Certificate of Conformity

VWR Catalogue Number	**See List**
Description	**Erlenmeyer Shaker Flask, Polycarbonate, Sterile**
Country of Origin	**Manufactured in China**
Date of Issue (yyyy-mm-dd)	**2023-04-24**

Catalogue Number	Capacity [mL]	Closure Type
214-0446	125	Plug seal screw cap
214-0447	125	Vented cap
214-0448	250	Plug seal screw cap
214-0449	250	Vented cap
214-0450	500	Plug seal screw cap
214-0451	500	Vented cap
214-0452	1000	Plug seal screw cap
214-0453	1000	Vented cap
214-0476	2000	Plug type cap
214-0477	2000	Vented cap
214-0478	3000	Plug type cap
214-0479	3000	Vented cap
214-0480	5000	Plug type cap
214-0481	5000	Vented cap

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%.

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).
	Membrane:	Polytertafluoroethylene (PTFE).
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).	
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.
Shelf Life	3 Years.

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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