

EU DECLARATION OF CONFORMITY

Distributor: JBM CAMPLLONG, S.L.U.

Address: CIM La Selva – Crta. Aeroport Km 1.6 Nave 2.2, 17185 Vilobí d'Onyar

CIF (VAT number): B17419292

Description of the product: FFP2 protective mask

Manufacturer's reference number: SY95-1

Distributor's reference number: 537870

The object of the declaration is in conformity with the Regulation (EU) 2016/425 on personal

protective equipment and the following standard:

Standard	Title	Edition/Date
EN149	Respiratory protection equipment. Filtration and protection	2001+A1:2009
	masks against particles. Requirements, tests and marking.	

EU type certificate issued by:

Universal Certification and Surveillance Service Trade Ltd. Co.

Notified Body No.: 2163

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No: 44/84 Yukarı Dudullu

Ümraniye-Istanbul

Turkey

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Homologation No.: 2163-PPE-635/01

Test report No.: PPE-2163-636

Signed by:



Eduard Godoy

Purchasing department director



CERTIFICATE OF CONFORMANCE

Certificate Nr: 2163-PPE-635/01

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

HANGZHOU SHANYOU MEDICAL EQUIPMENT CO. LTD.

at the following manufacturing site

No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou, 311266, Zhejiang, 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. The details of compliance is given in technical report numbered 2163-PPE-636/01

Model	Class	EU Type	Examination C	Certificate
WIOUEI	Class	Serial Nr.	Date	Issuing NB Nr.
SY95-1	FFP2	2163-PPE-635	28/04/2020	2163

Product Definition

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 28/04/2020 and will be valid for one year, until 27/04/2021 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.



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<u>Suat KAÇMAZ</u> UNIVERSAL CERTIFICATION Director



The validity of this certificate can be verified online.



EU TYPE EXAMINATION CERTIFICATE

Certificate Nr: 2163-PPE-635

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

HANGZHOU SHANYOU MEDICAL EQUIPMENT CO. LTD.

No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou, 311266, Zhejiang, 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. The details of essential requirement compliance is given in technical report numbered 2163-PPE-636.

Product Definition

Brand Name: WORK 沃克 Model: SY95-1

Filtering half mask Total Inwards Leakage: Class – FFP2

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 **28/04/2020** 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 KAÇMAZ UNIVERSAL CERTIFICATION Director



The validity of this certificate can be verified online.



TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 28.04.2020 / PPE-2163-636

Client: HANGZHOU SHANYOU MEDICAL EQUIPMENT CO., LTD Centre Address: No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou, 311266, Zhejiang, CHINA

This report is for the, given above, manufacturer prepared according to the test results obtained for the product dated 25.04.2020 with ID 04-2020-T-050 based on EN 149: 2001 + A1: 2009 standard, 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 Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate No. 2163 - PPE - 635 issued to the manufacturer. The test results and issued certificate belong only to the tested product. The technical report consists of a total of 6 pages. **Product Description :** Particle Filtering Half Mask

Total Inward Leakage: Classification – FFP2 Trademark : WORK Model : SY95-1



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THE CLAUSES OF EN 149: 2001 + A1: 2009 STANDARD RELATED TO EUROPEAN UNION DIRECTIVE EU 2016/425 REQUIREMENTS

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 prossible 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 fore seeable 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 permessible user impediment

Any inpediment 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:

- a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
- b) 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;
- c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
- d) Suitable PPE accessories and the characteristics of appropriate spare parts;
- e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
- f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
- g) The type of packaging suitable for transport;
- h) The significance of any markings(see 2.12)
- i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);

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i) 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

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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 rem ain perfectly legible throughout the foreseeableuseful 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 al lor 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

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

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

						:2009 Standa					
Irticle		Tot	al Inward L	and the second	ication – FFP2						
lrticle 1.4	mechani	cal damage.			are packaged to protect them from contamination before use and with cardboard boxes to preven ring half masks, according to the simulated wearing treatment and temperature conditioning reports; It						
Article 1.5	understo failure o	od withstan	d handling iece or strat	and wear over	the period for	which the parti	cle filtering hal	f mask is design	ned to be us	onditioning report ed, suffered mech t constitute a haz	
Article 1.6	Cleanin	g and Disin	fection : Pa	rticle filtering l	half mask is not	t designed to be	as re-usable.				
	Practica	l Performa	nce : 39 (A	.R), 40 (A.R)					_		
		A	ssessed Elei	ments	Positive	Neg	ative	Requirements in 149:2001 + A			
			ace piece fit		2	and the second se		52 B I	111	L Comp the	
Article			harness con		2	and the second se) Po	sitive results sho performance			
7.7			rity of faster ch clearness		2)	implementation			
	1		of vision		2)				
			rials compa	tibility	2)	No im	perfections	k l	
	0-11	with sk	cin .				,		-		
				ived, original	1.			العمد على محمد م	aua aham -	dage and do not a	
Article 7.8	Finish o burrs.	of Parts: Pa	article filteri	ng half masks,	, which are like	ly to come into	contact with fi	ie user, do not i	lave sharp e	dges and do not o	
	Total In	ward Leak	age:					-			
		Test Subject	No.of sample	Condition	1,Walk	Head left /right	Head up/down	Speech	2. Walk	Average	
		1	32	A.R	5,01	4,70	4,64	5,12	4,89	4,87	
		2	33	A.R	5,12	4,95	4,69	5,10	4,95	4,96	
		3	34	A.R	5,25	5,16	5,12	5,15	5,00	5,14	
		4	35	A.R	5,10	4,95	4,78	5,09	4,85	4,95	
		5	36	A.R	5,19	5,06	5,10	4,98	4,70	5,01	
Article	-	6	16	T.C. T.C.	5,56	5,14 4,89	5,17 4,92	4,95	5,40	5,18	
7.9.1	-	7 8	17	T.C.	5,78	5.02	5,04	5,16	5,53	5,31	
7.9.1		9	19	T.C.	5,45	5,16	5,25	5,08	5,23	5,23	
		10	20	T.C.	5,50	5,47	5,46	5,13	5,35	5,38	
		and the second second			Transfer 1				6.13	6.12	
		Average			5,36	5,05	5,02	5,08	5,12	5,13	
	_	Min			5,01	4,70	4,64	4,95	4,70	4,87	
	Conditi	Max	R) As Rece	ived, original	5,78	5,47	5,46 Results P	(%) Leakage Va		5,50	
	Continu			ture conditioni	and the second se	meet with FFP.					
	Penetra	tion of filte	er material:	Sodium Chlor							
	C	Condition		. of iple	Sodium Chlor 95 L/min 1			ents in accordanc 9:2001 + A1:20		Result	
		(A.R.)	23		3,65						
		(A.R.)	24	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	3,72			10000		ing half masks fu	
		(A.R.)	25		3,83		_	$FFP1 \leq 20\%$		irements of the sta	
Article		(S.W.)	1		3,94 4,24		=	FFP2 ≤ 6 %		EN 149:2001 + A n in 7.9.2 in range	
7.9.2		(S.W.) (S.W.)	2		4,24 4,19			1112 20 70		t and second prote	
		(S.W.) I.S. T.C.)	7		4,46			FFP3 ≤ 1 %		class	
		I.S. T.C.)	8		4,51					(FFP1, FFP2)	
	(N	1.S. T.C.)	9		4,40						
	Conditi			ical Strength					95 L	/min = 1,6 dm ³ .sn	
				ature Condition	ung						
			10	eived, original ted wearing trea	atment			CI	EN TUTIO		
	, 1	(5.	w.j simula	ee wearing the	atment			151	1	21	
11								An	Car	121	
	14								1.	ZIN	

UNIVERSAL SERTIFIKASYON VE GÖZETIM HIZM. TIC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com



			North	Paraffin Oil T	esting Rec	uirements in accordance		Pagult	
	Co	ondition	No. of Sample	95 L/min ma		EN 149:2001 + A1:2009	R	Result	
		(A.R.)	26	4,17					
		(A.R.)	27	4,20			Filtering ha	lf masks fi	lfill the
		(A.R.)	28	4,16		FFP1 ≤ 20 %	requiremen		
I.		(S.W.)	4	3,94			EN EN 149		
Article		(S.W.)	5	3,88		$FFP2 \leq 6\%$	given in 7.9		
.9.2		(S.W.)	6	3,91		EED2 -1.0/	first and s	second prot	ection
		1.S. T.C.)	10	4,06		FFP3 ≤ 1 %	(FF	class FP1, FFP2	10
		.S. T.C.)	11	4,14			(FI	FI, FFF2	
		I.S. T.C.)	12	4,17					
	Conditioning : (ature Conditioning						
		Constraint Annual Constraint and	eived, original	6					
			ted wearing treatm	nent					
Article					hood of mask m	aterials in contact with the	skin causin	g irritation	or other
7.10	adverse effect on								21-8 - 1
	Flammability :	No.	of		Requirer	nents in accordance with I	EN		
	Condition	n Samp		isual inspection		149:2001 + A1:2009	A Laboration	Result	a distan
	(A.R.)	37		1,3		Filtering half mask		Passed	K.
Article	(A.R.)	38		1,4		shall not burn or not			
7.11	(T.C.)	21		1,1		continue to burn for		ing half ma	
	(T.C.)	22		1,2		more than 5 s after moval from the flame	ree	quirements standar	
	Conditioning : (AR) As Rec	eived original		IC	moval nom me name		Standar	u
			ature Conditioning	ø					
	The second second second second second second second second second second second second second second second se		e inhalation air:	5					
			Contraction of the second	112 2 2 2 2 2 2 2 2	An average		series (a)	10010670	Saw See
	Condition	No. of	CO2 content of	f the inhalation air	CO2 content of			R	esult
	Condition	Sample	[%] b	[%] by volume the		the inhalation EN 149:2001 + A1		.2009	
Article	(A D)	41	0	,81	air			р	assed
7.12	(A.R.) (A.R.)	41		.80		00	1.0		
	(/1.1.)	72		,00	0.0	CO ₂ content of the inh		Filtering	, half mas
	(1.0.)	43	0	.79	0,8	shall not exceed an a 1,0% by volur			ulfill
	(A.R.)		0	,19		1,070 09 10101			nents of the
	Conditioning : (A D) As Dec	aived original					Sta	undard
			and the second se		é – je v Dok sou				c 1
Article 7.13	Head harness: position, for tota			rt, No adverse effe	cts have been re	eported for holding the n	hask of the	head harn	ess firmly
									uum seessaar
Article 7.14	Field of vision :	In Practical P	erformance report	t, No adverse effect	s were reported I	for the field of vision featu	res.		
	Breathing Resis	stance: Inhala	tion						
					Inhalation Resist	tance (mbar)	Requirer	monte in	Result
	Condition	No. of	Flow Rate		irements in	Flow Rate	accordar		Result
	Condition	Sample	30 L/mi	accord	ance with EN $01 + A12009$	95 L/min	EN 149	:2001 +	
				149:20	01 + A1:2009		A1:2	2009	all share
	(A.R.)	29	0,4			1,4			
	(A.R.)	30	0,5	FF	$P1 \le 0,6$	1,4	FFPI	$\leq 2,1$	
Article	(A.R.)	31	0,5	rri	1 20,0	1,6	1111	,.	
7.16	(S.W.)	1	0,5	FF	$P2 \le 0,7$	1,6	FFP2	≤2,4	Passed
	(S.W.)	2	0,5 0,6			1,5	-		
	(S.W.)	3 13	0,6	FF	$P3 \le 1,0$ —	- 1,7	FFP3	≤ 3,0	
	(T.C.) (T.C.)	13	0,6			1,7			
	(T.C.)	15	0,6			1,8			
	Conditioning :						0		
			ated wearing treat rature Conditionin						
		(1.C.) Tempe	rature conditionin	ig		1.1	SERV		
						(c)	12/12	1	
	/					A/-	~	2)	
Mol							C.	121	
199						()CA	C.	0	
and the second						1 Parts		Sh	
	12.12.20		ev.00			1. 1	² Page	516	



i.

	No. of Sample	Resistance : Ex Condition	Flow rate	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
	29			2,1	2,1	2,1	2,1	2,1		
	30	As received		2,0	2,1	2,2	2,0	1,9		
	31		-	2,1	2,1	2,0	2,1	1,9		
Article	1	R. 11		2,2	2,0	2,1	2,3	2,0	$FFP1 \leq 3,0$	
7.16	2	Simulated wearing	1601/min	2,0	2,2	1,9	2,0	1,9	FFP2 ≤ 3,0	Passed
	3	treatment		2,0	2,1	2,0	2,1	2,2	FFP3 ≤ 3,0	
	13			2,2	2,1	1,9	2,0	2,1	1115 25,0	
	14	Temperature conditioned		2,0	2,3	1,9	2,2	2,2		
	15	conditioned		2,1	2,1	1,9	2,0	2,0		
4rticle 7.17.2	00 0			ditioning le Filtering	Half Mask w					
<i>Article</i> 7.17.3	Penetration	of filter materia	l: This test is	not applied	to Particle Fi	ilterin <mark>g</mark> Half Ma	ask which	is not reu	sable.	
Article 7,18	Demountabl	e Parts: There a	e no demoun	table parts	on the produc	t.				
Article 9	Marking – P	ackaging: Nece	ssary marking	gs are availa	ble on the pro	oduct and its pa	ckaging.			
Article 10	Information	to be supplied l	y the manuf	acturer: 1	n each of the	smallest comme	ercially av	ailable pa	ckaging of the product,	implementation

REPARED BY		APPROVED BY	C SUS
Murat AYDEMİ l PPE Expert	R Mithelly	Suat KAÇMAZ General Manager	Cert Kling 3
			Molling Sold

UNIVERSAL SERTIFIKASYON VE GÖZETIM HIZM. TIC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazil Bulvan, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com