

Certificate of Quality

VWR Catalogue Number	See List
Description	VWR® Cell Culture Flasks
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2024-06-25

VWR Catalogue Number	Capacity [ml]	Cap Type	Culture Area [cm ²]	Surface Treatment
10062-862	250	Standard	75	Treated
10062-860	250	Vented	75	Treated
10062-870	25	Standard	12.5	Treated
10062-868	25	Vented	12.5	Treated
10062-874	50	Standard	25	Treated
10062-872	50	Vented	25	Treated
10062-866	600	Standard	182	Treated
10062-864	600	Vented	182	Treated
10062-886	850	Standard	300	Treated
10062-884	850	Vented	300	Treated

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.

Product Specifications

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

Material

Flask - Polystyrene (PS), Compliance with USP Class VI
Cap - High density PolyEthylene (HDPE), Compliance with USP Class VI

Sterilization	Product labelled as sterile are EB (Electron Beam) irradiated and dose released upon ISO 11137 recommended practices in effect at the time of validation and they meet 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	The product is latex free.
BPA Statement	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Not applicable.
RoHS	Raw materials comply with the requirements of the Directive 2002/95/EC, as amended, and 2011/65/Eu concerning the limits of cadmium, lead, mercury, hexavalent chromium, Polybrominated Biphenyls (PBB) and Polybrominated Diphenyl Ethers (PBDE).
REACH Statement	Not applicable.
Storage Conditions	Store at 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.
This document has been produced electronically and is valid without a signature.

Version History

Sl.no	Version number	Description	Month & Year
1	1.0	Created General CoQ using new layout	March 2021
2	1.0	Additional information added. 1. Added Surface treatment information. 2. Added USP Class VI information. 3. Added regulation to BSE-TSE statement.	June 2024