

Certificate of Analysis

Item Name	VAGINAL SPECULUM Spanish Type	Spec.& Model	M
Quantity	2000pcs	LOT	20240810
Mfg.date	20240810	expiration date	20290809
Test Date	2024.10.15	Report Date	2024.10.15
Test Gist: YY0336-2020, TKY/CE-TD-VS-001			
Test Item		Technical Request	Test Result
Physical Capacity 1	Back Outer Height h	Size should be measured up TKY/CE-TD-VS-03 3.1	OK
	Appearance	Should be smooth ,no edges and corners on the cirque ,no burr, no dust and no watermark	OK
	Close neatly and no baffling	Vaginal Speculum should operate with single hand, close neatly and no baffling	OK
	Axes and axes hole	Operate neatly between axes and axes holes, no casting when used	OK
	Expanding neatly	Expand neatly and no baffling	OK
	No parts prevent eyeshot	No parts prevent the eyeshot	OK
	Flexibility	Vaginal Speculum expands the last position , the flexibility value $\leq 30\text{mm}$ under the 20N rated loading	OK
	Intensity	Vaginal Speculum expands the last position, close to the upper part 20mm,any part should not rupture under 30N quiet loading	OK
Physical Capacity 2	l	Measured up TKY/CE-TD-VS-033.1	OK
	w	Measured up TKY/CE-TD-VS-033.1	OK
	b	Measured up TKY/CE-TD-VS-033.1	OK
	Top Difference between Upper parts and lower parts	Top Difference between Upper parts and lower parts $\leq 2\text{ mm}$	OK
Biology Capability	Sterile	Should be sterile	OK
	Cell toxicity	The reaction is no more than 1 grade.	0
	Sensitization	The skin reaction is no more than I grade	OK
	Skin irritatin	No skin reaction, P II is 0~ 0.4.	0
Remarks			

Tester: Lin yan

Checker: Sun Juping

