

MA

No. 注 20140870

-Henan Medical Equipment Inspection Institute

Inspection & Test Report

Product Name: Medical disposable protective clothing

Inspection Category: Registration Inspection

Inspection & Test Report

Report No. : 注 20140870

Sample Name	Medical disposable protective clothing	Number of samples	20 Packs
	Select () Sampling ()	Specifications	170cm
Client		LOGO	Graphics
Production address		Sample lot number	20140715
Manufacturer		Production Date	/
To be Inspected			
Sampling unit	/	Test category	Registration Inspection
Sampling base	/	Sample status	Normal
Sampling date	/	Weighing date	
Sampling location	/	Inspection location	laboratory of this Institute
Sampling order number	/	Inspection date	
Test items	Full Item		
Test Basis	GB 19082-2009 Technical standards for medical disposable protective clothing		
Conclusion	The tested product meets the technical requirements of GB 19082-2009 technical standards for medical disposable protective clothing		
Remarks	----- Means item does not apply		

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Medical disposable protective clothing				
Test items	Standard & clause	Standard requirement	Test results	Conclusion
Appearance	4.1.1	Protective clothing should be dry, clean and free of mildew spots, and no defects such as adhesion, cracks, holes, etc. are allowed on the surface		Qualified
	4.1.2	The connection part can be processed by stitching, bonding or heat sealing. The eye of the needle should be sealed, and the stitch pitch should be 8 to 14 stitches per 3CM. After processing, such as bonding or heat sealing, the part should be flat, sealed, and free of air bubbles.	Meet the requirements, Number of stitches: 9-pin-10-pin / 3cm, others meet requirements	Qualified
	4.1.3	Zippers should not be exposed. The slider should be self-locking.	Meet the requirements	Qualified
Structure	4.2.1	Protective clothing consists of hooded tops and pants, which can be divided into one-piece structure and split-type structure. The one-piece structure and the two-piece structure are shown in Figures 1 and 2.	one-piece type	Qualified
	4.2.2	The structure of the protective clothing should be reasonable, easy to put on and take off, and tightly bonded.	Meet the requirements	Qualified
	4.2.3	Elastic cuffs should be used for cuffs and ankles, and elastic cuffs, drawstrings, or buckles should be used for the caps and waists.	Elastic cuffs	Qualified
Size	4.3	The sizes of the protective clothing are 160, 165, 170, 175, 180, 185. The specifications of the sizes are shown in Table 1. Table 2	Size 170, meet the requirements	Qualified
Impermeability	4.4.1	The hydrostatic pressure of key parts of protective clothing should not be lower than 1.67 Kpa (17 cm H ₂ O)	33.46 Kpa	Qualified
Moisture permeability	4.4.2	The moisture permeability of protective clothing materials should not be less than 2500g (/ m ² · d)	3170 g (/m ² -d)	Qualified
Synthetic blood penetration	4.4.3	Anti-synthetic blood penetration should not be less than the requirements of level 2 in Table 3	level 4	Qualified
Surface moisture resistance	4.4.4	The level of water on the outer side of the protective clothing should not be less than the requirement of level 3.	level 4	Qualified

Breaking strength	4.5	The breaking strength of the key parts of the protective clothing should not be less than 45N	Vertical 85N Horizontal 46N	Qualified
Elongation at break	4.6	The elongation at break of the key parts of the protective clothing is not less than 15%	Vertical 91% Horizontal 86%	Qualified
Filtration efficiency	4.7	The filtering efficiency of non-oily particles in the material and joints of key parts of protective clothing is not less than 70%	filtering efficiency: 87%-91%	Qualified
Flame retardant performance	4.8	Damage length of protective clothing with flame retardant performance is not larger than 200mm	---	
		Flame duration time does not exceed 15s	---	
		Flame retardant time does not exceed 10s	---	
Antistatic	4.9	The electric charge of protective clothing should not be greater than 0.6 uc / piece	0.5 uc/ piece	Qualified
Static decay	4.10	Static decay time of Protective clothing material does not exceed 0.5s	decay time: 0.4s-0.5s	Qualified
Skin irritation	4.11	The primary stimulus score should not exceed 1	Meet the requirements	Qualified
Microbial index	4.12.1	Protective clothing should meet the requirements of standard microbiological indicators in GB15979-2002	---	---
Aseptic	4.12.2	Masks marked with "sterilized" or "sterile" on the package	Aseptic	Qualified
Residual ethylene oxide	4.13	Protective clothing sterilized by ethylene oxide, the residual ethylene oxide should not exceed 10ug / g	No ethylene oxide detected	Qualified