

Certificate of Conformity



Article no.	Retrace Code/Batch/Lot no.
9569000001	211212-069

Article description
PIPET,SERO,PLAS,TD,5ML

Item No.	Manufacturing Date	Expiry Date
56900-5110	2021-12-12	2024-12-12

The articles listed under "article number" are hereby confirmed to have been produced using a quality system conforming to ISO 9001 and comply with the DWK Life Sciences quality standards. This product is manufactured in accordance with ISO 13485 in a class 100,000 clean room.

Material

This product is manufactured from Polystyrene (GPPS).
Material compliance with USP Class VI.

Expiry Date

3 years after month of production (see above).

Sterilization

This product has been irradiated and dosimetrically released upon ISO11137 recommended practices in effect at the time of validation. Sterilization records are reviewed and signed off by qualified personnel for product release. Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6} .

Non-Pyrogenic

This product has been validated per FDA guidelines on LAL (Limulus Amebocyte Lysate) testing for medical devices and company guidelines. The acceptance level for this product is less than 0.5 EU/ mL.

DNase/ RNase free

This product has been tested and is free of any detectable DNase/ RNase contamination.

Non-cytotoxic

Testing is conducted to qualify all material resins using USP Class VI Chapter <87> / Chapter <88> and ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

Statement on BSE/TSE

This product does not contain materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

Latex

This product does not contain naturally occurring latex, natural rubber as intentionally added components during the manufacturing process. Therefore this product is deemed latex free.

Please note that analysis of the finished goods for presence of the above mentioned substances is not performed on a routine basis.

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Graduation accuracy

Each lot has been taken some samples random from total Lot as representative sample for graduation accuracy and they comply with our product specification. Serological pipets are accurate to +/- 2% at full scale.

Production and inspection

The products are inspected and controlled through the entire production process in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.

Certified by: 
Sherry Roberts
Quality Specialist

Date: 2022-07-20