



DOCUMENTATION

MASK ULTRA PROTECTION FFP2

MASCARILLA ULTRA PROTECCIÓN FFP2

MASQUE FFP2 ULTRA PROTECTION FFP2

MASCHERINA PROTEZIONE ULTRA FFP2

REF. CV-41
DR.HZ / HZ96



MASTER BOX: 1000 pcs



ITEM: HZ96

DESCRIPTION: NAAMIO

MATERIAL:

5 PLY (47% non woven, 31% Meltblown, 22% algodón).

QUANTITY: 1.000

G.W

N.W

CNT SIZE

BATCH NUMBER:

PRODUCTION DATE:

VALIDITY:

产品名称: FFP2防护口罩(非医用)
执行标准: EN149:2001+A1:2009
生产厂商: 深圳市和正实业发展有限公司
生产地址: 深圳市龙华区观湖街道松元厦社区环境中路172号兆业厂房601
MADE IN P.R.C.



FFP2
Equipo de Protección Individual (EPI)
Personal Protective Equipment
EN 149:2001+A1:2009
CE 2161 FFP2 NR
Filtration Efficiency ≥ 95%
PC25

MASCARILLA
ULTRA PROTECCIÓN FFP2

3. Alta eficiencia
Eficacia de protección
≥ 95%


4. Alta movilidad
Eficacia de maniobrabilidad
≥ 95%


5. Confortable para el usuario
Confortable para el usuario
≥ 95%


6. Resistente al agua
Resistente al agua
≥ 95%


FFP2
EQUIPO DE PROTECCIÓN INDIVIDUAL
PERSONAL PROTECTIVE EQUIPMENT
EN 149:2001+A1:2009
CE 2161 FFP2 NR
Filtration Efficiency ≥ 95%
PC25

MASCARILLA
ULTRA PROTECCIÓN FFP2



EU DECLARE OF THE CONFORMITY

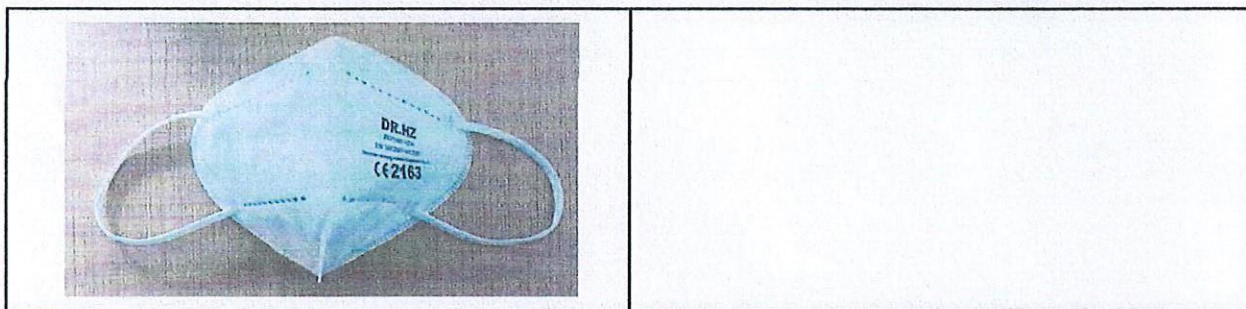
We

Company name:	Shenzhen Hezheng Industrial Development Co., Ltd
Postal address:	601 Zhaoye Workshop, No.172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen City, Guangdong Province, China
Postcode:	518110
City:	Shenzhen

Declare that the DoC is issued under our sole responsibility and belongs to the following products:

Apparatus model/Product:	HZ96
Type:	Filtering half mask

Object of the declaration(identification of apparatus allowing traceability. It may include a colour image of sufficient clarity where necessary for the identification of the appearance)



The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

Personal protective equipment Regulation(EU)2016/425

The following harmonised standards and technical specifications have been applied:

Title, Date of standards/specification:

EN149:2001 +A1 :2009

Notified body (where applicable)	4 digit notified body number
UNIVERSAL CERTIFICATION AND SURVEILLANCE SERVICE TRADE LTD. CO.	2163
Certificate Number:	2163-PPE-1400
Technical report numbered:	2163-KKD-1400

Signed for and on behalf of

Guangdong,China

Sep.07.2020

Place of issue

Date of issue



Name,function,signature General Manager

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1400

Respiratory protective devices, filtering half masks to protect against particles manufactured by
Shenzhen Hezheng Industrial Development Co., Ltd.

601 Zhaoye Workshop, No. 172, Huanguanzhong Road, Songyuanxia Community, Guanhu
Street, Longhua District, Shenzhen City, Guangdong Province, China

are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices -
Filtering Half Masks to Protect Against Particles -
Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file
according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved
that the product meets the requirements of the regulation.

Product Definition

Brand Name: Dr.HZ **Model:** HZ96

Filtering half mask

Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as
shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2)** or **Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **02/09/2020** and will be valid for 5 years, if there is no
change in the relevant harmonised standard affecting the essential health and safety
requirements.



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director



CERTIFICATE OF CONFORMANCE**Certificate No: 2163-PPE-1400/01**

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Shenzhen Hezheng Industrial Development Co., Ltd.

601 Zhaoye Workshop, No. 172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen City, Guangdong Province, China

Continues to fulfil the requirements of

**EN 149:2001 + A1:2009 Respiratory Protective Devices -
 Filtering Half Masks to Protect Against Particles -
 Requirements, Testing, Marking**

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
Dr. HZ / HZ96	FFP2 NR	2163-PPE-1400	02.09.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **29/09/2020** and will be valid for one year, until **28/09/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.




Suat KACMAZ
 UNIVERSAL CERTIFICATION
 Director



TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 02.09.2020 / 2163-KKD-1400

Manufacturer: Shenzhen Hezheng Industrial Development Co., Ltd.

Address: 601 Zhaoye Workshop, No. 172, Huanguanzhong Road, Songyuanxia Community, Guanhu Street, Longhua District, Shenzhen City, Guangdong Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Guojian Testing Technology Co., Ltd. accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L10118 for the product identified below, dated 22.06.2020 with Serial Id (2020)WSZ FHL NO.6182 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 28 August, 2020 Version 01 provided by the manufacturer.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personal Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

Product Description: Particle Filtering Half Mask

Classification: FFP2 NR

Brandname: Dr.HZ **Model:** HZ96



**ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425
CORRESPONDING RISKS FOR THE PRODUCT**

1.1. Design principles

1.1.1. Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level.

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other inherent nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

1.3 Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

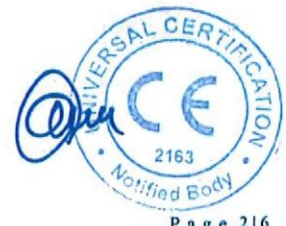
Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

1.4. Information supplied by the manufacturer

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

- In addition to the name and address of the manufacturer and/or his authorized representative established in the Community
- Storage, use, cleaning, maintenance, servicing and disinfection, cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
- Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
- Suitable PPE accessories and the characteristics of appropriate spare parts;
- The classes of protection appropriate to different levels of risk and the corresponding limits of use;
- The obsolescence deadline or period of obsolescence of PPE or certain of its components;
- The type of packaging suitable for transport;
- The significance of any markings (see 2.12)
- Where appropriate the references of the Directives applied in accordance with Article 5(6) (b);
- The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination



2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by 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.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must remain perfectly legible throughout the foreseeable useful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.

If PPE (or a PPE component) is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.

The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.

The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.

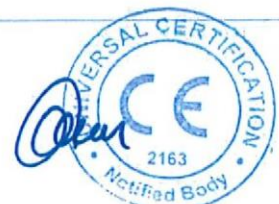
In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.



Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the
(EU) 2016/425 Directive



Conforming to EN 149:2001 + A1:2009 Standard Requirements

Article 5	<p>Classification: Particle Filtering Half Mask The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as; Filtering Efficiency and Maximum Total Inward Leakage: Classified as FFP2 Mask is classified for single shift use, NR</p>																																							
Article 7.4	<p>Packing: Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report.</p>																																							
Article 7.5	<p>Material: Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users.</p> <p>Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.</p>																																							
Article 7.6	<p>Cleaning and Disinfection: Particle filtering half mask is not designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.</p>																																							
Article 7.7	<p>Practical Performance: The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfections reported during total inward tests about the comfort, field of vision and fastening issues.</p> <table><tr><th>Assessed Elements</th><th>Positive</th><th>Negative</th><th>Requirements in accordance with EN 149:2001 + A1:2009 and Result</th></tr><tr><td>2.Head harness comfort</td><td>2</td><td>0</td><td rowspan="3">Positive results are obtained from the test subjects No imperfections</td></tr><tr><td>3.Security of fastenings</td><td>2</td><td>0</td></tr><tr><td>5.Field of vision</td><td>2</td><td>0</td></tr></table> <p>Conditioning: (A.R.) As Received, original</p>	Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result	2.Head harness comfort	2	0	Positive results are obtained from the test subjects No imperfections	3.Security of fastenings	2	0	5.Field of vision	2	0																									
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3.Security of fastenings	2	0																																						
5.Field of vision	2	0																																						
Article 7.8	<p>Finish of Parts: Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.</p>																																							
Article 7.9.1	<p>Total Inward Leakage: The Total Inward Leakage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the conduction of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each excersize are available in the test report.</p> <p>It was reported that: All 50 exercise measurement results are smaller or equal to 11%, the values varies between 2.4% and 6.1%. All 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 3.5% and 5.0%.</p> <p>According to the reported results, the product meets the limits for FFP2 classification.</p>																																							
Article 7.9.2	<p>Penetration of filter material: Sodium Chloride Testing</p> <table><tr><th>Condition</th><th>No. of Sample</th><th>Sodium Chloride Testing 95 L/min max (%)</th><th>Requirements in accordance with EN 149:2001 + A1:2009</th><th>Result</th></tr><tr><td>(A.R.)</td><td>-</td><td>0.1</td><td rowspan="3">FFP1 ≤ 20 %</td><td rowspan="10">Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1, FFP2 and FFP3 classes.</td></tr><tr><td>(A.R.)</td><td>-</td><td>0.1</td></tr><tr><td>(A.R.)</td><td>-</td><td>0.2</td></tr><tr><td>(S.W.)</td><td>-</td><td>0.1</td><td rowspan="2">FFP2 ≤ 6 %</td></tr><tr><td>(S.W.)</td><td>-</td><td>0.2</td></tr><tr><td>(S.W.)</td><td>-</td><td>0.1</td><td rowspan="5">FFP3 ≤ 1 %</td></tr><tr><td>(M.S. T.C.)</td><td>-</td><td>0.2</td></tr><tr><td>(M.S. T.C.)</td><td>-</td><td>0.3</td></tr><tr><td>(M.S. T.C.)</td><td>-</td><td>0.2</td></tr><tr><td>(M.S. T.C.)</td><td>-</td><td>0.2</td></tr></table> <p>Conditioning: (M.S.) Mechanical Strength (T.C.) Temperature Conditioning (A.R.) As Received, original (S.W.) Simulated wearing treatment</p> <p>95 L/min = 1,6 dm³.sn⁻¹</p>	Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result	(A.R.)	-	0.1	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1, FFP2 and FFP3 classes.	(A.R.)	-	0.1	(A.R.)	-	0.2	(S.W.)	-	0.1	FFP2 ≤ 6 %	(S.W.)	-	0.2	(S.W.)	-	0.1	FFP3 ≤ 1 %	(M.S. T.C.)	-	0.2	(M.S. T.C.)	-	0.3	(M.S. T.C.)	-	0.2	(M.S. T.C.)	-	0.2
Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result																																				
(A.R.)	-	0.1	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1, FFP2 and FFP3 classes.																																				
(A.R.)	-	0.1																																						
(A.R.)	-	0.2																																						
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(M.S. T.C.)	-	0.2																																						



Article 7.9.2	Penetration of filter material: Paraffin Oil Testing					
	Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result	
	(A.R.)	-	0.2	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1, FFP2 and FFP3 classes.	
	(A.R.)	-	0.3			
	(A.R.)	-	0.3			
	(S.W.)	-	0.3			
	(S.W.)	-	0.3			
	(S.W.)	-	0.2			
	(M.S. T.C.)	-	0.8			
	(M.S. T.C.)	-	0.7			
(M.S. T.C.)	-	0.9				
Conditioning: (M.S.) Mechanical Strength (T.C.) Temperature Conditioning (A.R.) As Received, original (S.W.) Simulated wearing treatment						
Article 7.10	Compatibility with skin: In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.					
Article 7.11	Flammability:					
	Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result	
	(A.R.)	-	Burn for 0.1s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed Filtering half masks fulfill requirements of the standard	
	(A.R.)	-	Burn for 0.1s			
	(T.C.)	-	Burn for 0.1s			
	(T.C.)	-	Burn for 0.1s			
Conditioning: (A.R.) As Received, original (T.C.) Temperature Conditioning						
Article 7.12	Carbon dioxide content of the inhalation air:					
	Condition	No. of Sample	CO ₂ content of the inhalation air [%] by volume	An average CO ₂ content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
	(A.R.)	-	0.7057	0.70[%]	CO ₂ content of the inhalation air shall not exceed an average of 1,0% by volume	Passed Filtering half masks fulfill requirements of the standard
	(A.R.)	-	0.7015			
	(A.R.)	-	0.7027			
Conditioning: (A.R.) As Received, original						
Article 7.13	Head harness: In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.					
Article 7.14	Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is worn.					
Article 7.15	Exhalation Valve(s): The model under inspection have no valves.					
Article 7.16	Breathing Resistance: Inhalation					
	The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temperature conditioning and 3 simulated wearing treatment complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min. Passed.					

Article 7.17	Clogging: This test is not applied to Particle Filtering Half Mask which is not reusable. (For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)
Article 7.18	Demountable Parts: There are no demountable parts on the product.
Article 8	Testing: All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask.
Article 9	Marking – Packaging: Necessary markings are available on the product package (box). The name and trademark of the manufacturer is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the year of end of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 9.1 of the technical file. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing HZ96. The mask template (drawing) indicates that the mask will carry information about the name and the brandname (Shenzhen Hezheng Industrial Development Co., Ltd. / Dr.HZ) of the manufacturer, type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. Even the tested samples by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model HZ96 drawing exists in the technical file of the manufacturer, Annex 6 of technical file.
Article 10	Information to be supplied by the manufacturer: In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate, Annex 8. The manufacturer shall include this documented user information text in every smallest commercially available package.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert 	Suat KAÇMAZ Director  

Test Report No.: 178139783a 001

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Client: Shenzhen Hezheng Industrial Development Co., Ltd
601 Zhaoye workshop, No. 172, huanguanzhong Road, Songyuanxia community,
Guanhu street, Longhua District, Shenzhen

Contact Person: Fang Fang

Sample Description As Declared :

No. Of Sample : 90 Pcs
Product Description : KN95 Particulate Respirator(HZ96)
Colour : White
Country of Origin : China
Sales Destination(country) : US/ EU(country name not provided)
Product End Use : Protection
Test type : Partial Test
Product type : Single shift use only
Claimed Classification : **FFP2 NR**

Sample obtaining method: Sending by customer**Sample Receiving date:** 2020-05-06**Delivery condition:** Apparent good, Samples tested as received**Test Period:** 2020-05-09 to 2020-06-19**Test specification:****Test result:**

Particulate respirator-half facepiece
EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks
to protect against particles - Requirements, testing, marking^

Please refer to result page

For and on behalf of

TÜV Rheinland / CCIC (Qingdao) Co., Ltd.



2020-06-22

Alex Zhou / Senior Manager

Date

Name/Position

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed.
This test report relates to the above mentioned test sample. Without permission of the test center this test report is not
permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Material list

Material	Color	Location
Textile	White	White folding mask

Note:

	Shading shows the clauses requested
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "result details section for more information.
Fail	Requirement not satisfied. Refer to the "result details section for more information.
NAs	Assessment not carried out.
NAP	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

Result:

EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirement, testing, marking.

7.4 Package[^] PASS¹

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

Note 1: In accordance with the requirement.

7.5 Material[^] PASS²

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Note 2: In accordance with the requirement.

Specimens -08, -20, -37 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.

Specimens -14, -28, -44 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

7.6 Cleaning and disinfecting[^] NAP³

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.

Note 3: Single shift use only.

7.7 Practical performance[^]
PASS⁴

The particle filtering half mask shall undergo practical performance tests under realistic conditions

Note 4: No imperfections.

Specimen and subject details:

Specimen	Subject
-47	SM
-63	LCF

7.8 Finish of parts[^]
PASS⁵

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note 5: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 Total inward leakage[^]
PASS⁶

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3;

And, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3.

Note 6: 46 out of the 50 individual exercise results were not greater than 11%; 8 of the 10 individual wearer arithmetic means were not greater than 8%. Detailed data are showed below.

Table 7.9.1-A Inward leakage test data

Test specification: EN149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head Up/down(%)	Talk(%)	Walk(%)	Mean(%)
LZM	-09	A.R.	2.4	6.5	10.8	6.4	3.5	5.9
YZF	-22	A.R.	5.0	9.0	9.9	10.5	5.5	8.0
GJB	-36	A.R.	5.8	8.1	5.8	6.1	2.9	5.7
JLX	-56	A.R.	4.7	9.4	6.6	5.0	4.9	6.1
TLX	-74	A.R.	3.6	12.6	11.6	7.6	7.2	8.5
TS	-13	T.C.	3.8	10.3	5.6	7.3	5.5	6.5
SM	-29	T.C.	6.3	10.3	8.6	7.2	6.1	7.7
LCF	-43	T.C.	7.0	14.3	14.7	8.2	6.7	10.2
ZH	-62	T.C.	6.5	8.5	8.1	4.4	6.3	6.8
YB	-80	T.C.	2.9	8.1	6.7	6.0	4.2	5.6
Maximum permitted			11					8

Table 7.9.1-B Facial dimension

Subject	Face length(mm)	Face width(mm)	Face Depth(mm)	Mouth Width(mm)
LZM	118	157	124	44
YZF	113	151	106	48
GJB	109	154	109	57
JLX	119	152	109	59
TLX	104	153	112	40
TS	97	146	102	51
LCF	119	165	121	56
SM	116	144	109	49
ZH	102	152	113	55
YB	112	150	119	66

7.9.2 Penetration of filter material^

PASS

The penetration of the filter of the particle filtering half mask shall meet the requirements of below:

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	≤ 20%	≤ 20%
FFP 2	≤ 6%	≤ 6%
FFP 3	≤ 1%	≤ 1%

Table 7.9.2- Penetration of filter material

Test specification: EN149-2001 Clause 8.11

Test specification: EN14126:1 Clause 5.1.1					
Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			After 3 minutes	Max. during exposure	
Sodium chloride test	A.R.	-17	0.39		PASS
		-27	0.16		
		-64	0.25		
	S.W.	-19	0.11		
		-46	0.40		
		-68	0.16		
	M.S. + T.C.	-23	0.63	0.70	
		-51	0.39	0.39	
		-72	0.42	0.42	
Paraffin oil test	A.R.	-30	0.25		
		-52	0.45		
		-75	0.24		
	S.W.	-35	0.24		
		-55	0.32		
		-04	0.37		
	M.S. + T.C.	-42	0.38	0.83	
		-58	0.43	0.93	
		-03	0.51	1.07	
Maximum permitted		6			
Flow conditioning:		Single filter: 95.0 L/min			

7.10 Compatibility with skin[^]
PASS⁷

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.

Note 7: Specimens -10, -21, -38, -53, -69 (A.R.) and specimens -15, -33, -45, -61, -73 (T.C.) were tested. No irritation or any other adverse effect to health.

7.11 Flammability[^]
PASS

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Table 7.11- Flammability

Test specification: EN149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
A.R.	-24	Burn for 0.4 s	PASS
	-39	Burn for 0.8 s	
T.C.	-31	Burn for 0.5 s	
	-50	Burn for 0.6 s	

7.12 Carbon dioxide content of the inhalation air[^]
PASS

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).

Table 7.12- Carbon dioxide content of the inhalation air

Test specification: EN149-2001 Clause 8.7

Condition	Sample No.	Result	Assessment
A.R.	-18	0.42%	PASS
	-54	0.43%	
	-60	0.46%	
Maximum permitted		1.0%	

7.13 Head harness[^]
PASS⁸

The head harness shall be designed so that the particle 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 particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Note 8: Specimens -12, -26, -49, -65, -76 (A.R.) and specimens -16, -34, -59, -71, -05 (T.C.) were tested. Head harness (ear straps) can be donned and removed easily, adjustable or self-adjusting, have sufficiently robust to hold the face mask firmly enough to satisfy the total inward leakage requirements. See 7.9.1 for results.

7.14 Field of vision[^]
PASS⁹

The field of vision is acceptable if determined so in practical performance tests.

Note 9: Specimens -41 and -67 (A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 Exhalation valve^
NAP

A particle filtering half mask 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 particle filtering half mask to comply with 7.9.

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 faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

7.16 Breathing resistance^
PASS ¹⁰

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min x 2.0 l/stroke)
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

Note 10: FFP2 Filtering face mask. Test result are shown in below Table.

Table 7.16 Breathing resistance (mbar)

Test specification: EN149-2001 Clause 8.9

Specimen	Condition	Inhalation resistance(mbar)		Exhalation resistance(mbar)				
		At 30 l/min	At 95 l/min	Breathing machine(25 cycles/min x 2.0 l/stroke)				
				A	B	C	D	E
-11	A.R.	0.36	1.34	2.92	2.91	2.93	2.94	2.91
-25		0.37	1.36	2.95	2.92	2.91	2.96	2.95
-32		0.38	1.38	2.96	2.98	2.92	2.91	2.94
-40	T.C.	0.35	1.29	2.87	2.86	2.86	2.84	2.81
-48		0.36	1.31	2.87	2.86	2.81	2.81	2.85
-57		0.35	1.30	2.89	2.92	2.87	2.83	2.81
-66	S.W.	0.36	1.34	2.92	2.89	2.91	2.87	2.86
-70		0.37	1.36	2.98	2.92	2.83	2.93	2.95
-79		0.35	1.31	2.91	2.87	2.85	2.89	2.85
	A.R. + F.C.							
	T.C. + F.C.							
Maximum permitted		0.7	2.4	3.0				

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side.

7.17 Clogging^

 NRq¹¹

7.17.2 Breathing resistance

Valved particle filtering half masks:

After clogging, the inhalation resistances shall not exceed,

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95 l/min continuous flow;

The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Valveless particle filtering half masks:

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95 l/min continuous flow.

7.17.3 Penetration of filter material

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	≤ 20%	≤ 20%
FFP 2	≤ 6%	≤ 6%
FFP 3	≤ 1%	≤ 1%

Note 11: Single shift use only.

7.18 Demountable parts^

 NAp¹²

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

Note 12: No demountable parts were used.

9 **Marking^** NRq
9.1 **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.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". ID This letter shall follow the classification marking preceded by a single space.

9.2 **Particle filtering half mask^**

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space(see 9.2.4).

Example FFP3 NR D, FFP2 R D.

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

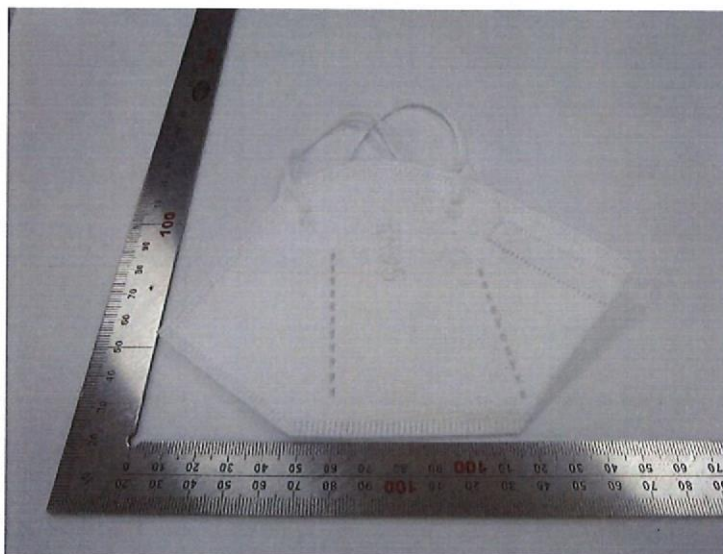
10 Information to be supplied by the manufacturer^

NRq

- 10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.
- 10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.
- 10.3 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; use; maintenance(e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.
- 10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.
- 10.5 Warning shall be given against problems likely to be encountered, for example:
- fit of particle 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.
- 10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.
- 10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.

Remark: "^" indicates that the test is sub-contracted to the lab China Academy of Safety Science and Technology which complies with the requirement of ISO/IEC 17025:2017, the registration No. CNAS L0118.

Photo:



- END -

1.1 These G

2. **Quotations**
Unless otherwise agreed, all quotations submitted by TÜV Rheinland can be changed by TÜV Rheinland without notice prior to its acceptance and confirmation by the other party.

3. Coming into

4.1 The scope and type of the services to be provided by TÜV Rheinland shall be specified in the contractually agreed service scope of TÜV Rheinland by both parties. If no such separate service scope of TÜV Rheinland exists, then the written

4.2 The agreed services shall be provided at the time the contract is entered into.

4.3 In the case of inspection work, TÜV Rheinland shall not be responsible for the accuracy or checking of the safety programmes or safety regulations on which the inspections are based, unless otherwise expressly agreed in writing.

4.6 If mandatory legal regulations and standards or official requirements for the agreed service scope change after conclusion of the contract, with a written notice to the client,

5.1 The contractually agreed periods/dates of performance are based on estimates of the work involved which are prepared in line with the details provided by the client. They shall only be binding if being confirmed as binding by TÜV Rheinland in writing.

5.3 Articles 5.1 and 5.2 also apply, even with extensions of agreed periods/dates of payment.

6. The client's obligation to cooperate

6.1 The client shall guarantee that all cooperation required on its part, its agents or third parties will be provided in good time and at no cost to TDV

6.2 Design documents, supplies, and all of the services shall be made available to the contractor.

if the client breaches the aforesaid representations and warranties, TÜV Rheinland is entitled to 1) immediately terminate the contract order without prior notice; and 2) withdraw the issued testing certificates if any.

7.1 If the scope of performance is not laid down in writing when the order is placed, invoicing shall be based on costs actually incurred. If a prior is agreed in writing,

7.2 Unless otherwise agreed
work.

8.1 All invoice amounts shall be due for payment without deduction on receipt of the invoice. No discounts and rebates shall be granted.

8.2 Payments shall be made to the bank account of TÜV Rheinland as indicated on the invoice, stating the invoice and check numbers.

8.3 In cases of default of payment, TÜV Rheinland shall be entitled to claim default interest at the applicable short term loan interest rate publicly announced by a

8.4 Should the client default in a reasonable grace period. The

Acceptance of work

Any part of the work result ordered which is complete in itself may be presented to TÜV Rheinland for acceptance as an instalment. The client shall be obliged to present it immediately.

deceased to have taken part in the work, unless the client is found to be a habitual offender.

It is also to be understood that lump-sum damages in the amount of 10% of the order amount as compensation for expenses if the server is not called within one year after the order has been placed. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above mentioned lump sum.

The disclosing party shall mark all confidential information disclosed in written form as confidential before passing it onto the receiving party. The same applies to confidential information transmitted by e-mail. If confidential information is disclosed orally, the receiving party shall be appropriately informed in advance and the disclosing party shall confirm in writing the confidentiality nature of the information within five working days of oral disclosure. Where the disclosing party

All confidential information which the discloses to the receiving party and which

The receiving party may disclose any confidential information received from the disclosing party only to those of its employees who need this information to perform the services required for the contract. The receiving party undertakes to oblige the employees to observe the same level of secrecy as set forth in this confidentiality clause.

All confidential information shall remain the property of the disclosing party. The receiving party hereby agrees to immediately (i) return all confidential information, including all copies, to the disclosing party, and/or (ii) on request by the disclosing party, to destroy all confidential information, including all copies, and confirm the destruction of this confidential information to the disclosing party in writing, at no time if so requested by the disclosing party but at the latest and on or before the date of the termination of this Agreement.

Copyrights and rights of use, publications

TUV Rheinland shall retain all exclusive copyrights in the reports, expert reports/opinions, test reports/results, results, calculations, presentations etc.

use such reports, expert reports/opinions, test reports/results, results calculations, presentations etc. prepared within the scope of the contract for the contractually agreed purpose.

Any publication or duplication of the work
further use of the work results beyond the

Liability of TÜV Rheinland

of a contract for annually recurring
of a contract expressly charged on
from an individual amount to less

The client to support TÜV Rheinland in the performance of its services under the contract, unless such personnel made available is regarded as a vicarious agent of TÜV Rheinland. If TÜV Rheinland is not liable for the acts of the personnel made available by the client under the foregoing provision, the client shall indemnify TÜV Rheinland against any claims made by third parties arising from or in connection with such engagement by the client.

in passing on the services provided by TÜV Rheinland or parts thereof to third parties in Greater China or other regions, the client must comply with the respectively applicable regulations of national and international export control law, notification of a request with the client is subject to the region that these are in

entitled to terminate the contract for the...

reason for deletion arises. Data subjects may exercise the following right of information, right of rectification, right of deletion, right of processing limitation, right of objection, right of data transferability. In addition, persons concerned by the data processing have the right to revoke their consent any time with effect for the future, as well as the right to file a complaint with the competent data protection supervisory authority. For further details

TÜV Rheinland by

damaged test material shall be stored by TÜV Rheinland for four (4) weeks after completion of the test. If a longer storage period is desired, TÜV Rheinland charges an appropriate storage fee.

15.2

terminate the contract which includes but is not limited to the following:

- the client does not immediately notify TÜV Rheinland of changes in the conditions within the contract;
- the company which is relevant for certification or signs of such changes;
- the client misuses the certificate or certification mark or uses it in violation of the contract;
- in the event of several consecutive delays in payment (at least three times);
- substantial deterioration of the financial circumstances of the client occurs and as a result of this the client is no longer able to fulfil its obligations.

contractual relationships
the cost of termination with

that HIV Related within the scope of a certification procedure and the certificate therefor has to be withdrawn (for example during the performance of monitoring audits). Clause 16.3 applies accordingly.

Should one or several of the provisions under the contract and/or these terms and conditions be or become ineffective, the contracting parties shall replace the invalid

if TUV Rheinland is in question is legally registered and existing in Taiwan, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Taiwan.

if TUV Rheinland is in question is legally registered and existing in Hong Kong, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Hong Kong.

People's Republic of China, to China International Economic and Trade Arbitration Commission (CIETAC) to be settled by arbitration under the Arbitration Rules of CIETAC in force when the arbitration is submitted. The arbitration shall take place in Beijing, Shanghai, Shenzhen or Chongqing as appropriately chosen by the claiming party.

Arbitration is submitted in accordance with these rules. The arbitration shall take place in Hong Kong.