

国家食品药品监督管理局北京医疗器械质量监督检验中心

检验报告首页

The national food and drug administration, Beijing medical device
quality supervision and inspection center

Inspection report home page

报告编号: W(X)-2184-2013

Report number: : W(X)-2184-2013

样品名称 Sample name	康祝系列远红外护具 far-infrared protector of Kangzhu		样品编号 Sample number	/
	送样 (√) Send samples (√)	抽样 () Sampling ()		
商标 Trademark	康祝 KANGZHU		型号规格 Model specification	型号: KZ-SJ Model: KZ-SJ 规格: L Specification: L
委托 commission	北京康达五洲医疗器械中心 Beijing Kangda Wuzhou Medical Devices Center		检验类别 Inspection category	注册检验 Registration test
委托方地址 Principal address	北京市东城区东滨河路 17 号一层 No. 17, east binhe road, dongcheng district, Beijing		产品编号/批号 Product number / lot number	20121007006
生产单位 Production unit	北京康达五洲医疗器械中心 Beijing Kangda Wuzhou Medical Devices Center		抽样单编号 Sample documents number	/
受检单位 The prosecution unit	北京康达五洲医疗器械中心 Beijing Kangda Wuzhou Medical Devices Center		生产日期 Production Date	/
抽样单位 Sampling unit			样品数量 Sample quantity	two
抽样地点 Sample location			抽样基数 Sampling base	/

抽样日期 Sampling date		检验地点 Inspection site	本检验中心通州实验室 本检验中心丰台实验室 This inspection center, Tongzhou laboratory This inspection center, Fengtai laboratory
收样日期 Collection date	2012 年 10 月 08 日 October 08, 2012	检验日期 Inspection date	2012-10-15~2013-07-31
检验项目 Inspection item	外观：外形：远红外法向发射率：拉伸弹性回复性等全性能 Appearance: Shape: Far Infrared Normal Emissivity: Tensile elastic recovery and other full performance		
检验依据 Inspection basis	YZB-京 0521-2012 《far-infrared protector of Kangzhu》		
检验结论 Inspection conclusion	被检样品符合 YZB/京 0521-2012 注册产品标准要求 The inspected samples conform to the standard requirements of the registered products of yzb / Beijing - 2012 (检验报告专用章或检验单位公章) (special seal for inspection report or official seal of the inspection unit) 签发日期 2013 年 08 月 05 日 Date of issue August 05, 2013		
备注	(1) 报告中的“—”表示此项不适用，报告中的“/”表示此项空白。 (1) the "-" in the report does not apply, and the "/" in the report indicates the blank. (2) 远红外法向发射率项 (4.3)、拉伸弹性回复率项 (4.4)、远红外波长范围项 (4.5)、甲醛含量及其他指标项 (4.6) 由国家纺织制品质量监督检验中心分包，报告编号为 BA12002224。 (2)far-infrared normal emissivity term (4.3)、Stretch elastic recovery rate term (4.4)、Far-infrared wavelength range (4.5)、Formaldehyde content and other indicators terms (4.6) Subcontracted by the National Textile Products Quality Supervision and Inspection Center, the report number is BA12002224. (3)皮肤刺激性项 (4.7)、皮肤致敏性项 (4.8)、细胞毒性项 (4.9)、纤维含量项 (4.10) 认可本中心的检验报告，报告编号为 W(X)-1781-2009，批号为 090929000063900048 (3) Skin irritation term(4.7)、Skin Sensitization(4.8)、Cytotoxic term(4.9)、		

	Fiber content term (4.10) Approves the inspection report of the center, the sport number is W(X)-1781-2009,the lot number is 090929000063900048
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Inspection report

报告编号: W(X)-2184-2013

产品编号/批号: 20121007006

Report number: : W(X)-2184-2013

Product number / lot number: 20121007006

Report number / 报告编号	Product name / 产品名称	Lot number / 批次	Serial number / 序号	检验项目 Inspection item	标准条款 Standard terms	标准要求 Standard requirements	检验结果 Test results	单项结论 Single conclusion
1	外观 Appearance	4.1.1	1	外观 Appearance	护具表面应光洁平整，无明显的凹凸现象： The surface of the protector should be smooth with no obvious concave and convex phenomenon:	符合要求 Meet the requirements	符合 accord with	
		4.1.2			护具表面应清洁，无污染，色泽均匀一致： The surface of the protector should be clean, free of pollution and uniform color	符合要求 Meet the requirements	符合 accord with	
		4.1.3			护具各缝纫部分应无跳针、跳线、开裂现象。 The sewing parts of the protector should be free of jumping needle, jumping line and cracking.	符合要求 Meet the requirements	符合 accord with	
2	外形 Shape	4.2	2	外形 Shape	护具应符合下列要求，型号：KZ-SJ，规格：L 全宽：730mm±20mm: The protector should meet the following requirements, model: KZ-SJ, specification: L Total width: 730 mm ±20 mm:	偏差： deviation -20mm	符合 accord with	

			袖口宽: cuff width 170mm±10mm	偏差: deviation -10mm	符合 accord with	
3	远红外法向 发射率 Far-infrared normal emissivity	4.3	≥78%(波长在 8 μ m~15 μ m 波段) The wavelength is in the 8 μ m ~ 15 μ m band.	80%	符合 accord with	
4	拉伸弹性回 复率（横向） Stretch elastic recovery rate	4.4	≥70%	82%	符合 accord with	
5	远 红 外 波 长 范 围 Far-infrare d wavelength range	4.5	应在 8 μ m~15 μ m 波段 Should be in the 8 μ m ~ 15 μ m band	符合要求 Meet the requirem ents	符合 accord with	
6	甲 醛 含 量 及 其 他 指 标 Formaldeh yde content and other indicators terms	4.6	甲醛含量应小于 75mg/kg, The formaldehyde content should be less than 75 mg / kg	未检出 Not detected	符合 accord with	
			其他指标应符合 GB 1818401-2010《国家 纺织产品基本安全技术规范》规定的 要求: Other indicators should be consistent with GB 1818401-2010 "National Safety Technical Code for Textile Products" requirements:	6.6	符合 accord with	
			PH 值 PH value	4.0~8.5	4-5 级 level 4-5	符合 accord with
			耐水色牢度 Color fastness to water	变色: ≥3 级 Discoloration : Level 3	4-5 级 level 4-5	符合 accord with
				沾色: ≥3 级 Color staining : ≥ Level 3	4-5 级 level 4-5	符合 accord with
			耐酸汗渍色牢度 Color fastness to acid and	变色: ≥3 级 Discoloration : Level 3	4-5 级 level 4-5	符合 accord with

			perspiration	沾色：≥3 级 Color staining : ≥ Level 3	4-5 级 level 4-5	符合 accord with
			耐碱汗渍色牢度 Color fastness to alkali and perspiration	变色：≥3 级 Discoloration : Level 3	4-5 级 level 4-5	符合 accord with
				沾色：≥3 级 Color staining : ≥ Level 3	4-5 级 level 4-5	符合 accord with
			耐干摩擦色牢度 Color fastness to dry rubbing	≥3 级 ≥Level 3	4-5 级 level 4-5	符合 accord with
			异味 Peculiar smell	无 Nothing	无异味 No peculiar smell	符合 accord with
			可分解致癌芳香胺染料-24 种 Decomposable carcinogenic aromatic amine dyes -24 species	≤20mg/kg	未检出 Not detected	符合 accord with

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Inspection report

报告编号：W(X)-2184-2013 产品编号/批号：090929000063900048
Report number：：W(X)-2184-2013 Product number / lot number: 090929000063900048

序 号 Serial number	检 验 项 目 Inspection item	标准条款 Standard terms	标准要求 Standard requirements	检 验 结 果 Test results	单 项 结 论 Single conclusion

1	皮肤刺激性 Skin irritation	4.7	护具应无皮肤刺激性 The protectors should have no skin irritation	符合要求 Meet the requirements	符合 accord with
2	皮肤致敏性 Skin Sensitization	4.8	护具应无皮肤致敏性 The protectors should have no skin Sensitization	符合要求 Meet the requirements	符合 accord with
3	细胞毒性 Cytotoxic	4.9	护具的细胞毒性应不大于Ⅱ级 The cytotoxicity of the protectors should not be greater than grade II	2 级 Level 2	符合 accord with
4	纤维含量 Fiber content	4.10	护具面料成分应符合如下要求： 棉：61%±5% The material of protectors should meet the following requirements: Cotton: 61%±5%	58%	符合 accord with
			涤纶：32%±5% Polyester fiber: 32%±5%	37%	符合 accord with
			氨纶：7%±2% Spandex: 7%±2%	5%	符合 accord with