Runlab 浙江润兰科技有限公司
Zhejiang Runlab Technology CO., Ltd

Certificate of Compliance No.:20011901TTS

Product Name	#PIP4210 Transfer pipettes		**Type**	3ml capacity, large bulb,sterile	
Lot No.	6591228		**Expire Date**	2024-12	
Packaging	1/bag, 500/case	**Samples Tested**	20pcs	**Lot Quantity**	8500pcs

SPECIFICATIONS

Material	Non-toxic low-density Polyethylene	APPROVED
Appearance	Color transparent, raw material color. There is no edges, holes, bubbles, missing material, bending deformation. There is free from scratches, grease, dust, or other foreign matter. The shape of airbag is intact and no deformation is observed. The notch is neat, no oblique mouth and galling.	APPROVED
Performance	(1)Length size:160mm±1.5mm (2)Working Capacity:3ml±5%	APPROVED
Weight (EA)	1.45±0.15g	APPROVED
Sterilization	Ethylene Oxide sterile	APPROVED

Quality System Compliance –Zhejiang Runlab Technology CO.,Ltd products are manufactured under the ISO 13485 system. Management system 13485 with SOPs andclean 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: 19 Jan 2020
Zhejiang Runlab Technology CO., Ltd

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