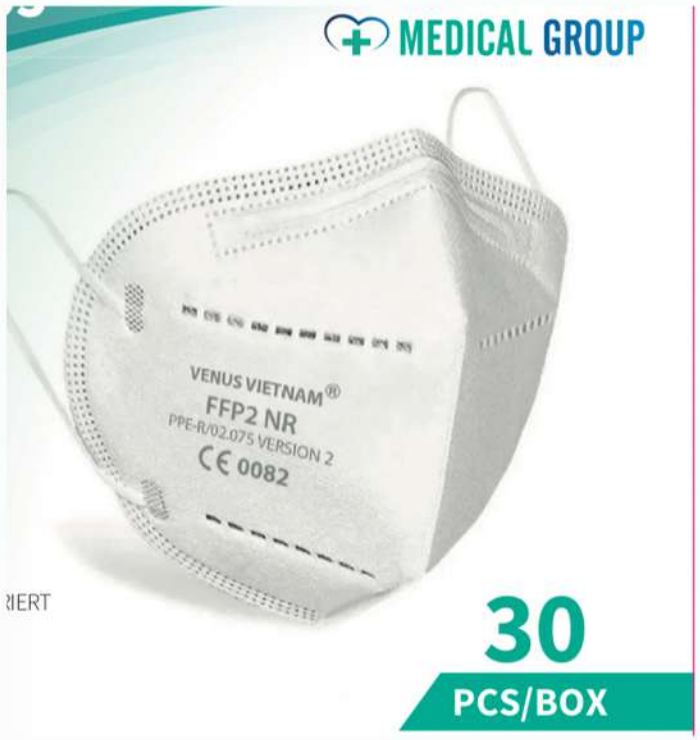
COMMITTED TO SAFETY

Products

VENUS

RESPIRATOR FFP2 - VENUS VIETNAM
Made in Vietnam



COMMITTED TO SAFETY

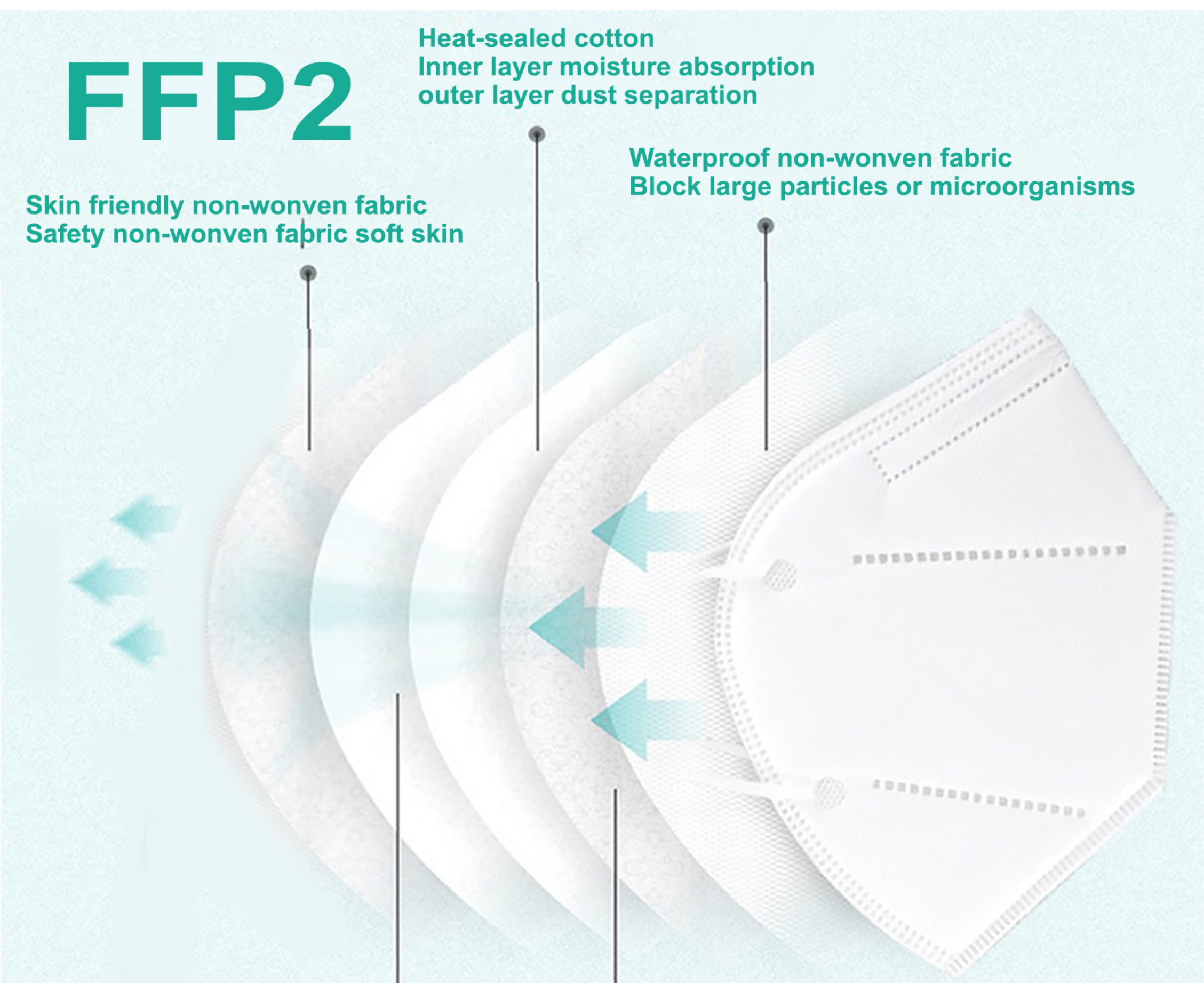
VENUS

FFP2

Heat-sealed cotton
Inner layer moisture absorption
outer layer dust separation

Waterproof non-wonven fabric
Block large particles or microorganisms

Skin friendly non-wonven fabric
Safety non-wonven fabric soft skin



Meltblown cloth
filtration of smaller particles

Heat-sealed cotton

COMMITTED TO SAFETY

Certifications

VENUS

CE 0082

FDA

VIỆN TRANG THIẾT BỊ CÔNG TRÌNH Y TẾ

TCVN 8389-1:2010

SÚKL
State Institute for Drug Control

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS

EUROVINA
zdraví je zlato!

ISSQ
INSTITUTE FOR STANDARD AND QUALITY DEVELOPMENT STUDIES
ISO 13485:2016

Certificates & test reports

ASSESSMENT REPORT - APAVE

Respiratory protective device

EU TYPE-EXAMINATION CERTIFICATE - APAVE

PPE category III – Filtering half mask to protect against COVID-19

PROPOSAL OF AGREEMENT - APAVE

Filtering half-mask to protect against COVID-19

REGISTRATION OF APPLICATION_APAVE

Registration of application for supervised product checks at random intervals (Module C2)

FDA REGISTRATION & ISO CERTIFICATE

For face masks, respirators, gloves & gowns

APAVE SUDEUROPE SAS, organisme notifié, identifié sous le numéro 0082
APAVE SUDEUROPE SAS, notified body, identified under number 0082

Testing and Certification Center
17, Boulevard Paul Langevin
38600 FONTAINE - France
Tél. +33.(0)4.76.53.52.22

Viet Nam Venus Import And Export Investment Joint Stock Company
km35 - Provincial road 379
Tan Tien Town
VAN GIANG DISTRICT - Hung Yen Province
Viet Nam

PPE REGULATION 2016/425 – ANNEX V
MODULE B – EU TYPE EXAMINATION
ASSESSMENT REPORT
Respiratory protective device

Report n°	**20.1428**
Technical referential	**European coordination sheet PPE-R/02.075 version 2**
Type of device	**PPE category III** **Filtering half mask to protect against COVID-19**
Trade mark	**Venus**
Model	**Venusmask95**
Reference	**Venus95**

Fontaine, the 14/12/2020
Report sent for the attention of Nguyen Thi Thu Trang to the email address xnkvenus.vn@gmail.com
This report includes 13 pages

The technical assessment manager
Immaterial original

M.MEPI.324.V1

Summary

1.Introduction - Description of the service

This assessment report concerns PPE category III – Filtering half mask to protect against COVID-19 as defined in European coordination sheet PPE-R/02.075 version 2.

Its purpose is to assess the conformity of the PPE with the PPE REGULATION 2016/425, with a view to be placed on the European market exclusively.

The assessment was conducted in accordance with purchase order signed on 06/07/2020 placed by Viet Nam Import And Export Investment Joint Stock Company.

Company: Viet Nam Venus Import And Export Investment Joint Stock Company - km35 - Provincial road 379 - Tan Tien Town - VAN GIANG DISTRICT - Hung Yen Province Viet Nam

2.Use of the report

This assessment report only concerns the equipment identified in clause 4 and described in clause 7.

Only an integral reproduction of this assessment report is authorized.

The manufacturer, or his representative, commits himself not to use this assessment report for equipment that is not strictly identical to the equipment covered by this assessment report.

3.Economical operator(s)

Viet Nam Venus Import And Export Investment Joint Stock Company - km35 - Provincial road 379 Tan Tien Town - Van Giang District - VAN GIANG DISTRICT - Hung Yen Province – Viet Nam

4.Identification of the equipment

Trade mark: Venus

Model: Venusmask95

Reference: Venus95

5.Conditions for use of the equipment

This filtering half mask is designed for protection against COVID-19 only. As requested by World Health Organization recommendations, for this specific use, the nominal protection factor given by this filtering half mask is the same than the FFP2 nominal protection factor defined in EN 149:2001+A1:2009. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.

6.Reference specification

The assessment of conformity with Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" was conducted taking into account the provisions of European coordination sheet PPE-R/02.075 version 2 "Respiratory protective device – Filtering half mask to protect against COVID-19".

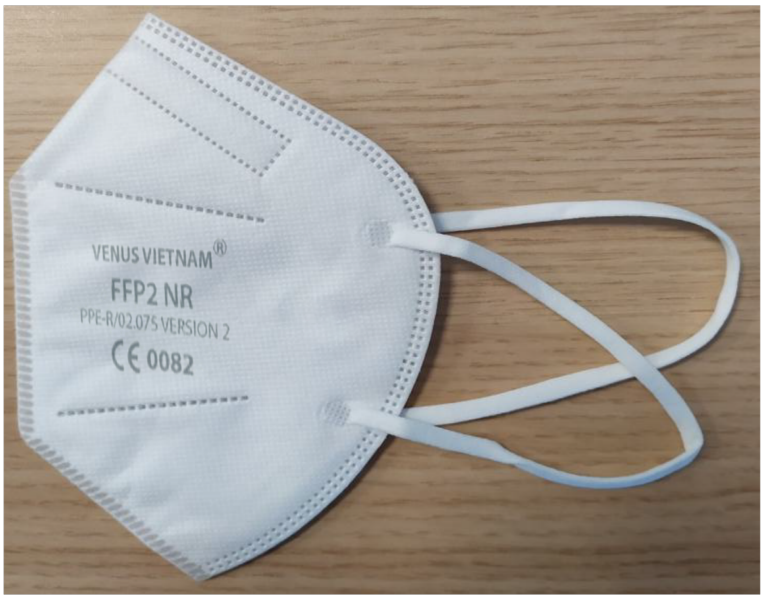
7.Technical Documentation

7.1.Identification

Identification of the assessed Technical Documentation:

1. Authorized representative – Company: Nguyen Thi Thu Trang - Viet Nam Venus Import And Export Investment Joint Stock Company
2. Commitment signature date: 03/12/2020
3. Technical Documentation reference: YT 337-20

7.2.Drawing



7.3.Description

Filtering half mask to protect against COVID-19 without exhalation valve, limited to one shift use. The half mask is foldable with a vertical fold flat shape, designed with a noseclip in high density polyethylene and two self-adjusting ear loop harnesses in rubber fibers and cotton. The filter media is composed of five layers in polypropylene.

7.4.Description of components

Detailed description of components in the Technical Documentation.

7.5.CE Marking

× Notified body in charge of assessment control to article 19c) of PPE regulation (module C2 or D):

APAVE SUDEUROPE SAS - France

× CE mark: **CE 0082**

× Graphic of letters C and E: **Conform**

× Height of mark: **5 mm**

× Marking clear and permanent: **Conform**

× Location of the marking: **Printed on the surface of the mask**

7.6.Packaging

Month and year of manufacture and month and year of obsolescence are indelibly and unambiguously marked on the packaging.

8.Correlation between the articles of PPE Regulation 2016/425 and the reference standard

The following table shows the correlation between the essential health and safety requirements of Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" and the articles of the European coordination sheet PPE-R/02.075 version 2 "Respiratory protective device – Filtering half mask to protect against COVID-19".

PPE Regulation 2016/425 Annex II	**Clauses of the RfU**
1.1.1	3.7; 3.9
1.1.2.1	3.7; 3.9; 3.11
1.1.2.2	3.9
1.2.1	3.6; 3.11; 3.13; 3.15
1.2.1.1	3.5; 3.6; 3.7; 3.10
1.2.1.2	3.7; 3.8
1.2.1.3	3.7; 3.13
1.3.1	3.7
1.3.2	3.4; 3.5; 3.7
1.4	5
2.1	3.12
2.3	3.13
2.4	3.6; 4; 5
2.6	5
2.8	5
2.9	3.12 ; 3.16
2.12	4
3.10.1	3.6; 3.7; 3.8; 3.9; 3.11; 3.15; 4; 5

WARNING: Other requirements and other EU Directives maybe applicable to the products falling within the scope of this Recommendation For Use.

9.Examination report

Article of PPE-R/02.075 version 2	Content	Conformity			Comments
		Yes	No	N-A	
Art. 3	**Requirements**				
Art 3.3	**Visual inspection** The visual inspection shall also include the marking and the information supplied by the manufacturer	✓			
Art 3.4	**Packaging** Filtering half masks against COVID-19 shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	✓			
Art 3.5	**Material** Materials used shall be suitable to withstand handling and wear over the period for which the filtering half masks against COVID-19 is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	✓			
Art 3.6	**Cleaning and disinfecting** If the filtering half masks against COVID-19 is designed to be cleaned and disinfected, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Cleaning and disinfection method can be accepted only if they are scientifically proved in peer reviewed scientific publications effective against the SARS-CoV-2, or have been recommended by European Centre for Disease Prevention and Control, ECDC With reference to 3.9, after cleaning and disinfecting the filtering half masks against COVID-19 shall satisfy the penetration requirement.			✓	

Article of PPE-R/02.075 version 2	Content	Conformity			Comments
		Yes	No	N-A	
Art 3.7	**Practical performance** The filtering half masks against COVID-19 shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test houses hall provide full details of those parts of the practical performance tests which revealed these imperfections.				Date of test: 03/09/2020 No imperfection determined
	Here are the comments of the test subjects:				
	a) head harness comfort	✓			No comment
	b) security of fastenings	✓			No comment
	c) field of vision	✓			No comment
	d) any other comments reported by the wearer on request	✓			No comment
	During the practical performance test, the test subject should pay particular attention to the ability of the product to maintain a good faceseal. If the wearer observes that a good faceseal is not maintained, they shall be instructed to readjust the filtering half mask according to the user instructions. Should the test subject experience further difficulties with maintaining a good faceseal during the practical performance test, the filtering half mask shall be considered unsatisfactory.	✓			No comment
Art 3.8	**Finish of parts** Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs	✓			

Article of PPE-R/02.075 version 2	Content	Conformity*			Comments
		Yes	No	N-A	
Art 3.9	**Penetration of filter material** The Maximum penetration of sodium chloride aerosol at 95l/min of the filter of the filtering half masks against COVID-19 shall not exceed 6%.	✓			Date of test: 03/09/2020
Art 3.10	**Compatibility with skin** Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	✓			Manufacturer statement
Art 3.11	**Carbon dioxide content of the inhalation air** The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	✓			Date of test: 03/09/2020 CO_2 (As Received) 0,73% 0,75% 0,72%

* The measurement uncertainties are not taken into account for the assessment of conformity.

Sodium chloride penetration of filter material tests results

Conditioning	As Received		
Exposure (120mg)	1,1	1,1	1,1
Penetration (3min)	1,1	1,0	1,0

Values in %

apave

Article of PPE-R/02.075 version 2	Content	Conformity*			Comments
		Yes	No	N-A	
Art 3.12	**Head harness** The head harness shall be designed so that the filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the filtering half mask firmly in position.	✓			Self-Adjusting ear loop harness
Art 3.13	**Field of vision** The field of vision is acceptable if determined so in practical performance tests	✓			See Art 3.7
Art 3.14	**Exhalation valve(s)** A filtering half masks against COVID-19 may have one or more exhalation valve(s), which shall function correctly in all orientations			✓	
	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the filtering half masks against COVID-19 to comply with 3.9.			✓	
	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.			✓	
	When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10 N applied for 10s.			✓	
Art 3.15	**Breathing resistance** The breathing resistances apply to valved and valveless filtering half masks and shall meet the requirements FFP2 of Table 2.				Date of test: 03/09/2020
	Tableau 2 – Breathing resistance				
	Classification / Maximum permitted resistance (mbar) — inhalation 30 l/min: FFP1: 0.6; FFP2: 0.7; FFP3: 1 — inhalation 95 l/min: FFP1: 2.1; FFP2: 2.4; FFP3: 3 — exhalation 160 l/min: FFP1: 3.0; FFP2: 3.0; FFP3: 3.0	✓			
Art 3.16	**Demountable parts** All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.			✓	

* The measurement uncertainties are not taken into account for the assessment of conformity.

Breathing resistance tests results

Conditioning	As Received		
at 30l/min	0,37	0,35	0,35
at 95l/min	1,29	1,25	1,26
at 160l/min	1,73	1,65	1,68

Values in mbar

Article of PPE-R/02.075 version 2	Content	Conformity			Comments
		Yes	No	N-A	
Art. 4	**Marking**				
Art 4.1	**Packaging**				
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.				
	- The name, trademark or other means of identification of the manufacturer or supplier.	✓			
	- Type-identifying marking.	✓			
	- The intended use, which must be stated only as “Filtering half mask to protect against COVID-19”	✓			
	- The number and version of This RFU. Eg ; PPE-R/02.075 version 2	✓			
	- At least the month and year of end of shelf life. The end of shelf life may be informed by a pictogram.	✓			
	- The sentence ‘see information supplied by the manufacturer’, at least in the official language(s) of the country of destination, or by using a pictogram.	✓			
	- The manufacturer’s recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram.	✓			
Art 4.2	**Filtering half mask**				
	Filtering half-mask against COVID-19 complying with this Recommendation for use shall be clearly and durably marked with the following:				
	- The name, trademark or other means of identification of the manufacturer or supplier.	✓			
	- Type-identifying marking.	✓			
	- The intended use, which must be stated only as “COVID-19”	✓			
	- The number and version of This RFU. Eg ; PPE-R/02.075 version 2	✓			
	- Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.			✓	
Regulation	CE Marking (CE + Notified body in charge of module C2 or D) ;	✓			
	The CE marking shall be affixed visibly, legibly and indelibly to the PPE ;	✓			
	For PPE subject to ageing: the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging ;	✓			
	Name and address of the manufacturer ;	✓			
	Type, batch or serial number or other means of identification	✓			

Article of PPE-R/02.075 version 2	Content	Conformity			Comments
		Yes	No	N-A	
	Concerning the instruction for use: Only the English version has been checked. It is the responsibility of the manufacturer to supply the instruction for use in the official languages of the country of destination				
Art. 5	**Information to be supplied**				
	Information supplied by the manufacturer shall accompany every smallest commercial available package.			✓	
	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.			✓	
	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on				
	- application/limitations;	✓			
	- the meaning of any colour coding;			✓	
	- checks prior to use;	✓			
	- donning, fitting. In particular, the user information shall includes a clear and comprehensive fit test and shall includes warnings that the fit is critical to the performance of the product	✓			
	- use;	✓			
	- maintenance (e.g. cleaning, disinfecting), if applicable;			✓	
	- storage;	✓			
	- the meaning of any symbols/pictograms used of the equipment.	✓			
	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	✓			
	Warning shall be given against problems likely to be encountered, for example:				
	- fit of filtering half mask (check prior to use);	✓			
	- it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;	✓			
	- air quality (contaminants, oxygen deficiency);	✓			
	- use of equipment in explosive atmosphere.	✓			
	With the absence of a flammability test, a specific warning shall be included:	✓			
	- “Warning - this product is not flame resistant and must not be used in areas with open flames”				
	The information shall provide recommendations as to when the filtering half mask shall be discarded.	✓			
	For devices without cleaning, disinfecting procedure, a warning shall be given that the filtering half mask shall not be used for more than one shift.	✓			
	The Information to be supplied by the manufacturer shall include the sentence: “This filtering half mask is manufactured for COVID-19 protection only. As requested by World Health Organization recommendations, for this specific use, the nominal protection factor given by this filtering half mask is the same than the FFP2 nominal protection factor defined in EN 149:2001+A1:2009. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.”	✓			
Regulation	Name and address of the manufacturer;	✓			
	Name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE (module B and module C2 or D) ;	✓			
	EU declaration of conformity or the internet address where the EU declaration of conformity can be accessed ;	✓			
	The risk against which the PPE is designed to protect ;	✓			
	The reference to this Regulation	✓			
	The references to the relevant harmonised standard(s) used, including ; the date of the standard(s), or references to the other technical specifications used ;	✓			

10.Conclusion

The PPE category III – Filtering half mask to protect against COVID-19 identified in paragraph 4 meets the Essential Health and Safety Requirements of PPE Regulation 2016/425 of 9th march 2016.

The assessment of conformity takes into account the compliance of the PPE with the provisions of European coordination sheet PPE-R/02.075 version 2, and with the conformity of manufacturer's technical documentation.

M.MEPI.325.V1

In enforcement of Regulation 2016/425 of the European Parliament and of the Council of 9th March 2016 on Personal Protective Equipment and repealing the Directive 89/686/EEC and in compliance with the Module B Certification Scheme of Apave 'M.MEPI.45' in force,
En exécution du Règlement 2016/425 du Parlement Européen et du Conseil du 9 mars 2016 relatif aux Equipements de Protection Individuelle et abrogeant la Directive 89/686/CEE et en respect du Programme de Certification Module B de l'Apave 'M.MEPI.45' en vigueur,

APAVE Sudeurope SAS, notified body identified under number 0082, awards the
APAVE Sudeurope SAS, organisme notifié identifié sous le numéro 0082, attribue l'

EU TYPE-EXAMINATION CERTIFICATE

Attestation d'examen UE de type

N° 0082/3823/079/12/20/0851

The following PPE type complies with the applicable essential health and safety requirements
Le type de l'EPI suivant est conforme aux exigences essentielles de santé et de sécurité applicables

PPE: PPE category III – Filtering half mask to protect against COVID-19
EPI : *EPI de catégorie III – Demi-masque filtrant pour protéger de la COVID-19*

Trademark: **Venus**
Marque commerciale

Model: **Venusmask95** Reference: **Venus95**
Modèle *Référence*

Manufacturer: Viet Nam Venus Import And Export Investment Joint Stock Company km35 - Provincial road 379 - Tan Tien Town - VAN GIANG DISTRICT - Hung Yen Province - Viet Nam
Fabricant

Description: Filtering half mask to protect against COVID-19 without exhalation valve, limited to one shift use. The half mask is foldable with a vertical fold flat shape, designed with a noseclip in high density polyethylene and two self-adjusting ear loop harnesses in rubber fibers and cotton. The filter media is composed of five layers in polypropylene (detailed description in EU type examination report 20.1428).
Description : *Demi-masque filtrant pour protéger de la COVID-19 sans soupape expiratoire, limité à un seul port. Le demi-masque est de forme plate à pliage vertical, conçu avec une barrette nasale en polyéthylène haute densité et deux brides auto-réglables en fibres de caoutchouc et coton portées derrière les oreilles. Le média filtrant est composé de cinq couches en polypropylène (description détaillée dans le rapport d'examen UE de type 20.1428).*

Technical referential in use: European coordination sheet PPE-R/02.075 version 2
Référentiel technique utilisé

Date of signature (day/month/year): 17/12/2020
Date de signature (jour/mois/année)

Date of issue (day/month/year): 17/12/2020
Date de délivrance (jour/mois/année)

Date of renewal (day/month/year): first edition
Date de renouvellement (jour/mois/année) *1ère édition*

Date of expiry (day/month/year): 17/12/2021
Date d'expiration (jour/mois/année)

PPE Certification Manager
Le Responsable de la Certification EPI
Immaterial original

VILA COSARSI
validation électronique

Accréditation N° 5-0596
Scope available on
Portée disponible sur
www.cofrac.fr

Apave Sudeurope SAS
Centre d'Essais et de Certification EPI
17, Boulevard Paul Langevin
38600 FONTAINE - France
Tél. +33.(0)4.76.53.52.22

For category III PPE, the certificate shall only be used in conjunction with one of the conformity assessment procedures referred in point c) of Article 19
Pour les EPI de catégorie III, l'attestation ne doit être utilisée qu'en liaison avec l'une des procédures d'évaluation de la conformité visées à l'article 19, point c).
The manufacturer shall inform the notified body of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate *(article 7.2 – annex V)*
Le fabricant informe l'organisme notifié de toutes les modifications du type approuvé et de toutes les modifications de la documentation technique qui peuvent remettre en cause la conformité de l'EPI aux exigences essentielles de santé et de sécurité applicables ou les conditions de validité de cette attestation (article 7.2 – annexe V)

APAVE SUDEUROPE SAS
PPE TESTING AND CERTIFICATION CENTRE
17 boulevard Paul Langevin
38600 FONTAINE - France
Tel : +33 (0)4 76 53 52 22

PPE – SUPERVISED PRODUCT CHECK (MODULE C2 – PPE REGULATION)

PROPOSAL OF AGREEMENT N° M.MEPI.405.En.V1

FILTERING HALF-MASK TO PROTECT AGAINST COVID-19

Dear Madam, Dear Sir,

You will find hereafter our proposal of contract for the check of your PPE Category III – filtering half-mask to protect against COVID-19 according to PPE-R/02.075 - in application of requirement of annexe VII (module C2) of the PPE Regulation 2016/425.

Please make sure that this proposal meets your needs.

If you are satisfied with this proposal of agreement, please send us back the completed purchase order form in appendix 1 with the PPE samples.

We remain at your disposal for any further information.

Hoping to be honoured by your confidence, we ask you to accept the expression of our sincere greetings.

The PPE Technical manager

Enclosed documents:

- Supervised product check (module C2)
- Appendix 1 : Purchase order – simple form
- Appendix 2 : Certification program
- Appendix 3 : APAVE General Conditions of Sale and Intervention

PPE ASSESSMENT ACCORDING TO MODULE C2

1- CERTIFICATION PROGRAMM

The certification scheme is enclosed in appendix 2 of the present proposition.
This proposal fits into the framework of an extraordinary event as defined in the certification scheme.

2- PPE LIST

One model of filtering half-mask to protect against COVID-19 according to PPE-R/02.075 for which a type-examination certificate (annex V, module B of the PPE Regulation 2016/425) has been issued by APAVE SUDEUROPE SAS.

We remind you that PPE which have been the subject of a type-examination certificate but for which no 'module C2' service has been carried out within a period of one year cannot be placed on the market with CE 0082 marking.

3- DESCRIPTION OF THE ASSESSMENT

The assessment consists in the following phases:

3.1- PPE sampling

Sampling must be performed according to following conditions:

- Masks being considered as PPE relatively not voluminous, the samples of the PPE concerned have to be sent to our laboratory by your company not later than 8 months after the date of issue of the type-examination certificate.

Please note that to avoid customs fees, samples shipped from a country outside of the European Union must:
1- Be clearly identified as "samples for destructive testing, without commercial value". With a maximum declared value of 22 Euros.
2- Add the following complete sentence: "definitive import with community code C33 (exonerate from customs duties and VAT)"
Any customs fees that we would have to pay will be charged back to you.

- **Number of samples to send**: 5 boxes of the smallest sales unit and at least 50 masks (including instructions for use in French or in English)

Examples:

The sales unit is a box of 2 masks	→ Send 25 boxes
The sales unit is a box of 5 masks	→ Send 10 boxes
The sales unit is a box of 10 masks	→ Send 5 boxes
The sales unit is a box of 20 masks	→ Send 5 boxes
The sales unit is a box of 50 masks	→ Send 5 boxes

3.2- Tests on sampled PPE

The tests according to PPE-R/02.075 will be carried out by our laboratory and the results will be compared with the limits admitted by the technical standard taken as reference.
The process followed in case of non-compliance is described in the attached certification scheme.

3.3- Control of the certified PPE, instruction for use and marking

APAVE controls:

- the homogeneity of the batch (comparison between samples received)
- by comparison the identity of at least one sample with one archived PPE during the type examination (module B).
- the compliance of the instruction for use and marking with the applicable requirements

3.4- Evaluation report and certificate of PPE check

An evaluation report reflecting the results of the tests and controls carried out on the samples taken will be sent to the manufacturer.

If this report does not show a lack of homogeneity of production or a non-conformity with the type described in the type-examination certificate and the essential health and safety requirements, a certificate of PPE check according to module C2 will be sent to the manufacturer.

4- PRICE CONDITIONS

On the basis defined above, the amount for our service is:

- **Checking 2021 for 1 model of filtering half-mask to protect against COVID-19 according to module C2**

4 350 Euros

Note: provided that the applicable requirements to your PPE do not change and that your PPE is not modified, the tests carried out within the framework of the C2 control may be taken into account for the renewal of the EU type-examination certificate (module B).

This price includes:
1. The tests of the sampled PPE
2. The controls defined above
3. The electronic sending of the assessment report in English and of the certificate of PPE check (in English and French) according to module C2

This price does not include:
1. Any additional test or control following the tests and controls carried out on sampled PPE

5- OTHERS CONDITIONS

5.1- Validity of the offer

This offer is only valid as long as the extraordinary event is proven and for a maximum of 8 months from the date of sending this proposal by email.

5.2- Payment

At the signing of the proposal of agreement, the customer expressly agrees that 100% of the total value of the contract subscribed will be charged to the order.

In case of premature interruption of the service, the invoices issued will be considered as acquired.

Payment will be made by check or wire transfer, within 30 days of the date of invoicing. These conditions prevail over any other condition.

5.3- General conditions of intervention

This offer is subject to the APAVE General Conditions of Sale and Intervention edition November 2019.

6- DEMATERIALIZATION OF DOCUMENTS

This proposition of agreement is sent by email only.

Certification documents (report and certificate) will be sent in pdf files by email only to address(es) indicated in the purchase order in appendix 1.

The customer acknowledges the validity and probative value of these files. All precautions must be taken by the Customer so that this mail can be received in good conditions (warning in case of change of recipient or address, antispam ...)

APPENDIXES

Appendix 1 – Purchase order – To be sent with the samples

For each model you want to send for module C2, please fill in the form below then send us your samples with the complete copy of this offer to:

Shipping address

APAVE SUDEUROPE SAS
CENTRE D'ESSAIS ET DE CERTIFICATION EPI
17 boulevard Paul Langevin
38600 FONTAINE - France

Customs fees

Please note that to avoid customs duties, samples shipped from a country outside the European Union must:
1- Be clearly identified as "samples for destructive testing, with no commercial value". With a declared value of 22 Euros maximum
2- Add the following complete sentence: "final import with Community code C33 (exempts customs duties and VAT)"

WARNING, samples must be sent to our laboratory by your company no later than 8 months after the date of issue of the certificate.

Order's form:

The applicant, hereinafter defined, declares that he has read and accepted this proposal including the certification program and the general conditions of sale and intervention APAVE SUDEUROPE SAS.

Company placing the purchase order (will receive the invoices)	
Company name: ..... Postal address: .... Email address to send the invoice: ..... VAT number (for EU company only):	Name and position in the company: .... Date : ..... Signature : ***Company stamp*** ↓
Email address(es) to send module C2 report and certificate	

The purchase order will be validated by APAVE after verification of the information supplied by the applicant, sending the order acknowledgment serving as acceptance.

Concerned PPE:

We wish to carry out the supervised product check (Module C2) for the filtering half-mask to protect against COVID-19 identified below:

PPE: Filtering half mask to protect against COVID-19 - PPE-R/02.075	
EU type examination certificate number	0082/
Manufacturer name	
Date of issue	
Trademark	
Model	
Reference	
Number of boxes sent for module C2	

Appendix 2 - Certification scheme (M.MEPI.43_V2)

1- GOAL

This document constitutes the certification program for the control of PPE production (Personal Protection Equipment) in application of module C2 ('Conformity to type based on internal production control plus supervised product checks at random intervals') of PPE Regulation (EU) 2016/425.

2- PURPOSE

This certification program applies to PPE covered by the scope of Apave's notification which can be consulted on the Nando webpage at (http://ec.europa.eu/growth/tools-databases/nando/).

NOTE: in the following program, the term 'customer' also includes the PPE 'manufacturer' as well as their potential representative.

3- APPLICABLE REFERENCES

1- **Regulation (EU) 2016/425** of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC,

2- **State of the art** specified in the proposition of certification agreement sent to the customer:
The harmonized European standards (whether applicable in part or whole) published in OJEU,
The applicable European coordination sheets
Any other applicable technical specification to meet the essential health and safety requirements of the Regulation.

4- PPE CONTROL ACTIVITIES MODULE C2

This paragraph concerns any evaluation following an initial request or a renewal of the certification decision.

1.1. Evaluation

APAVE:

Verifies the completeness of the evaluation request.

In order to verify the homogeneity of production of the PPE and their conformity with the EU type-examination certificate and to the applicable essential health and safety requirements:

1. Carries out on-site evaluation (at least once a year, at random intervals).
2. If applicable, verifies the treatment of non-conformities issued during the previous evaluation
3. Samples the manufactured PPE in order to determine if the manufacturing process ensures homogeneous production.
4. Examines the sampled PPE and conducts appropriate tests (*) in order to verify the PPE conformity with the type described in the EU type-examination certificate and the applicable essential health and safety requirements.

(*) The tests are conducted:

Either within APAVE laboratories, in compliance with ISO Standard 17025 (accreditation scope available on the Cofrac website at www.cofrac.fr),
Or sub-contracted to a laboratory qualified by APAVE.

Where the EU type-examination certificate has been issued by this another notified body, APAVE will make contact with this body in the event of difficulties arising related to evaluating the sample's conformity.

1.2. Reports

APAVE will deliver to the customer an evaluation report, based on module C2, listing the activities carried out.

Where the type meets the applicable essential health and safety requirements, APAVE will deliver to the customer a PPE production control statement based on module C2.

The PPE production control statement limit of validity, based on module C2, is a maximum of one year.

Note: in the event of an extraordinary event, the assessment described above may be affected, see chapter 7.

5- APAVE RESPONSIBILITIES

If the examinations and tests reveal that the production is not homogeneous or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, APAVE will take measures appropriate to the fault(s) recorded and will inform the notifying authority thereof.

APAVE will ensure compliance with the use of APAVE deliverables and the CE conformity marking.

Information relating to the customer obtained from sources other than the customer itself (for example, from a complainant or the regulation authorities) is considered to be confidential.

Publicly available information

APAVE updates and provides, upon request, the following information:

a) information on the PPE certification scheme,

b) description of the customer's rights and responsibilities, including the requirements, restrictions or limitations regarding the use of the APAVE name, as well as how to indicate that certification has been issued.

APAVE informs the customer of any non-conformities.

If one or several non-conformities arise, and if the customer wishes to pursue the certification process, APAVE will provide information on the additional evaluation tasks required in order to verify that the non-conformities have been corrected.

If the customer gives their agreement to perform the additional evaluation tasks, the evaluation process must be repeated in order to perform these tasks.

The customer will be informed of any decision, taken by APAVE, to refuse to issue a statement based on module C2, by specifying the reasons why.

If the certification is terminated (upon request from the customer), suspended or withdrawn, APAVE will take the measures described by the Regulation.

APAVE will inform the customer in the event of a revision or new requirement to this certification scheme.

APAVE follows developments in generally-recognized industry practices. Where this development suggests that the type approved would no longer comply with the applicable essential health and safety requirements, APAVE will determine if supplementary examinations are required. If this is the case, APAVE will inform the customer thereof.

APAVE keeps an up-to-date directory of certified products, including, as a minimum:

a) the product identification,

b) the legal texts upon which conformity was based,

c) the customer's name,

d) the validity of said certification.

This information may be provided upon request. The certifying body must, as a minimum, provide, on request, information relating to the validity of a certificate issued.

6- CUSTOMER RESPONSIBILITIES

The customer stamps the CE marking and, under APAVE's responsibility, its identification number 0082 on each PPE conforming to the type described in the EU type-examination certificate and meeting the applicable requirements of the PPE Regulation.

The customer takes all measures necessary for the manufacturing process, and the monitoring thereof, to ensure homogeneity of production and the manufactured PPE's conformity with the type described in the EU type-examination certificate and the applicable requirements of the Regulation.

The certification agreement commits the customer to comply with, as a minimum, the following points:

a) implement any appropriate change communicated by APAVE ;

b) make any declarations regarding the PPE certificate in accordance with the documents issued by APAVE;

c) not to use the certification of its products in such a way which could harm APAVE, nor make a declaration regarding the certification of its products which APAVE may consider to be misleading or unauthorized;

d) in the case of a refusal to issue the module C2 statement or upon expiry of the certification :

- cease placing on the market the PPE concerned,
- cease using all the publicity means which refer to the certification,
- undertake any other measure required;

e) reproduce in their entirety the copies of the certification documents issued by APAVE to others;

f) comply with any other requirements which may be specified in the product certification program relating to the use of the conformity marking and to the product information;

g) inform APAVE of any findings of non-quality registered between two module C2 production controls which may impact the PPE's conformity with the essential health and safety requirements;

h) correct, by means of appropriate action, any incorrect references in this certification scheme or any misleading use of the production control statement based on module C2, the marking, or any other means of indicating that a product is certified, appearing in the documentation or on other publicity means.

7- EXTRAORDINARY EVENTS

This chapter describes the taking into account of an "extraordinary event" on the evaluation module C2.

According to the terms of the document IAF ID 3 (« Management of Extraordinary Events or Circumstances […] »), are considered as 'extraordinary event' an event (or circumstance) such as: war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters

If such an event is confirmed and prevents meeting the deadlines granted to the evaluation actions, the following process is used and the customer is informed.

If Apave has already issued a module C2 evaluation report to the customer, the expiration date of the certificate of conformity for module C2 can be extended by 6 months.

If this is not possible (examples: initial control, beyond the 6-month extension, etc.) the on-site assessment (see 4.1 a)) is not carried out.

Customer responsibility

The customer must guarantee by mail that the manufacturing process and its monitoring ensure the homogeneity of production and the conformity of the PPE manufactured to the type described in the EU type examination certificate and to the applicable requirements. of the Regulation.

ARTICLE 1 - SCOPE

These general conditions define APAVE's general conditions of sale and intervention.
The umbrella term APAVE is used to refer to any of the following entities within the Apave group: Apave, Apave Alsacienne SAS, Apave Parisienne SAS,
Apave Nord Ouest SAS, Apave Sudeurope SAS, Apave Développement SAS and generally any Apave entity. There shall be no joint and several liability between the Apave entities.
Only the entity signatory of Apave's offer or the contract with the client is liable for the services provided for therein and liable for damages or litigation rise during execution of the same.
The special conditions and potentially the technical appendices attached to the offer or contract may be complement of this document. In case of conflict, contradiction or inconsistency between the general conditions and the special conditions, the special conditions will prevail over these general conditions solely in relation to these points of divergence. In case the Client's general conditions of purchase are applicable, these general conditions of sale prevail over the points of divergence, unless specific agreement.
Apave's missions are defined in Apave's offers, in the contracts entered with clients or in Apave' service sheets available on request.

ARTICLE 2 - CLIENT OBLIGATIONS

Apave acts upon the request of the client. For periodic audits as may be required by applicable regulations, Apave can propose a schedule of visits by sending a notice of intervention. However, this procedure can in no way commit Apave in respect of the periodicity of the audits as the responsibility for compliance therewith lies exclusively with the client who must initiate them.
It is the client's responsibility to make all arrangements to ensure the successful completion of the Apave mission and in particular:

- In terms of health and safety, the client must comply with regulations in force, particularly those relating to missions performed by an external company;
- It must appoint a qualified person (also with the necessary authorizations, as required) to assist the Apave service provider at the request of Apave;
- It must manage the operations necessary for the execution of the mission and operate the installations;
- It must provide a means of access to the equipment and installations falling within the scope of the intervention;
- It must provide all technical documents relating to the equipment and installations falling within the scope of the project;
- It must provide all information on changes and incidents occurring in relation to equipment and installations falling within the scope of the project;
- Depending on the field of intervention, it must comply with the special provisions as outlined in the appendices of the offer;

In general, it must provide sufficient resources to enable the Apave contractor to effectively complete their intervention, without wasting time and in normal safety conditions.
In the event of recurring non-compliance issues, Apave reserves the right to exclude the concerned installations and devices from its scope of mission, by notifying the client through registered letter with acknowledgment of receipt ("AR").
Unless stated otherwise, the report is sent as a PDF file by email. The client recognizes the validity and the probative force of this file. The Client must take all necessary precautions to ensure that the email is received in good conditions (notification in the case of a change of recipient or address, antispam filters, etc.).
When the intervention gives rise to a written report and/or the signing of regulatory registers at the time of the intervention, the client is responsible for storing the reports, minutes and other relevant documents, unless otherwise required by regulations.
If the client does not receive the report within the time frame specified by regulations or, failing that, within 5 weeks of the agreed date, it should submit a claim to Apave, by any means and providing proof of such a claim. In the absence of such a claim, the client is deemed to have received the report.
In general, Apave strives to personally perform interventions with which it is entrusted. However, it reserves the right to subcontract all or some of its responsibilities insofar as this is not prohibited by regulations.
As part of its accreditations, the Apave employee is likely to be accompanied on site by a Cofrac appraiser

ARTICLE – 3 PRICING AND INVOICING

Unless specifically stated otherwise, prices are given in Euros, exclude taxes and either:
Correspond to the price scale in force on the date of the service provision; or
Are negotiated between the parties for each service within the context of an accepted quote.
They are established according to the information provided by the client and appearing on a proposal submitted for its acceptance.
Any intervention outside of business hours - that is to say not between the hours of 8 a.m. and 5 p.m., on evenings, weekends, public holidays and in emergencies, will be subject to the following surcharge:
50% at night;
25% on Saturdays;
100% on Sundays and public holidays;
40% in emergencies (meaning if the time between the receipt of the request and the start of the intervention is less than 48 hours).
Moreover, an additional amount may be charged in the following cases:
€70 for every hour spent waiting to perform the service;
20% of the initial amount of the service in the case of the Apave service provider was not accompanied by a representative of the client.
Any event occurring during the execution of the project for which the client is responsible and which leads to an increase in the duration of the project will be subject to an additional charge of €350 per half day excluding taxes.
Any intervention that is canceled less than 3 days before the scheduled start date, at the request of or because of the client, will give rise to a charge of €350 excluding taxes.
In addition, if the Apave service provider had to travel, the corresponding expenses will be invoiced separately, with the corresponding price scale being available to the client upon request.
Invoices will be issued according to the conditions provided for in the contract:
A provisional invoice issued at the beginning of the year with a final statement being issued after the execution of the intervention; or
An invoice sent after the completion of the work for projects of a short duration; or
Advance payment invoices issued as the work progresses with the final statement being issued after the completion of the work.
Apave reserves the right to automatically terminate the contract in the case of non-payment of its compensation after a reminder sent by registered mail with AR has remained without effect.
If the client requests a subsequent change to the scope of the service, it will notify Apave of this in writing. Any change that is likely to significantly affect the duration and scope of Apave's services, including during the first mission, will be subject to a price adjustment.

ARTICLE 4 – PRICE REVISION

For contracts that are automatically renewable, prices will be revised on January 1 each year, without prior agreement, according to the following revision formula: P=P0(0.4SYN/SYN0 + 0.6 ICHTrev-TS/ICHTrev-TS0) in which: P = updated price, P0 = price on the contract date, SYN = Syntec index (last known index), SYN0 = Syntec index on the contract date, ICHTrev-TS = all employee hourly labor cost (last known index), ICHTrev-TS0 = same index on the contract date.
For non-recurring interventions and those exceeding twelve months, prices will be revised according to the above mentioned formula.

ARTICLE 5 - DELAI DE PAIEMENT – PENALITES DE RETARD

Invoices are payable within the statutory time frame without discount in accordance with the payment schedule set out in the offer.
Unless stated otherwise, invoices are payable within 30 days of the invoice date.
Any delayed or defaulted payment will entitle Apave, without prior notice, to liquidated damages equal to three times the legal interest rate in force, calculated from the net amount appearing on the invoice.
In accordance with the provisions of Law No. 2012-387 of March 22, 2012, Apave reserves the right to require payment of a lump-sum compensation of €40 excluding taxes from the client to cover collection costs, without any prior formality. Where the collection costs incurred by Apave are greater than this lump sum compensation, Apave may ask the Client for additional compensation upon presentation of supporting documents.

ARTICLE 6 – CONFIDENTIALITY AND INTELLECTUAL AND INDUSTRIAL PROPERTY

Apave ensures the confidentiality of information relating to objects, inspected installations, communicated documents or companies involved. No information will be made publicly available, except if required to do so pursuant to any legal obligations.
No document relating to the project may be disclosed to third parties without the prior written consent of the client, except in case of obligations resulting from authorizations, notifications, requisitions or other administrative constraints. However, unless the client expressly objects thereto, it agrees to appear on the reference lists of Apave, who undertakes to respect the client's brand image and comply with its communication policy.
IP rights included in any document established by Apave and delivered to the client remains the property of Apave. The client is granted a right of use for his own needs or for compliance with the regulations in force. Any other use, such as for example, without this list being limited, resale or reuse for purposes of external training to the client, is prohibited except express agreement, written and prior to Apave.
Any use of the APAVE trademark or logo is prohibited unless expressly agreed in writing in advance with Apave's Management. Apave's clients are not authorized to use the COFRAC trademark.

ARTICLE 7 – DONNEES PERSONNELLES

The Parties undertake to comply with the regulations in force applicable to the processing of personal data, set out in the General Data Protection Regulation (the "GDPR") of the European Parliament and of the Council of 27 april.
Apave uses information held about the client in the following ways : Business and Contract related communications ; notification, execution of the contract , in accordance with the data protection policy available on our website : https://www.apave.com/politique-de-protection-des-donnees. The client acknowledges that Apave reserves the right to unilaterally update its data protection policy as needed, which the client expressly accepts.
In the event of sub-contracts, an agreement on the subcontracting of personal data will be formally concluded.

ARTICLE 8 - LIMITATIONS – LIABILITIES

- Apave acts as a service provider and is subject to an obligation of means.
- Apave provides its services with reference to the technical and scientific data existing at the time of its interventions.
- For every intervention, the client must ensure that the Apave employee is accompanied at all times by a qualified person who will provide all relevant information to ensure the safe completion of the project.
- The Apave contractor must never be allowed to supervise or use the device, machine, installation or more generally the item on which he/she is working. As a result, Apave cannot be held liable for the operation and use of these installations, devices, machines or accessories falling within the scope of inspection interventions to be carried out. The client retains custody and liability, including in cases where the Apave service provider has been forced to stand in for the client, who has not complied with the conditions defined above (Article 2) or if it is acting upon the instructions of the client.
- Apave service providers cannot carry out by themselves any assembly or disassembly work or a destructive survey.
- Apave is prohibited from any involvement in the management or handling of the work, operation, use and maintenance of installations and equipment.
- Unless stated otherwise in the special conditions, Apave is not responsible for ensuring that its observations, information or advice are acted upon.
- Apave works on installations that are presented to it by the client and therefore it cannot be held liable in the case of audits that would not involve the entire installation.
- Unless stated otherwise, Apave performs audits using surveys (in a statistical sense) or sampling. Information provided by Apave can thus be regarded as being exhaustive in nature.
- Apave cannot be held liable for the degradation or destruction of equipment and installations submitted for trials or tests, if this is the result of trials or tests that have been performed in usual and standard conditions. Only gross negligence by the Apave service provider having carried out the operations is likely to result in Apave being potentially liable.
- Apave's liability is strictly limited to compensation for direct damages suffered by the client and up to 5 times the net amount of the fees paid. In any event, indirect and/or consequential damages (particularly loss of profits, loss of revenues, loss of image) suffered by the client or any third party are expressly excluded.
- Beyond the limits and exclusions provided for in the preceding paragraph, the client waives all rights of recourse against Apave and its insurers and must obtain the same waivers from its own insurers. The client will indemnify and hold Apave and its insurers harmless from any recourse if it does not manage to obtain the said waivers.
- The claims and appeals process is described in the Apave Quality Manual available at www.apave.com

ARTICLE 9 – TERMINATION

In the case of periodic audits and unless stated otherwise, the contract is concluded for a minimum duration of 1 year and is automatically renewable from year to year, unless otherwise stipulated by either party, by registered letter with AR, with a notice of at least 3 months before the expiry date.

In the event of a failure by the client to perform any of its obligations, Apave reserves the right terminate any services in progress, without compensation, within a period of 1 month after formal notice sent by registered letter with AR has remained unsuccessful. The foregoing is without prejudice to any damages that Apave may claim. In this case, the services will be payable by the client within 30 days, it being understood that any completed visit will be due.

ARTICLE 10 - ETHICS AND SUSTAINABLE DEVELOPMENT

Apave is committed to an ethical approach defined in its Codes and reference documents available on its website https://www.apave.com/a-propos/ethique-et-quality. The customer acknowledges having read and accepted these documents.

ARTICLE 11 - INSURANCE

Apave has an insurance policy covering its civil liability. A certificate can be sent to the client upon request.
The client must be insured against risks that may affect Apave's service providers as well as incidents and accidents for which the client would be liable.

ARTICLE 12 - FORCE MAJEURE

In the case of force majeure affecting one party, the parties agree that such party will not be held liable for the partial or total non-performance of any of its obligations under the contract.
To this end, they agree to consider strikes and the inaccessibility of the client's site because of a strike or exceptional weather conditions as cases of force majeure, in addition to those cases traditionally accepted as such by the jurisprudence of the French courts.

ARTICLE 13 - JURIDICTION

THESE GENERAL TERMS AND CONDITIONS ARE SUBJECT TO FRENCH LAW.
ANY CLAIM BETWEEN THE PARTIES AND ANY DISPUTE THAT MAY ARISE WILL FALL WITHIN THE EXCLUSIVE COMPETENCE OF THE COMMERCIAL COURTS OF THE HEAD OFFICE OF THE APAVE ENTITY WHO PERFORMED THE SERVICES.

SPECIAL TERMS FOR MEASURING AND TESTING

These conditions are specific to laboratory work, measurement, tests and analyses. They are a supplement to the general terms Apave. In the event of any contradiction between these special terms and the general Apave terms, the former prevail over the latter.

1. CODES AND STANDARDS

Except in the case of written instructions from the customer, the tests and/or analyses shall be performed in accordance with applicable standards or, if appropriate, with our internal procedures, which include any existing industry standards.

If a standard exists, the laboratory shall use the most recent applicable version, no later than 9 months following its publication and except in the case of any other specific requirements.

Services performed under COFRAC Laboratory's accreditation shall be performed by all or part of the accredited Apave sites numbered 1-1457, 1-1458, 1-1461, 1-0292, 1-0970, 1-1269, 1-0678, 1-0943, 1-6424 (list of accredited sites and scopes available on www.cofrac.fr).

2. ORDER

Prior to any service provision, the customer must confirm its agreement, either by means of a written order or by returning a signed and stamped quotation.

In the absence of a written order, the quotation with the most recent index is presumed to meet its requirements. The arranging of an appointment with Apave to perform the assignment, or the sending of samples, implies acceptance by the customer of the terms of the contract.

3. CANCELLATION OR POSTPONEMENT OF THE LABORATORY ASSIGNMENT PRIOR TO COMMENCING

Any cancellation of the assignment by the customer within 5 working days or less will be subject to billing for an amount equal to the cost of a day of service by a scheduled participant plus any expenses already incurred.

4. MODIFICATIONS DURING THE SERVICE PROVISION PHASE

Any new data sent or made available at the start of the service provision may modify the content and, if necessary, be the subject of an amendment. If the initial content of the assignment is modified during the tests at the request of the customer, the customer must notify those involved on-site and give its consent in writing for the drafting of an amendment noting this modification and its financial consequences.

In the absence of written agreement, the performance of assignments subject to modifications, specified in the report, is presumed to meet the requirements and implies acceptance by the customer.

In the case of changes or adjustments in the conditions for performing the assignment compared to those stipulated in the contract, the customer shall be warned in advance in the case of a negative impact (the impact is evaluated according to applicable contractual and regulatory requirements).

5. REQUESTS FOR SUPPLEMENTARY TESTS

Any request for supplementary tests subsequent to the findings shall be the subject of a quotation and additional billing.

6. TRANSPORT - PACKAGING

Unless specified otherwise in the contract, the transport of material between Apave and the customer's site, together with transport insurance costs, shall be paid by the customer.

Subsequently, risks related to transport and their financial and other consequences are the responsibility of the customer, which is fully liable for these operations, even when organized by Apave.

7. RESULTS AND REPORTS

7.1. Provisional results

Provisional results sent prior to the report are communicated for information purposes only and are not binding upon Apave. Under no circumstances they may be deemed a substitute for the report, which cancels and replaces any provisional results.

7.2. Canceled and replaced reports

The customer agrees to return the copies of any reports that have been canceled and replaced with a new index, or take all measures to withdraw the distributed reports from circulation.

7.3. Measurement uncertainties

In the absence of a written request from the customer, and except if required by a standard explicitly applicable under the contract, uncertainties are not provided with results.

In cases where measurement results are compared to regulatory minimum/maximum values to evaluate compliance, uncertainties are provided, but not taken into account, except in cases of a written request from the customer or if required by a standard explicitly applicable under the contract.

7.4 Opinions and interpretations

Opinions or interpretations will be provided for the Customer if Apave deems they are necessary for understanding the results.

8. PRESERVING SAMPLES THAT HAVE BEEN TESTED AND ANALYZED

Unless specified otherwise in the quotation, samples that have been tested or analyzed are kept for a period of two months as from the date of sending the report, before disposal.

Beyond this period, if the customer wishes to preserve the samples, according to its needs or obligations, it is the customer's responsibility to claim them from the laboratory. Any dispatch costs incurred by returns at the request of the customer are subject to additional billing.

For analyses of drinking water, samples are kept for 20 days or 10 days in cases of putrescible samples. They may be recovered at the initiative of the customer, in exchange for a receipt.

9. CHEMICAL ANALYSIS

Case 1 - Apave collects and transports the samples to the laboratory:

Apave undertakes to take measures and comply with applicable standards to ensure an acceptable level of preservation of samples prior to analysis or testing.

Case 2 - The customer collects and sends the samples:

The customer is presumed to know or to have obtained information from the laboratory as regards indications of applicable standards in terms of preservation periods and conditions (including transport), bottling and volume.

In the case of failure to comply with indications of applicable standards and if necessary, Apave shall notify the customer in order to decide whether to continue with the analysis and reserves the right not to perform the analysis.

10. TESTS ON PRODUCTS

Apave is not bound to provide any reimbursements for products or prototypes damaged during the implementation of tests or when performing tests.

11. SAFETY

Our employees are equipped with PPE (Personal Protection Equipment) corresponding to normally predictable risks noted in our Single Document. Any specific PPE outside of this framework that is required by the relevant site will be billed additionally and will be subject to an amendment.

EDITION NOVEMBRE 2019

APAVE SUDEUROPE SAS
PPE TESTING AND CERTIFICATION CENTER
17 bd Paul Langevin
38600 FONTAINE – France

To: Viet Nam Venus Import And Export Investment Joint Stock Company
km35 - Provincial road 379
Tan Tien Town
VAN GIANG DISTRICT - Hung Yen Province
Viet Nam

Ref: FTPL1/**20.12.4890**
Object: Registration of application for supervised product checks at random intervals (Module C2)

Fontaine, the 17/12/2020

To Whom It May Concern,

We hereby confirm that according to PPE regulation 2016/425 annex VII article 3, the manufacturer Viet Nam Venus Import And Export Investment Joint Stock Company lodges an application for supervised product checks at random intervals (module C2) with us (notified body APAVE SUDEUROPE SAS, n°0082) for:

Type of PPE:	Filtering half mask to protect against COVID-19
Trade mark:	Venus
Model:	Venusmask95
Reference:	Venus95

EU type examination (module B) Certificate Number:
0082/3823/079/12/20/0851

According to PPE regulation 2016/425 annex VII article 4.2, the first product checks will be carried out no more than one year after the date of issue of the EU type examination certificate.

Head of Testing and Certification Centre

Sébastien THIOLLIER

2020

CERTIFICATE OF REGISTRATION

This certifies that:

VIETNAM VENUS IMPORT AND EXPORT INVESTMENT JOINT STOCK COMPANY
Km. 35 Provincial Road, 379
Tan Tien Town
Van Giang District Hung Yen, VN 17000

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations.

Establishment Owner/Operator Number:	**10076510**
Device Classification Name:	**FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER HE GUIDANCE**
Product Code:	**QKR**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

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info@registrarcorp.com • www.registrarcorp.com

David Lashari
Executive Director
Registrar Corp
Dated: July 23, 2020

2020

CERTIFICATE OF REGISTRATION

This certifies that:

VIETNAM VENUS IMPORT AND EXPORT INVESTMENT JOINT STOCK COMPANY
Km. 35 Provincial Road, 379
Tan Tien Town
Van Giang District Hung Yen, VN 17000

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations.

Establishment Owner/Operator Number:	**10076510**
Device Classification Name:	**RESPIRATOR, SURGICAL**
Product Code:	**MSH**
Regulation Number:	**878.4040**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Leonarz
Executive Director
Registrar Corp
Dated: July 27, 2020

2020

CERTIFICATE OF REGISTRATION

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VIETNAM VENUS IMPORT AND EXPORT INVESTMENT JOINT STOCK COMPANY
Km. 35 Provincial Road, 379
Tan Tien Town
Van Giang District Hung Yen, VN 17000

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10076510**
Device Classification Name:	**RADIOGRAPHIC PROTECTIVE GLOVE**
Product Code:	**IWP**
Regulation Number:	**892.6500**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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David Lemarz
Executive Director
Registrar Corp
Dated: July 27, 2020

2020

CERTIFICATE OF REGISTRATION

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Tan Tien Town
Van Giang District Hung Yen, VN 17000

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10076510**
Device Classification Name:	**NON-SURGICAL ISOLATION GOWN**
Product Code:	**OEA**
Regulation Number:	**878.4040**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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David Lennarz
Executive Director
Registrar Corp
Dated: July 27, 2020

CERTIFICATE

No.: YT 337-20

VIET NAM VENUS IMPORT AND EXPORT INVESTMENT JOINT STOCK COMPANY

9Km 35 provincial road 379, Tan Tien commune, Van Giang district, Hung Yen province, Vietnam

has been assessed and found to conform
with the requirements of the following standard:

ISO 13485:2016

Quality Management System

for the following activities:

**Production and trading of medical masks;
trading of medical gloves and protective clothing for medical use**

This certificate is valid from:
29 / 6 / 2020 to 28 / 6 / 2023

CERTIFICATION BOARD
CHAIRMAN

Assoc. Prof. Dr. Hoang Thi Thanh Nhan

ON BEHALF OF DIRECTOR
VICE DIRECTOR

Dr. Ngo Tat Thang

INSTITUTE FOR STANDARD AND QUALITY DEVELOPMENT STUDIES
Office: No. 52, lane 46, Lien Mac road, Lien Mac ward, Bac Tu Liem district, Ha Noi city, Vietnam
Tel: 024 3266 1111 Email: tcvn@tiso.org.vn


COMMITTED TO
SAFETY
VENUS VIETNAM®
FFP2 NR
PPE-R/02.075 VERSION 2
CE 0082

Thank you!