



Winner Guilin Latex Co.,Ltd.

No. Wushan Road, Guilin, 541001, China

File Type(类型)	SOP	Record No.(记录编号)	GR1-518
File Name(文件名称)	Specification of Male Latex Condom(男用套技术要求): WHO TRS 1025 Annex-10:2020	Version No.(版本号)	A0
Record Name(记录名称)	Test Report of Latex Male Condom	Page No.(页码)	第1页 共1 页

Quality Assurance Testing Report (Certificate of Analysis)

检测报告 (质量分析证书)

Product Name 产品/品牌	Latex Male Condom- Standard	Standard(Norm) 产品标准	WHO TRS 1025 Annex-10:2020 & ISO4074: 2015
Batch No. 批号	00204795TA	Bxtah Size 批量	453600pcs.
Type 规格型号	W53±2mm	Samples Qty 检测样品数量	1200pcs.
Mfg Date 生产日期	2023/10	Expiry Date 失效日期	2028/09
Sampling date 抽样日期	2023/10/28	Testing Date 检验日期	2023-10-28-2023-11-05
Sampled by 抽样人员	Wu Yan	Tested by 检验员	Yang Jinying, Li Yin
UNFPA PO No.	70057561	UNFPA Buyer	Arlette MAKOBERO

Test Results 检测结果

No 序号	Item 检测类型	Specification 技术要求	WHO TRS 1025 Annex- 10:2020	ISO 4074:2015		Inspection level 检测水平	Code 代码	AQL	Max. Non- Compliers Acceptable 最大可接受 不合格数	No. of Non- Compliers Not Acceptable 不可接受 不合格数	No. of Condoms Tested 避孕套 检测数量	Mean 平均值	Min 最小值	Max 最大值	Non- Compliers Found 实际不合 格数量	Inferred Result 推断结果	
				Clause 条款	Annex 附件												
1	Freedom from holes 针孔	No leakage (unless 25mm or less from rim)	A10.2	12	M	G-I (M)	M	0.25	2	3	315	/	/	/	0	Pass	
	a) Leakage 渗漏	无渗漏, 距边25mm内不计		13	M			0.4	3	4	315	/	/	/	0	Pass	
	b) Visible defects可见缺陷	Critical/严重外观缺陷		14	M			0.4	3	4	315	/	/	/	0	Pass	
2	Burst vol.& pressure before aging	> 18.0 L	A10.2	10	H	G-1 Double Sampling	200[5,9] 200[12,13]	1.5	5	9	200	40	5.0	49	1	Pass	
	a) Burst Vol. 爆破体积 (L)								12	13	200	/	/	/	/	/	Pass
	b) Burst Pres爆破压力 (kPa)	> 1.0 kPa							5	9	200	2.05	0.80	2.45	1	Pass	
	c)Total nonconformity不合格总数								12	13	200	/	/	/	/	/	Pass
									/	/	/	/	/	/	/	0	Pass
									/	/	/	/	/	/	/	Pass	
2		Burst vol.& pressure after aging	> 18.0 L	A10.2	10	H	G-1 Double Sampling	200[5,9] 200[12,13]	1.5	5	9	200	40.5	28.0	51.0	0	Pass
	a) Burst Vol. 爆破体积 (L)		12							13	200	/	/	/	/	/	Pass
	b) Burst Pres爆破压力 (kPa)	> 1.0 kPa	5							9	200	1.90	1.40	2.30	0	Pass	
	c)Total nonconformity不合格总数		12							13	200	/	/	/	/	/	Pass
			/							/	/	/	/	/	/	0	Pass
			/							/	/	/	/	/	/	Pass	
3		Package Seal Integrity 包装密封完整性	No bubble袋中无无气泡漏出 No test fluid visible in pack 包装中无可见测试液体	A10.2	14	N	S-3	2.5	2	3	32	/	/	/	0	Pass	
			/									/	/	0	Pass		
4	Dimensions 尺寸	> 180mm	A10.5	9.3.1	D	S-2		1.0	0	1	13	188	185	190	0	Pass	
	a) Length 长度, mm			9.3.2	E				0	1	13	52.6	52.0	53.5	0	Pass	
	c) Thickness, 厚度, mm	0.065±0.01mm		9.3.3	F				0	1	13	0.072	0.068	0.075	0	Pass	
5	Design requirements设计要求	Smooth, Straight, parallel sides, without constrictions, with a visible shoulder leading to a reservoir tip	A10.5	N/A	N/A	S-2	E	1.0	0	1	13	/	/	/	0	Pass	
	a)Shape&Texture 形状&纹理								1.0	0	1	13	/	/	/	0	Pass
	b)Color 颜色	Natural 天然橡胶色							1.0	0	1	13	/	/	/	0	Pass
6	c)Odour 气味	Free from unpleasant odour 无难闻气味	A10.5	N/A	N/A	S-2	E	1.0	0	1	13	/	/	/	0	Pass	
6	Lubricant Qty (incl. powder) 总硅油数量 (包括固体粉末)	450±100mg	A10.5	9.2	C	S-2		4.0	1	2	13	495	473	500	0	Pass	
7	a) Pack design including colour, print, identification marking, 独立包装材料以及标识	Free from nonconforming pack 无不合格包装	A10.5	15.1 - 15.2	N/A	S-3		2.5	2	3	32	/	/	/	0	Pass	
	b) Manufacturer's name/address 制造商名称/地址	Check markings 检查标识		N/A	N/A	S-3		2.5	2	3	32	/	/	/	0	Pass	
	c) Lot No. /lot id. 批号/批次标识	Check markings 检查标识	N/A	N/A	S-3		2.5	2	3	32	/	/	/	0	Pass		
	d) Expiry date 有效期	Check markings 检查标识	N/A	N/A	S-3		2.5	2	3	32	/	/	/	0	Pass		
	e) No leaking packs 包装无泄漏	No evidence of leakage 无渗漏迹象, 无油渍	N/A	N/A	S-3		2.5	2	3	32	/	/	/	0	Pass		
	f) Clean surface 包装表面清洁	Check the surface of the pack is clean 包装表面整洁	N/A	N/A	S-3		2.5	2	3	32	/	/	/	0	Pass		
	g) No separation layer 铝箔无分 层	No separation of the layers of laminate 铝箔材料无分层	N/A	N/A	S-3		2.5	2	3	32	/	/	/	0	Pass		
	h) Perforated strips 产品联易分 离	If in strips, there will be perforations or other means to ensure packs are easily separated without interfering with the seals 成联产品易分 离, 不损坏独立包装	N/A	N/A	S-3		2.5	2	3	32	/	/	/	0	Pass		
	i) Easy to open 小包装易于打开	Easy to open without damaging the condom 易打开, 不损坏避孕套	N/A	N/A	S-3		2.5	2	3	32	/	/	/	0	Pass		
	Overall result 综合结果			Accept													

Approved by: Gan Huacheng

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