

PRODUKTBLAD

Silverlines AS, org.nr. 992722754 MVA. www.silverlines.no



Produkt/-er: Macomed Mykt Benkepapir, 30g pr. m², 50-60-70-80x200cm
Varenummer: 210100251, 210100264, 210100272, 210100288

Leverandør

Hanchuan Fumo Plastics Co.Ltd

Opprinnelsesland

Kina

Bruksområde

Produktet er beregnet for tildekking av overflater på behandlingsbenker o.l., og har ellers ikke noen restrestriksjoner for bruksområde, bortsett fra tildekking av varme overflater (som feks varmeovner).

Advarsler

Det er ingen advarsler for dette produktet

Produktinformasjon

MYKT MATERIALE: Komfortabelt «NonWoven» materiale; Dette papiret gir ingen lyd når pasienten beveger seg, og er mye mer holdbart i forhold til annet papir. NonWoven er heller ikke statisk, og fester seg derfor ikke til kunden eller annet utstyr når det oppstår kontakt. Papiret leveres på rull, og kan henges på holdere tilpasset dette (Hull: Ø35mm x bredden av papiret).

TYKKERE: Vårt benkepapir produseres med 30g pr.m², som er tykkere og mere slitesterkt enn mange andre merker på markedet (mange bruker 20g pr.m², som gjør at papiret rives fortere i stykker under bruk, og at kjemikalier lettere trenger gjennom). Tykkelsen gjør også at papiret gir mer beskyttelse av overflaten det brukes på.

PRECUT: Papiret er stiptet hver 200cm; og gjør at du får perfekte «ark» for hver behandling. Det vil si at du river disse enkelt av i perforeringen (som med toalettpapir/tørkerull), slik at du får ett ark på 2m lengde x bredden på papiret -enkelt, raskt og praktisk.Hver rull inneholder 50 ark.

HYGIENISK: I forhold til å bruke benken uten tildekning, eller med tildekning som feks. bomullslaken, er benkepapir mye mer hygienisk. Dette gjør at overflaten alltid er ren og bakteriefri for pasienten, og at du samtidig beskytter benken mot smuss, kjemikalier og skader. I tillegg gjør det også vedlikeholdet enklere, da benken ikke trenger like mye vask og behandling.

MILJØVENNLIG: PP (Polypropylen) NonWoven er Eko-vennlig, nedbrytningsbart og fornyelsesbart. Materialet lages av resirkulert plast, og kan kastes sammen med plast til gjenvinning.

Certificate of Registration



Declaration

Of Conformity with European Directives

Product: Disposable Roll, Sheet, Bed Cover, Blanket, Towel, Face and Headrest Cover, Bowl Cover, Bib and Apron, Gown, Washing Glove, Shoe Cover, Face Mask, Cap, Headband, Pants and Depilatory Paper

Applicant Manufacturer: Hanchuan Fumo Plastics Co., Ltd.
Address: 28# Zhengjie Road Chenghuang Town, Hanchuan City, Hubei Province, P.R. China

The submitted sample of the above product has been tested for CE marking according to the following European Directive(s):
93/42/EEC Medical Device Directive

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): EN ISO 13485 : 2012 EN ISO 13485 : 2012/AC:2012

Test report(s): WY20162087/WY20162088/WY20162089

Issued by: Shenzhen Testing Center of Medical Devices

Dates: 2016-02-28

The referred report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s).
The CE marking as shown below may be affixed on the product.

Date: 28 Feb 2016

FUMO:


General manager (Signature)





Certificate

Certificate No.:11883Q46689R0S

This is to certify that the Quality Management System of
HANCHUAN FUMO PLASTICS CO.,LTD.
566,Zhengjie Street,Cheng Huang,HanChuan,Hubei P.R.China 431606

P. R. C.:431606

It has been audited to conform to the following Quality Management System standard:

GB/T 19001-2016 idt ISO 9001:2015

This Quality Management System is valid for the

Production of disposable products: Coveralls, Caps, Lab Coats, Scrub Suits,
Headbands, Bowl Covers, Aprons, Face Mask, Bibs, Bedsheet, Table Rolls,
Pillowcovers, Headrest Covers, Shoe Covers, Isolation Gowns

Date of issue: Nov.11,2020
Valid period: Nov.10,2023

Issued by: *Xu Jieping*



BEIJING EAST ALL REACH CERTIFICATION CENTER



MANAGEMENT SYSTEM
CNAS C114-Q

This certificate will not remain valid only if the certified organization accepts at least one surveillance audit annually within the validity period of the certificate in which the surveillance audit conforming mark is in the designated position on the certificate. Please login into www.eacc.com.cn for this certificate's validity status.
EACC address: Room 2117 International Building 3, East Section, No.1, Ciyuan.

The 1st
Surveillance
Conforming
Mark

The 2nd
Surveillance
Conforming
Mark

The 3rd
Surveillance
Conforming
Mark

ISO 9001

ISO 9001

POSI

CERTIFICATE

This is to certify that the Quality Management System of

Wuhan AbleCare Tech Co., Ltd.

Business License Number: 91420100MA4KYBRR08

Registered Address: Room 208, R&D Building, Wuda Science and Technology Park, East Lake New Technology Development Zone, Wuhan, Hubei, China

Audit Address: Room 208, R&D Building, Wuda Science and Technology Park, East Lake New Technology Development Zone, Wuhan, Hubei, China

applicable to

Sales of disposable nonwoven products (isolation gowns, surgical gowns, facemasks, lab coats, coveralls, sleeve covers, bed sheets, pillowcases, fitted bedsheet covers, caps, shoe covers, patient gowns, shorts, scrub suits, surgical packs), disposable plastic products (aprons), disposable tissue poly products(bibs, bedsheets), gloves (PVC gloves, nitrile gloves, latex gloves, nitrile blended gloves), disposable syringes, disposable injection needles

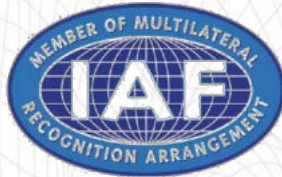
has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



A handwritten signature in black ink, appearing to read "Jie Chen".

General Manager

Certificate Registration No: 381210114R0S

Initial issue date: 2021.08.11

Issue date: 2021.08.11

Valid until: 2024.08.10



Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com

POSI

CERTIFICATE

质量管理体系认证证书

兹证明

武汉康凯依科技有限公司

统一社会信用代码： 91420100MA4KYBRR08

注册地址： 武汉东湖新技术开发区武大科技园四路研发楼二层208室

经营地址： 湖北省武汉东湖新技术开发区武大科技园四路研发楼二层208室

的质量管理体系适用于：

一次性无纺布制品（隔离服、手术衣、口罩、实验服、防护服、袖套、床单、枕套、床罩、帽子、鞋套、病人服、短裤、洗手服、手术包）、 一次性塑料制品（围裙）、 一次性纸膜制品（围兜，床单）、手套（PVC手套，丁腈手套，乳胶手套，混丁手套）、 一次性注射器、一次性注射针的销售

已经通过上海波西认证有限公司根据标准：

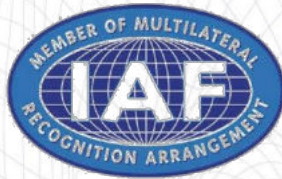
ISO13485:2016

审核和注册

本注册要求组织必须按照上述标准保持其质量管理体系，并由POSI进行监督。

查询网站： www.posicert.com

该证书信息可在国家认证认可监督管理委员会官方网站<http://cx.cnca.cn>查询。



总经理

证书编号： 381210114R0S

首次发证日期： 2021.08.11

本次发证日期： 2021.08.11

有效期： 2024.08.10



上海波西认证有限公司

上海市浦东新区世纪大道1500号1301-C-7室 Email: info@posicert.com



Fiscal Year 2021

CERTIFICATION OF REGISTRATION

This certifies that:

WUHAN ABLE CARE TECH CO., LTD

Room 302, R&D Building, Wuda Science and Technology Park, East Lake New Technology Development Zone, Wuhan, Hubei, 430223, CHINA

has completed the FDA Establishment Registration (as manufacturer, contract manufacturer, remanufacturer, reprocessor of single use devices, repackager/relabeler) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA SUNGO TECHNICAL SERVICE INC.
Communications: 6050 W EASTWOOD AVE APT 201, CHICAGO,
 ILLINOIS 60630, USA
 Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

Registration Number: 3015168506

Device Listing#: See annex

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

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Executive Director
Issued: Jan. 20 2021
Cert. No.: 2007US013518
Expiration Date: Dec. 31 2021





Fiscal Year 2021

CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2007US013518

Listing No	Code	Device Name
D340944	KME	BEDDING, DISPOSABLE, MEDICAL (exam sheet, fitted sheet, stretcher sheet, lift sheet, absorbent sheet, drape sheet; exam paper, table paper, flat sheet, emergency blanket, yellow blanket)
D374552	OEA	NON-SURGICAL ISOLATION GOWN (Non-Surgical Isolation Gown - CPE Gown; Isolation Gown, Lab Coat, Coverall)
D374529	LYU	ACCESSORY, SURGICAL APPAREL (earloop, disposable face mask)
D340948	NOD	BOARD, ARM (WITH COVER), NON-STERIL (ARMBOARD COVER)
D374554	FXP	COVER, SHOE, OPERATING-ROOM (Cover, Shoe, Operating-Room - Non Woven Shoe Cover/ Bootie Cover; Non-Skid Shoe Cover, PE Shoe Cover, CPE Shoe Cover; Sleeve Cover, Such As Poly Sleeve Cover, PVC Sleeve Cover, And Non Woven Sleeve Cover)
D374553	FYF	CAP, SURGICAL (Cap, Surgical - Caps, Non Woven Bouffant Cap, Clip Cap, Mesh Hairnet, Poly Shower Cap)
D340950	CCX	SUPPORT, PATIENT POSITION

END OF THE ANNEX

For FUMO Contract Customers Only