

## Certificate of Quality

VWR Catalogue Number	See List	
Description	VWR® Cell Culture Flasks Treated for Increased Cell Attachment, Sterile	
Country of Origin	Manufactured in China	
Date of Issue (yyyy-mm-dd)	2021-08-20	

VWR Catalogue Number	Capacity	Cap type	Growth area
10861-670	25 mL	Plug Seal Cap	12.5 cm <sup>2</sup>
10861-672	25 mL	Vent Cap	12.5 cm <sup>2</sup>
10861-640	50 mL	Plug Seal Cap	25.0 cm <sup>2</sup>
10861-642	50 mL	Vent Cap	25.0 cm <sup>2</sup>
10861-644	250 mL	Plug Seal Cap	75.0 cm <sup>2</sup>
10861-646	250 mL	Vent Cap	75.0 cm <sup>2</sup>
10861-648	600 mL	Plug Seal Cap	182.0 cm <sup>2</sup>
10861-650	600 mL	Vent Cap	182.0 cm <sup>2</sup>
10861-652	850 mL	Plug Seal Cap	300.0 cm <sup>2</sup>
10861-654	850 mL	Vent Cap	300.0 cm <sup>2</sup>

## **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 product specifications.

## **Product Specifications**

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

Material Flask Polystyrene (PS)

Cap High density Polyethylene (HDPE)



**Sterilization** Product is EB (Electron beam) irradiated, and dose released upon

ISO11137 recommended practices in effect at the time of validation. Product meets a minimum requirement of 10<sup>-6</sup> 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).

**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 No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr<sup>6+</sup>),

Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), 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** Store at room temperature.

Shelf-Life Products labelled as sterile has shelf-life period of 3 years which is not

applicable for non-sterile products.

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.