Certificate of Conformity

VWR Catalogue Number	214-0448
Description	Erlenmeyer Shaker Flask, 250 mL Capacity, Plug seal screw cap, Sterile
Lot Number	220608684A
Date of Manufacture (yyyy-mm-dd)	2022-06-08
Date of Sterilzation (yyyy-mm-dd)	2022-06-18
Expiry Date (yyyy-mm-dd)	2025-06-08
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2023-02-08

Quality System Compliance

Products are manufactured under the **ISO 9001:2015 & ISO 13485:2016** standard. Products are inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP.

QC Testing

Representative products samples are collected and inspected in accordance with current applicable QC requirements.

Accuracy of Graduations: Graduation accuracy comply with our product specification ±5%.

Autoclave Test: This product has been tested at 121℃ for 20 min in a autoclave and it is integrate, no distortion and no leak with cap after autoclave.

Low temperature test: This product has been tested at -80℃ for 24 hours in freezer and it is integrate, no distortion and no leak with cap after freezing.

Product Specifications

The product is Class I category device as defined by FDA in 21CFR Parts 862-892.

Material

Flask Polycarbonate (PC).
Cap High Density Polyethylene (HDPE). Compliance with USP Class VI
Growth Surface Type: Non-Treated

Sterilization	Product labeled as sterile are EB (Electron beam) irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Products labeled sterile meets a minimum requirement of 10^{-6} SAL with a specified dose range of 15-30 kGy.
ATP Assay	Not Applicable.
DNase & RNase Free	This product is free of any detectable DNase/RNase contamination.
BSE/TSE	No use of any raw material produced from or substances derived from animal origin. The manufacturing process of the product does not use any ingredient of animal origin and no material derived from or exposed to animals affected by or under quarantine for transmitting Animal Bovine Spongiform Encephalopathy/Spongiform Encephalopathy (BSE)/(TSE). according to EMEA 410/01 revision 3.
Cytotoxicity	Testing is conducted to quality all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.
Non-Pyrogenic Statement	The acceptance level for product is 0.5 EU/ml or less than 20 EU/device. (TAL Gel Clot Method). Test passed.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Not Applicable.
DEHP Statement	Not Applicable.
RoHS	No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr6+), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Bis(2-Ethyhexyl) Phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Diisobutyl Phthalate (DIBP)) are used in manufacturing the raw materials and final product. No routinely analyse is performed).
REACH Statement	Not Applicable.
Storage Conditions	Room Temperature.

Disclaimer: VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. The purpose of the product is for use in laboratory only.
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