Certificate of Quality

VWR Catalogue Number	See List
Description	VWR® Tissue Culture Plate Inserts, Polyester (PET) Membrane, Sterilized, Standard Line
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2021-11-22

VWR Catalogue Number	Number of wells	Cell growth area [cm²]	Insert size [mm]	Membrane	Pore size [µm]
10769-182	6	4.67	24	Transparent	0.1
76313-902	6	4.67	24	Transparent	0.4
10769-192	6	4.67	24	Translucent	0.4
10769-184	6	4.67	24	Translucent	1.0
10769-194	6	4.67	24	Transparent	3.0
10769-196	6	4.67	24	Transparent	8.0
10769-204	12	1.12	12	Transparent	0.1
76313-904	12	1.12	12	Transparent	0.4
10769-214	12	1.12	12	Translucent	0.4
10769-206	12	1.12	12	Translucent	1.0
10769-216	12	1.12	12	Transparent	3.0
10769-218	12	1.12	12	Transparent	8.0
10769-226	24	0.33	6.5	Transparent	0.1
76313-906	24	0.33	6.5	Transparent	0.4
10769-238	24	0.33	6.5	Translucent	0.4
10769-228	24	0.33	6.5	Translucent	1.0
10769-240	24	0.33	6.5	Transparent	3.0
10769-242	24	0.33	6.5	Transparent	8.0

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	Plate	Polystyrene (PS)
	Insert	Polystyrene (PS)
	Insert Membrane	Polyethylene terephthalate (PET)
	Membrane Thickness	0.1 mm
Sterilization	Product labeled as sterile is 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).	
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^{6+}), 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.
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