

C4i **communication**

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ISOLATION BOOT/SHOE COVER SERIES



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MEDICAL ISOLATING SHOE COVER C4SC

Class I medical supplies

Used for general isolation in outpatient, ward and laboratory of medical institution.

It is made of SS non-woven material and tailored.

Average size

Product name : Medical shoe cover

Packing specification : 10/bag 60 bags/case 600/case

Intended use : it is used for general isolation in outpatient service, ward and inspection room of medical institutions.

Main structure : It is made of SS non-woven material and tailoring and sewing.

Notes :

- (1) please read the instructions carefully before use and use within the warranty period.
- (2) after use, the product shall be disposed according to the requirements of the hospital or the environmental protection department.

Instructions for use :

- (1) before using the product, attention should be paid to the packaging, production batch number and expiry date.
- (2) non-sterile, disposable.
- (3) open the package when using and carry out routine operation as required.
- (4) routine treatment is required after use.

Storage method : well ventilated, stored at room temperature.



Scope of application

Medical supplies used in clinical health care in the medical system. Medical personnel use in medical institutions to prevent contact with potentially infectious patients blood, body fluids, secretions, etc., isolation, protection.



The characteristics of

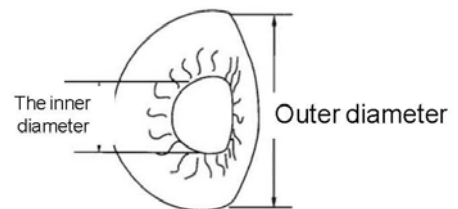
SS non-woven fabric, strong and durable, one-way breathable, exhaust internal heat, blocking external gas,



Model and specification

Specifications

Outer diameter : 320mm±10mm
The inner diameter : 160mm±10mm



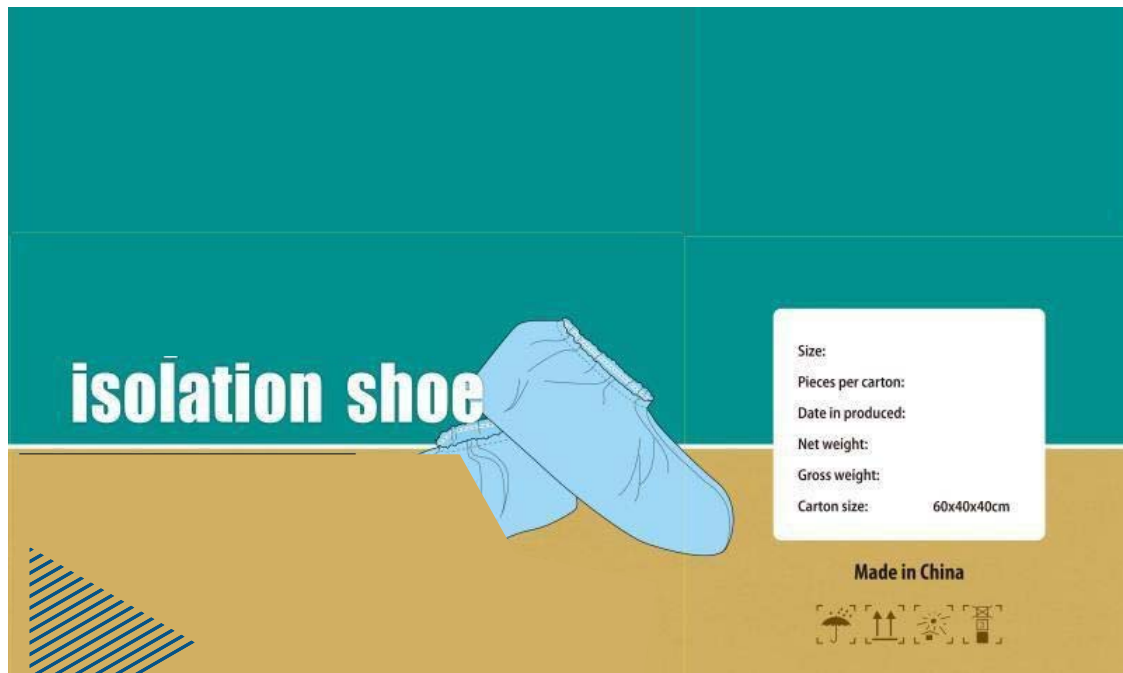
Storage

Store in a cool, dry, ventilated, clean and non-corrosive environment away from fire and inflammable materials, with relative humidity not exceeding 80%.

Packaging

Isolation shoe cover packing standard

Specification:	general purpose
Number of packages:	600 pairs/carton
Gross weight:	9.95kg/carton
Net weight:	8.25 kg/carton
Size:	60*40*40cm
Unit:	0.096 cubic meters



Relevant qualifications


FDA Registration Certificate
FDA 注册证明
Fiscal Year 2020

COMPANY	[REDACTED]
ADDRESS	[REDACTED]

Owner / Operator Number:	[REDACTED]
Device Listing #:	See Annex
Expiration Date:	Dec. 31, 2020

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Non-surgical isolation gown	OEA	1	[REDACTED]	Manufacturer
COVER, SHOE, OPERATINGROOM	FXP	1	[REDACTED]	Manufacturer
Face mask (except N95 respirator) for general public/healthcare personnel per IEC guidance	GKR	1	[REDACTED]	Manufacturer
CAP, SURGICAL	FYF	1	[REDACTED]	Manufacturer

Apr. 09, 2020
(Date)



Quality Management

Declaration of Conformity

Certificate No.: W1 [REDACTED]

Applicant: [REDACTED]

Address: [REDACTED]

Manufacturer: [REDACTED]

Address: [REDACTED]

Product Name: protective shoe cover

Model No.: 180179(S), 179180(M), 180190(L)

Trade Mark: /

Test Standard: EN 14126:2003

Test Report Number(s): W1 [REDACTED]

PFIE Directive (EU) 2016/425

The CE markings as shown below can be affixed on the product after preparation of necessary conformity documentation, as stipulated in article 10 of the Council Directive 93/68/EEC.

CE

Tony Bi
Technical Director

Mar. 24, 2020

Shenzhen Huaacetong Testing and Certification Co., Ltd.
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Web: www.sztlab.com Tel: 86-755-2392524 E-mail: rt_lab@foxmail.com

[REDACTED]

丹东华洋纺织服装有限公司：
根据相关法规要求，对你单位第一类医疗器械：医用隔离鞋套予以备案，备案号：辽丹械备 20200014 号。

丹东华洋纺织服装有限公司
2020年 [REDACTED]月 [REDACTED]日

企业名称	[REDACTED]			
负责人	[REDACTED]			
生产地址	[REDACTED]			
法定代表人	尹文强			
企业负责人	尹文强			
生产范围	2020年11月18日至2020年11月18日 18-6860-1-001116			
	2020年11月18日至2020年11月18日 18-14-14-01-1-001116			
生产产品列表	产品名称	产品备案号	登记日期	备注
	隔离衣	[REDACTED]	2020-01-30	
	医用帽	[REDACTED]	2020-03-23	
	医用隔离鞋套	[REDACTED]	2020-03-23	

[REDACTED] 辽丹械备 20200014 号
2020年 [REDACTED]月 [REDACTED]日



LEARN MORE: c4icommunication.com

FOR MORE INFORMATION: contact@c4icommunication.com or +1 (302) 981 1340