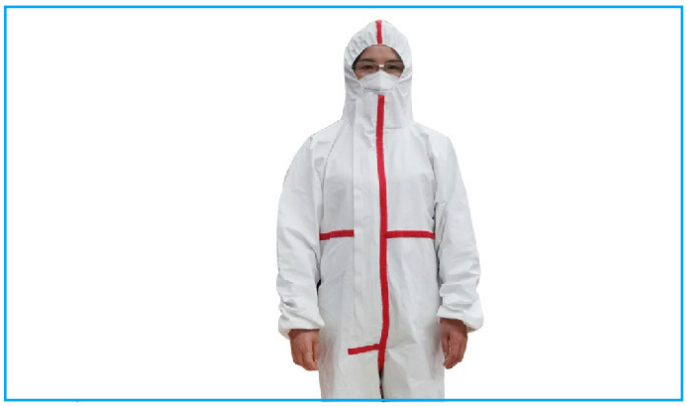
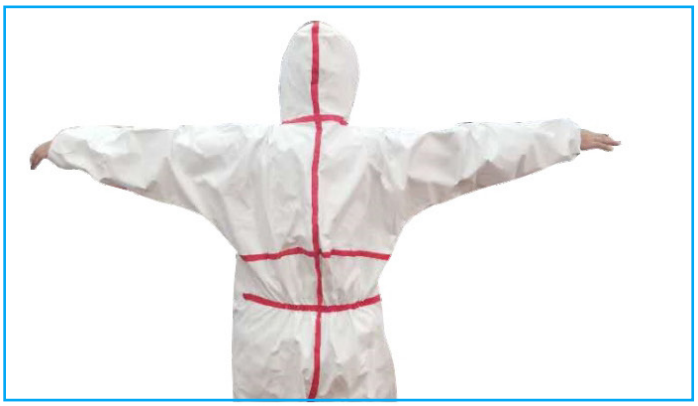
Medical Coverall Class I





Product details

The coverall is a high performance composite nonwoven fabric that provides a high level of moisture management and breathability, without reducing protection. It designed as protective clothing for medical staff in medical institutions.

It provides isolation and protection against potentially infectious blood, body fluids, secretions and airborne particulate matter exposed to by medical staff during work.

- **Name: Medical Coverall**
- **Size: S, M, L, XL, XXL, XXXL**
- **Intended Use: Coverall is used to prevent physical, chemical and biological external factors from harming the human body. The product is for single use only, and provided non-sterile.**

Symbol	Introductions	Symbol	Introductions
LOT	Batch Code	REF	Catalogue number
⚠	Warnings and Precautions		non-sterile
MD	medical device		Manufacture Date
	ManufactureName Address		Name and Address of European Union Representative
CE	CE Symbol		Do not reuse" are "single use, "Use only once

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the council regulation 2017/745/EU, SUNGO Europe B.V. performed all notification duties and responsibilities as the European authorized representative of:

Applicant: Jiangsu Ninestone Medical New Material Co.,Ltd.
Address: No.2 Nianfang road Urban Industrial Zone Jichuan Street, Taixing

The Manufacturer has provided SUNGO Europe B.V. with all the appropriate declarations according to the 2017/745/EU Regulation requirements including the EC Declaration of Conformity confirming that his medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Regulation 2017/745/EU.

Product(s): Medical face mask、Medical coverall
Type(s): Medical face mask: 17.5*9.5cm
Medical coverall: S, M, L, XL, XXL, XXXL
Product Classification: Class I

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU regulation(s) have and continue to be met.

The notification of aforementioned device has been completed by the European Representative in Netherlands. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration.

SUNGO
Executive Director
Sungo global service
CERTIFIED

Issued: Mar. 31 2020
Cert. No.: EU252518
Expiration Date: Mar. 30 2025

CE

*This is not a CE mark and is only provided as a template for informational

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File No: CE-TCF-001

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant
Name: Jiangsu Ninestone Medical New Material Co.,Ltd.
Address: No.2 Nianfang road, Urban Industrial Zone, Jichuan Street, Taixing City, Jiangsu

EC Representative
Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product
Name: Coverall

Type: S,M,L,XL,XXL,XXXL,XXXXL
Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)
Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2013
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013

Signature:

Date:

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CMA 171021110579 ilac-MRA CNAS

检验检测报告

TEST REPORT

STFWT20201520

产品名称 Product Name	防护服
委托单位 Trust Unit	江苏九石医用新材料有限公司
生产单位 Manufacturer	江苏九石医用新材料有限公司
检验检测类别 Test Category	委托送样检验

江苏省特种安全防护产品质量监督检验中心

JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

检 验 检 测 报 告

Test Report

STFWT20201520

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产品名称 Product Name	防护服	规格型号 Specification Type	18
		商标 Trademark	——
委托单位 Trust Unit	江苏九石医用新材料有限公司	电话 Tel	[illegible]
生产单位 Manufacturer	江苏九石医用新材料有限公司	样品等级 Sample Grade	——
样品数量 Sample Quantity	1件	送样日期 Sample Receiving Date	2020-02-21
检验检测类别 Test Category	委托送样检验	批号/编号 Serial Number	——
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	GB 19082-2009《医用一次性防护服技术要求》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合GB 19082-2009标准规定的要求。签发日期：[illegible] Signature Date		
备注 Remarks	[illegible]		

批准： Approver　审核： Examiner　主检： Major tester

检 验 检 测 结 果

Testing Results

STFWT20201520

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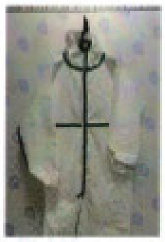
序号 Serial	检验检测项目 Test Items			单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	微生物指标	细菌菌落总数		CFU/g	≤200	16	合格
		大肠菌群		——	不得检出	未检出	
		致病性化脓菌	金黄色葡萄球菌	——	不得检出	未检出	
			绿脓杆菌	——	不得检出	未检出	
			溶血性链球菌	——	不得检出	未检出	
		真菌菌落总数		CFU/g	≤100	[illegible]	

样 品 图 片



以下空白

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