SILVERFOX

Fisaude

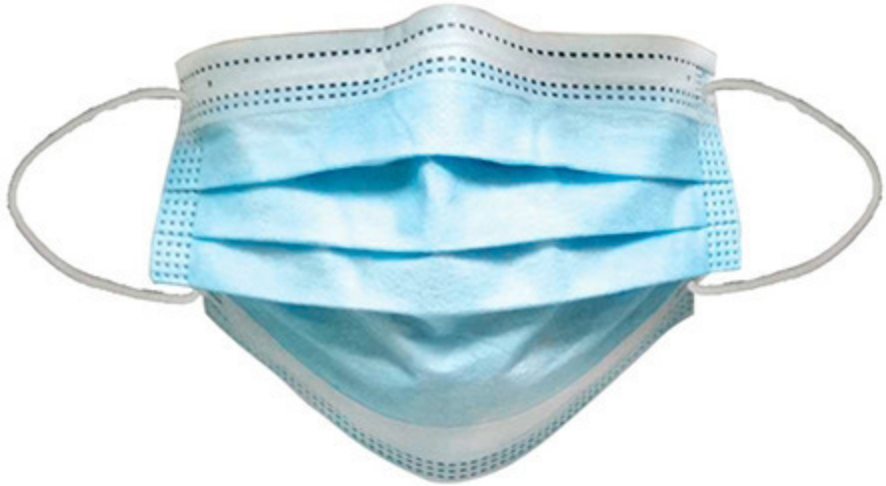
Click for health

3 Ply Disposable Medical Mask

BFE≥98%

50 PCS

EN 14683:2019+AC:2019



CE Type IIR

NON STERILE

2

MD

SILVERFOX

ISO13485

TÜV

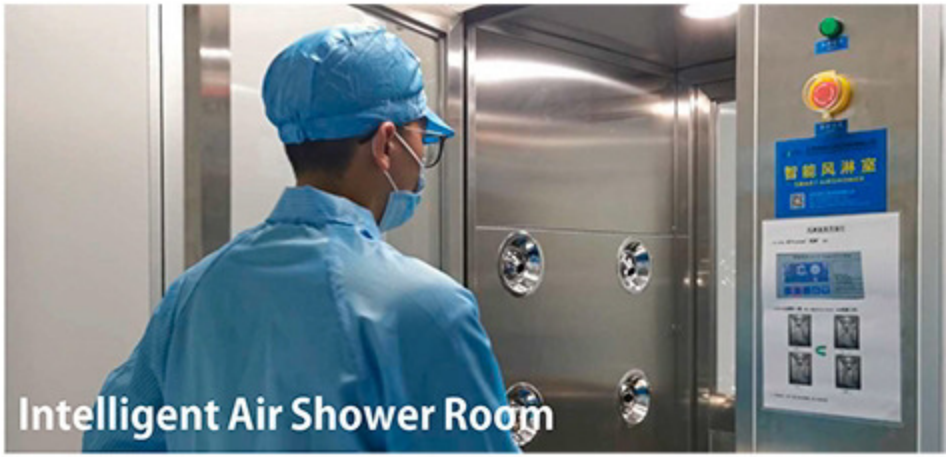
CE

1,500㎡ ten thousand level dust free workshop

SILVERFOX CORPORATION LIMITED

SILVERFOX


1,500m² ten thousand level dust free workshop


Intelligent Air Shower Room


Breathing Resistance Testing


Filtration Efficiency Testing


Microbial Cleanliness Testing

SILVERFOX

Trademark Registration Certificate

商标注册证

第 22527502 号

SILVERFOX

核定使用商品/服务项目（国际分类：10）

注 册 人 广东银狐医疗科技股份有限公司

注册人地址 广东省江门市蓬江区棠下镇棋乐一路18号

注册日期 2018年02月14日 有效期至 2028年02月13日

局 长 刘俊臣 发证机关 商标局

Business License

营业执照

（副 本）

统一社会信用代码 91440703770990637A

名 称 广东银狐医疗科技股份有限公司

类 型 股份有限公司（非上市、自然人投资或控股）

住 所 江门市蓬江区棠下镇棋乐一路18号

法定代表人 张熙

注册资本 人民币叁仟万伍佰捌拾万贰仟元

成立日期 2005年01月28日

营业期限 长期

经营范围 生产、销售、研发、维修：美容美发设备、医疗器械（凭有效的《医疗器械生产企业许可证》、《医疗器械经营企业许可证》）、保健器材及其电子配件；生产、销售：五金配件、塑料制品、木家具、木制品；加工：五金制品、塑料制品。（依法须经批准的项目，经相关部门批准后方可开展经营活动。）

登记机关 江门市工商行政管理局

2016 年 月 日

ISO 13485:2016

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: SILVERFOX CORPORATION LIMITED
No.18, 1st Tongle Road
TangXia Town, Pengjiang District
JiangMen City
Guangdong
529000
China

广东银狐医疗科技股份有限公司
中国
广东省
江门市
蓬江区棠下镇
棋乐一路18号
邮编：529000

Holds Certificate No: MD 609981

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and manufacture of atomizing machines for medical use, medical beds ,integral dental unit, and electro-therapeutic apparatus.
喷雾机、护理床、牙科综合治疗机及电疗仪的设计和制造。

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-05-23
Latest Revision Date: 2018-05-14

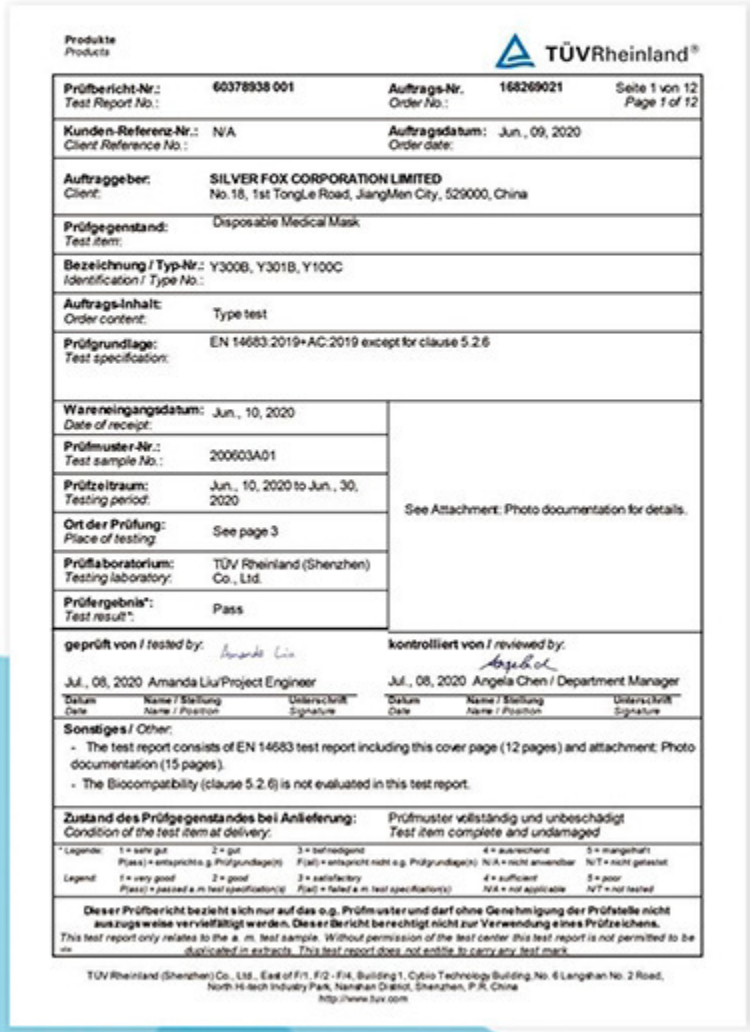
Effective Date: 2017-05-23
Expiry Date: 2020-05-22

Page: 1 of 1

..making excellence a habit.

SILVERFOX

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.18, 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			
Wareneingangsdatum: *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.			
Prüfergebnis*: *Test result*:*	Pass			

geprüft von / *tested by:* Amanda Liu

Jul., 08, 2020 Amanda Liu/Project Engineer

Datum / Date | Name / Stellung / Name / Position | Unterschrift / Signature

kontrolliert von / *reviewed by:* Angela Chen

Jul., 08, 2020 Angela Chen / Department Manager

Datum / Date | Name / Stellung / Name / Position | Unterschrift / Signature

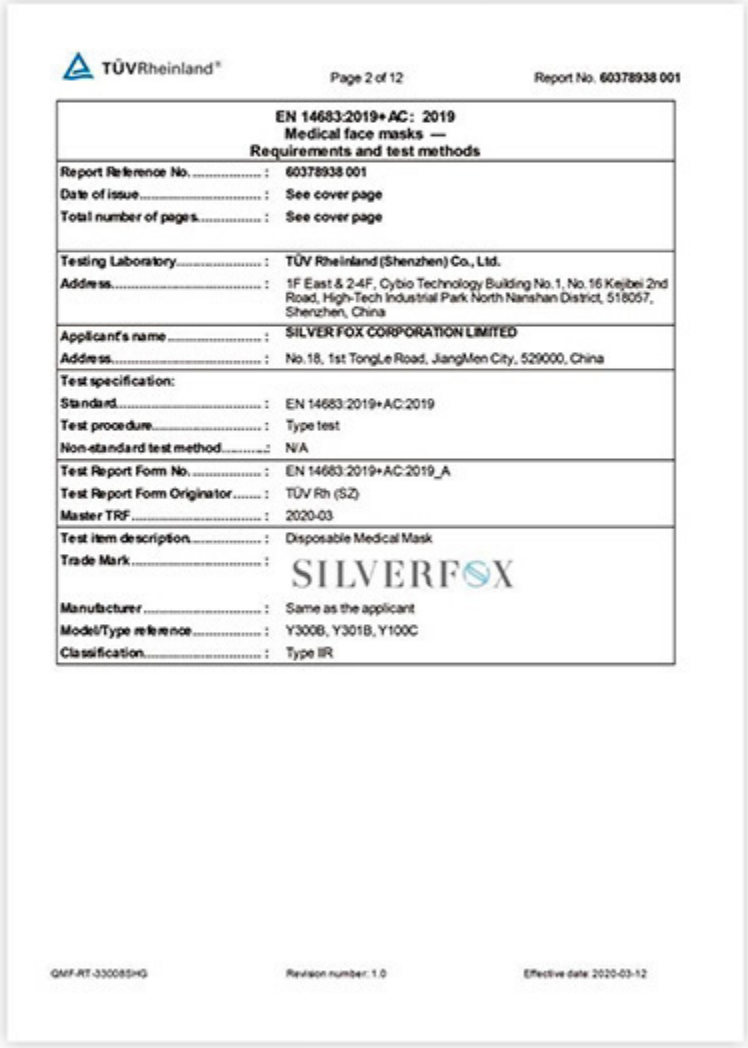
Sonstiges / *Other:*

- 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 P(ass) = entspricht o.g. Prüfgrundlage(n)	2 = gut	3 = befriedigend F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	4 = ausreichend N/A = nicht anwendbar	5 = mangelhaft N/T = nicht getestet
Legend:	1 = very good P(ass) = passed a. m. test specification(s)	2 = good	3 = satisfactory F(ail) = failed a. m. test specification(s)	4 = sufficient N/A = not applicable	5 = poor N/T = 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.



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, Cybio Technology Building No.1, No.16 Keijibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name	:	**SILVER FOX CORPORATION LIMITED**
Address	:	No.18, 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 Rh (SZ)
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

SILVERFOX

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× 147	63.6	28.3	2797	0	99.79	--
	2	164× 148	63.6	28.3			99.89	--
	3	165× 148	63.6	28.3			99.82	--
	4	165× 148	63.6	28.3			99.86	--
	5	165× 148	63.6	28.3			99.89	--

Supplementary information:
1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol: the inside of the test specimen.

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 4 h to bring them into equilibrium with

SILVERFOX

EU registration certificate

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 22 juni 2020
Betreft: notificatie medisch hulpmiddel klasse I

Geachte heer Wei,

Hierbij bevestig ik de ontvangst op 18 juni 2020 van de notificatie van het medische hulpmiddel klasse I, dat bedrijf SILVERFOX CORPORATION LIMITED, met Europees gemachtigde Lotus NL B.V., als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen.
Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over dit product het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Disposable medical mask,Surgical mask
(geen merknaam) (NL-CA002-2020-52171)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw product overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde gevraagd binnen achttien maanden bovenstaand hulpmiddel te registreren in Eudamed.[3]

[1] O.g.v. art. 29 MDR.
[2] O.g.v. art. 31 MDR.
[3] www.camd-europa.eu/wp-content/uploads/2020/05/FAQ_MDR_180117_V1.0 1.pdf. Zie vraag en antwoord nummer 20.

Pagina 1 van 2

Farmatec
Bezoekadres
Haarlem
Bijvoet 50
2015 BP Den Haag
T 070 340 6363
http://hulpmiddelen.farmatec.nl
Inlichtingen bij
R.A.C. Chi
medische_hulpmiddelen@
minvws.nl
Ons kenmerk:
CIBG-2020/8510
Bijlagen
-
Uw aanvraag
18 juni 2020
Correspondentie uitsluitend richten aan het rekeurantes met vermelding van de datum en het kenmerk van deze brief.

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

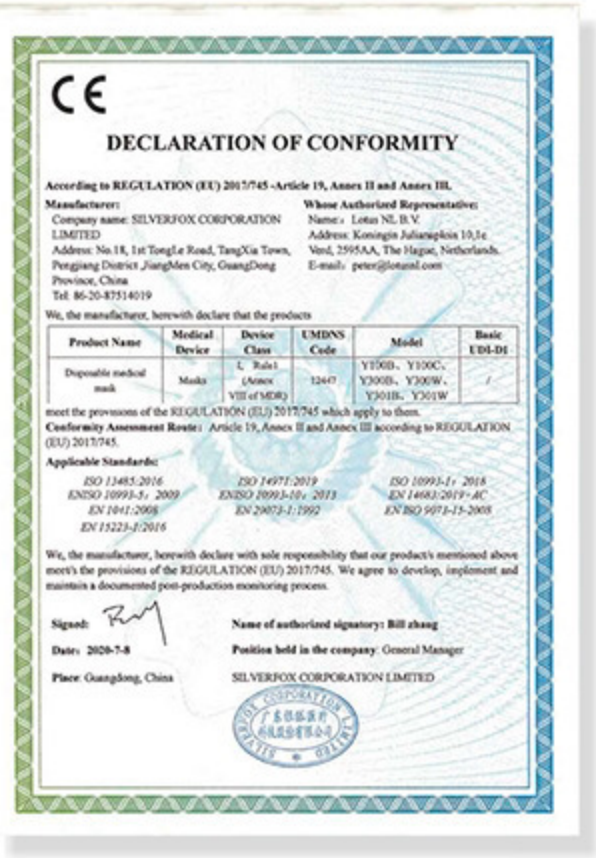
De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Pagina 2 van 2

DoC



CE

DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

Manufacturer:
Company name: SILVERFOX CORPORATION LIMITED
Address: No.18, 1st TongLe Road, TangXia Town, Pengjiang District ,JiangMen City, GuangDong Province, China
Tel: 86-20-87514019

Whose Authorized Representative:
Name：Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail：peter@lotusnl.com

We, the manufacturer, herewith declare that the products

Product Name	Medical Device	Device Class	UMDNS Code	Model	Basic UDI-DI
Disposable medical mask	Masks	I, Rule1 (Annex VIII of MDR)	12447	Y100D、Y100C、Y300B、Y300W、Y301B、Y301W	/

meet the provisions of the REGULATION (EU) 2017/745 which apply to them.
Conformity Assessment Route：Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable Standards:

ISO 13485:2016
EN ISO 10993-5：2009
EN 1041:2008
EN 15223-1:2016
ISO 14971:2019
EN ISO 10993-10：2013
EN 20073-1:1992
ISO 10993-1：2018
EN 14683:2019+AC
EN ISO 9073-15-2008

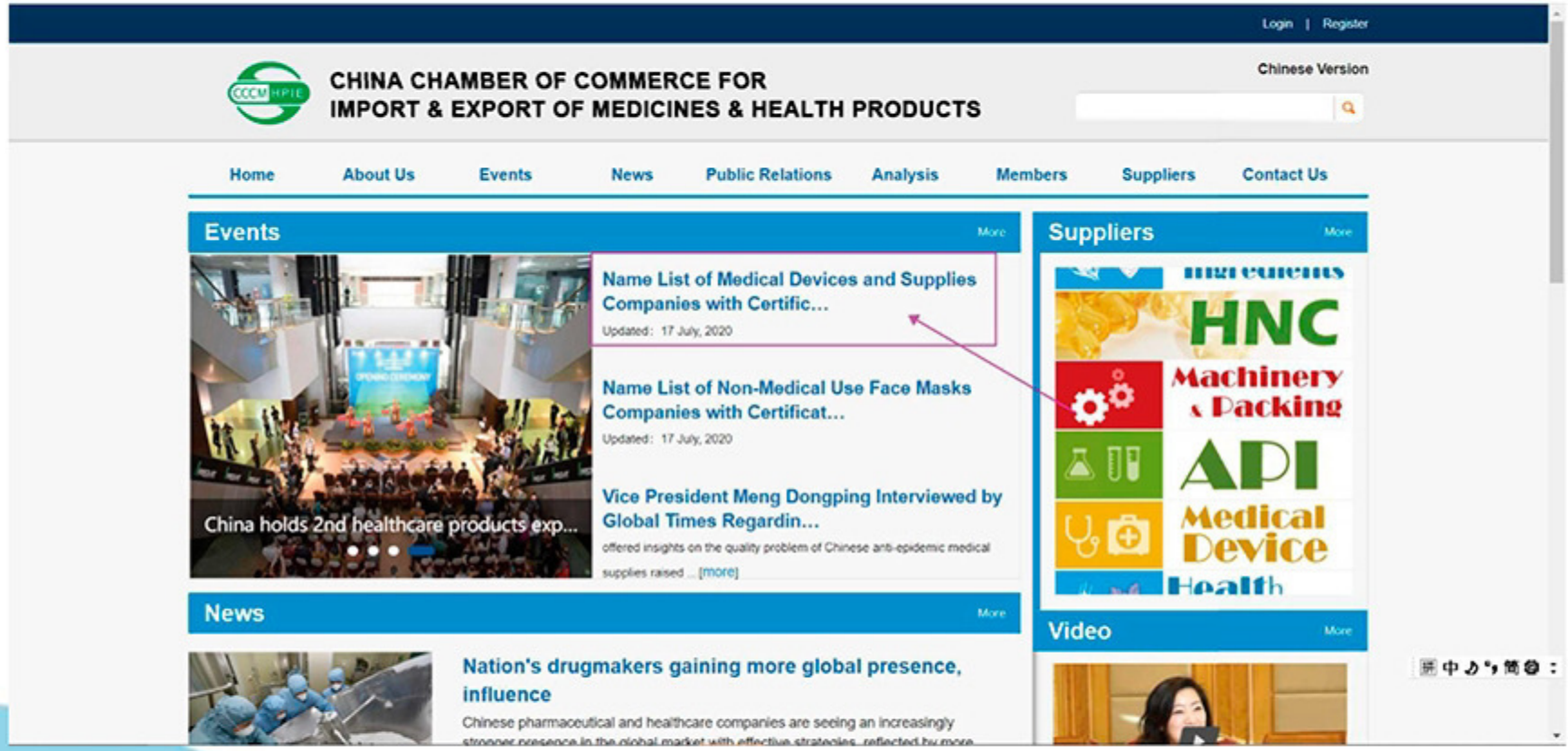
We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Signed:
Date：2020-7-8
Place: Guangdong, China

Name of authorized signatory: Bill zhang
Position held in the company: General Manager
SILVERFOX CORPORATION LIMITED

SILVERFOX

White List in CCCM



1830	广东银狐医疗科技股份有限公司 Silverfox Corporation Limited	91440703770990637 4

http://en.cccmhpie.org.cn/

SILVERFOX

①

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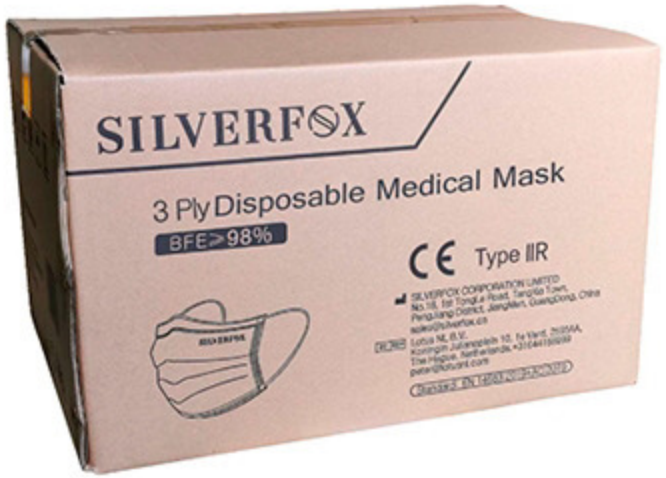
SILVERFOX

Surgical Mask

SILVERFOX

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

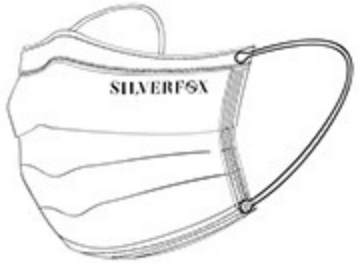
EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.+31644168999
peter@lotusnl.com

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
sales@silverfox.cn

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.+31644168999
peter@lotusnl.com

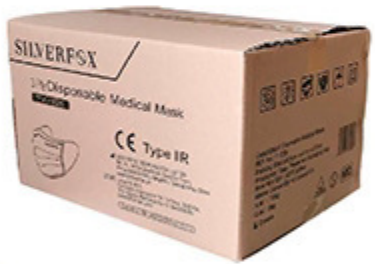
Standard: EN 14683:2019+AC:2019

Description: Disposable Medical Mask
REF No.: Y300B
Packing Size: 53.5 cm x 41cm 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

6 973134 770085

NON STERILE

MD



CTN SIZE: 535*410*330 mm

SILVERFOX

Fisaude
Click for health

BOX SIZE:190*100*75mm