

SILVERFOX   **fisaude**
Click for health

3 Ply Disposable Medical Mask

BFE \geq 98%

50 PCS

EN 14683:2019+AC:2019



 Type IIR



SILVERFOX



1,500m² ten thousand level dust free workshop

SILVERFOX CORPORATION LIMITED

SILVERFOX



Trademark Registration Certificate



Business License



ISO 13485:2016



TUV CE EN14683 Test report

Produkte Products		TÜVRheinland®	
Prüfbericht-Nr.: Test Report No.:	60378938 001	Auftrags-Nr.: Order No.:	168269021 Seite 1 von 12 Page 1 of 12
Kunden-Referenz-Nr.: Client Reference No.:	N/A	Auftragsdatum: Order date:	Jun., 09, 2020
Auftraggeber: Client:	SILVER FOX CORPORATION LIMITED No. 16, 1st TongLe Road, JiangMen City, 529000, China		
Prüfgegenstand: Test item:	Disposable Medical Mask		
Bezeichnung / Typ-Nr.: Identification / Type No.:	Y300B, Y301B, Y100C		
Auftrags-Inhalt: Order content:	Type test		
Prüfgrundlage: Test specification:	EN 14683:2019+AC:2019 except for clause 5.2.6		
Wareneingangdatum: Date of receipt:	Jun., 10, 2020	See Attachment: Photo documentation for details.	
Prüfmuster-Nr.: Test sample No.:	200603A01		
Prüfzeitraum: Testing period:	Jun., 10, 2020 to Jun., 30, 2020		
Ort der Prüfung: Place of testing:	See page 3		
Prüflaboratorium: Testing laboratory:	TÜV Rheinland (Shenzhen) Co., Ltd.		
Prüfresultat: Test result:	Pass		
geprüft von / tested by: <i>Amanda Liu</i>		kontrolliert von / reviewed by: <i>Angela Chen</i>	
Jul., 08, 2020 Amanda Liu/Project Engineer		Jul., 08, 2020 Angela Chen / Department Manager	
Datum Date	Name / Stellung Name / Position	Unterschrift Signature	Datum Date
Sonstiges / Other: - The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (15 pages). - The Biocompatibility (clause 5.2.6) is not evaluated in this test report.			
Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt Condition of the test item at delivery: Test item complete and undamaged			
*Legende: 1 = sehr gut 2 = gut 3 = befriedigend 4 = ausreichend 5 = mangelhaft (Pass) = entspricht g. Prüfgrundlage (Fail) = entspricht nicht g. Prüfgrundlage N/A = nicht anwendbar NT = nicht getestet Legend: 1 = very good 2 = good 3 = satisfactory 4 = sufficient 5 = poor (Pass) = passed a. in test specification (Fail) = failed a. in test specification N/A = not applicable NT = not tested			
Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. This test report only relates to the a. m. 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 test mark.			
TÜV Rheinland (Shenzhen) Co., Ltd., East of F11, F12, F14, Building 1, Cytio Technology Building No. 6 Langshan Rd. 2 Road, North Hi Tech Industry Park, Nanshan District, Shenzhen, P.R. China http://www.tuv.com			

TÜVRheinland®		Page 2 of 12	Report No. 60378938 001
EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods			
Report Reference No.:	60378938 001	Date of issue:	See cover page
Total number of pages:	See cover page	Testing Laboratory:	TÜV Rheinland (Shenzhen) Co., Ltd.
Address:	1F East & 2-4F, Cytio Technology Building No.1, No.16 KejiBei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China	Applicant's name:	SILVER FOX CORPORATION LIMITED
Address:	No. 16, 1st TongLe Road, JiangMen City, 529000, China	Test specification:	Standard: EN 14683:2019+AC:2019 Test procedure: Type test Non-standard test method: N/A
Test Report Form No.:	EN 14683:2019+AC:2019_A	Test Report Form Originator:	TÜV Rth (S2)
Master TRF:	2020-03	Test item description:	Disposable Medical Mask
Trade Mark:	SILVERFOX	Manufacturer:	Same as the applicant
Model/Type reference:	Y300B, Y301B, Y100C	Classification:	Type IIR

GMP-RT-030085HG Revision number: 1.0 Effective date 2020-03-12

TUV CE EN14683 Test report

EN 14683:2019+AC:2019								
Clause	Requirement + Test		Result - Remark			Verdict		
5.2.2	TABLE: Bacterial filtration efficiency (BFE)						P	
Batch/lot no.:	Test Specimen no.:	Dimension of the test specimen L x W (mm x mm)	test area (cm ²)	Flow rate (l/min)	Mean of the total plate counts of the two positive controls	Mean plate count of the negative controls	BFE for each test specimen (%)	Remarks
200603 A01	1	165 x 147	63.6	28.3	2797	0	99.79	--
	2	164 x 148	63.6	28.3			99.89	--
	3	165 x 148	63.6	28.3			99.82	--
	4	165 x 148	63.6	28.3			99.86	--
	5	165 x 148	63.6	28.3			99.89	--
Supplementary information: 1. Each specimen was conditioned at 21 °C and 85 % relative humidity for 4h to bring them into equilibrium with atmosphere prior to testing. 2. The side of the test specimen was facing towards the challenge aerosol: <u>the inside of the test specimen.</u>								

EN 14683:2019+AC:2019					
Clause	Requirement + Test		Result - Remark		Verdict
5.2.3	TABLE: Breathability (Differential pressure)				P
Batch/lot no.:	Test Specimen number - Test area number	Differential pressure for each test area (Pa/cm ²)	The averaged differential pressure for each test specimen (Pa/cm ²)	Flow rate (l/min)	Remarks
200603 A01	1-1	30.0	39.0	8.0	--
	1-2	42.5		8.0	--
	1-3	34.6		8.0	--
	1-4	46.8		8.0	--
	1-5	41.0		8.0	--
	2-1	31.0	34.6	8.0	--
	2-2	33.3		8.0	--
	2-3	32.9		8.0	--
	2-4	42.2		8.0	--
	2-5	33.7		8.0	--
	3-1	28.9	35.8	8.0	--
	3-2	39.7		8.0	--
	3-3	34.1		8.0	--
	3-4	32.3		8.0	--
	3-5	44.0		8.0	--
	4-1	33.4	35.4	8.0	--
	4-2	39.1		8.0	--
	4-3	34.6		8.0	--
	4-4	35.9		8.0	--
	4-5	34.0		8.0	--
5-1	33.4	34.1	8.0	--	
5-2	36.5		8.0	--	
5-3	37.7		8.0	--	
5-4	30.8		8.0	--	
5-5	31.9		8.0	--	
Supplementary information: Each specimen was conditioned at 21 °C and 85 % relative humidity for 4h to bring them into equilibrium with					

White List in CCCM

The screenshot shows the website for the China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCM). The main navigation menu includes Home, About Us, Events, News, Public Relations, Analysis, Members, Suppliers, and Contact Us. The 'Events' section is highlighted, featuring a list of news items. A red box highlights the first item: 'Name List of Medical Devices and Supplies Companies with Certificat...' with an update date of 17 July, 2020. A red arrow points from this box to the 'Suppliers' section, which lists various companies including HNC, Machinery & Packing, API, and Medical Device Health. The 'News' section below shows an article titled 'Nation's drugmakers gaining more global presence, influence'.

1830	广东银狐医疗科技股份有限公司 Silverfox Corporation Limited	914407037709906374
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<http://en.cccmhpie.org.cn/>

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③



④



⑤



⑥



⑦



⑧



⑨



SILVERFOX



Surgical Mask



SILVERFOX



Inner Box Qty: 50 PCS/Box
Master Carton Qty: 40 Boxes/Ctn



REF No.: Y300B
Size of mask: 17.5cm x 9.5cm
Standard: EN 14683:2019+AC:2019

 SILVERFOX CORPORATION LIMITED
No.18, 1st TongLe Road, TangXia Town, PengJiang District,
JiangMen, GuangDong, China
sales@silverfox.cn

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peter@lotusnl.com

SILVERFOX

SILVERFOX

3 Ply Disposable Medical Mask

BFE ≥ 98%



CE Type IIR

SILVERFOX CORPORATION LIMITED
No.18, 1st TongLe Road, TangXia Town,
PengJiang District, JiangMen, GuangDong, China
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EC REP

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peter@lotusnl.com

Standard: EN 14683:2019+AC:2019



Description: Disposable Medical Mask
REF No.: Y300B
Packing Size: 53.5 cm x 41 cm x 33cm
Production Date: Please see packaging bag
Inner Box Qty: 50 PCS/Box
Master Carton Qty: 40 Boxes/Ctn
N.W. : 7.8kg
G.W. : 9kg
2 years



CTN SIZE: 535*410*330 mm



Box of Mask: 17 Units (3 PLY) 5.5x16.5 CM
 Model: EN 14902:2014 AC 2014 0776114
 Manufacturer: Fisaude Corporation (USA) LLC
 No. 10, 101 Street, Atlanta, Georgia 30309, USA
 Telephone: 404-453-0300, 404-453-0301
 Website: www.fisaude.com
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 The People's Republic of China 520000
 www.fisaude.com

BOX SIZE: 190*100*75mm