ReLAB

上海睿齐实业有限公司
Shanghai ReLAB CO., LTD.

Certificate of Compliance

No.:166W20200901

Product Code	82341 17*100 mm culture tube		**Specification**	Rimed,Dual-position cap,Graduated,PS,EO Sterile	
Lot No.	09/02/20		**Expire Date**	09/01/25	
Packaging	Individual peel bag pack,50PCS/bag,10bags/Case	**Samples Tested**	32pcs	**Lot Quantity**	1000pcs

SPECIFICATIONS		Findings
Material	PS Non-cytotoxic.	yes
Appearance	There is no Impurity, Oiliness, incompletion, scratch onto tube/cap.	yes
	No contamination from dust or something else outside.	yes
	Color of body: transparency-the pure color of PS material	yes
	Color of Cap: transparency-the pure color of PE material	yes
	Printed figures are correct, clear and complete. No blur.	yes
	Printed lines are in correct position, no blur and segmentation.	yes
	The printed figures&lines will not disappear or lose color after scatch for at least 20 times.	yes
Performance	When pushing on the cap onto tube, the hand-feeling should be better.	yes
	External Diameter of cap: 21.5mm±0.3mm	yes
	Overall Height of Cap: 18.5mm±0.3mm	yes
	External Diameter of Tube: 18.0mm±0.3mm	yes
	Overall Length of Tube: 101.0mm±0.3mm	yes
	Total height(w/cap): 101.7mm±0.3mm	yes
Weight (EA)	Cap: 1.55±0.10(g); Tube: 4.27±0.20(g)	yes
Sterilization	Ethylene Oxide sterile	ETO

Quality System Compliance –Runlab Technology Co.,Ltd. products are manufactured under the ISO 13485 system. Management system 13485 with SOPs and clean control room grantee quality, and Stringent quality control protocols are followed at every process of production ranging from qualitative raw materials and process of production till final products.

Quality Control Testing –Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.

Sterilization – Runlab Products have been sterilized with Ethylene Oxide and found to conform to the sterility requirements of EN ISO11135:2014 .

The details and process of sterilization are as follows:

1. Type of sterilization cycle: overkill cycle
2. Gas mixture: EO density of 1Kg/m3
3. Maximum level of gas residue: 10ppm
4. Sterilization process:
   a. Load the products in the sterilization chamber.
   b. Load and locate 20 bio-indicators in the sterilization chamber for proving and check the sterility.
   c. Precondition at 45±5℃ temperature and 50-70%humidity for 30min.
   d. Initial vacuum: 50±1Kpa
   e. Inject the 20% ETO into the sterilization chamber and operate sterilization cycle at temperature 50±1℃ and 40-70%humidity with exposure pressure 135Kpa for 8 hours.
   f. Evacuate the gas to 70±2Kpa, then turn off the vacuum valve.
   g. Inject the fresh air into the sterilization chamber, when the pressure of chamber is atmosphere, turn off the air valve.
   h. Repeat the procedure of f and g for 3 times.

QA Dept. Director: Wang Guoli

Date: September 01, 2020