

**CERTIFICATE OF ANALYSIS**

Report No.: GM01-BN21

Product Name	Vaginal Speculum	Specification	S/M
Lot. No.	20210301	Quantity	30000pcs
Mfg. Date	20210301	Exp. Date	20260228
Test Standard	YY0336-2020	Report Date	2021.04.15
Item	Technical Requirement	Result	Conclusion
Appearance	The surface is clean, no impurities. The edges of the speculum should be round, smooth, no burr, no edges.	Comply	Qualified
Size	The deviation is not more than 2mm at the natural closed state.	Comply	Qualified
	The size of the speculum should meet the requirement.	Comply	Qualified
Performance	Flexible adjustment and without jamming.	Comply	Qualified
	The gear should be stable, no break or fall off.	Comply	Qualified
	No part shall block the opening of the field of view.	Comply	Qualified
Deformation Resistance	When expanding to the maximum and applying 20N force, the allowable deformation should be no more than 30mm	Comply	Qualified
Structural Strength	When expanding to the maximum and applying 30N force, no parts shall slip, crack or fracture.	Comply	Qualified
Sterile	The vaginal Speculum should be sterile	Sterile	Qualified
Residual of EO gas	After sterilized, the residual of EO gas should be no greater than 10µg/g	3.8µg/g	Qualified
Conclusion	Meet the requirement		

Inspector: Tom L  
Date: 2021.04.15

Checker: Leo Sun  
Date: 2021.04.15

