

# Certificate of Quality

<b>VWR Catalogue Number</b>	See List
<b>Description</b>	VWR® 3D Cell Culture Dishes and Plates, Surface Treated
<b>Country of Origin</b>	Manufactured in China
<b>Date of Issue (yyyy-mm-dd)</b>	2022-02-07

## 3D Dishes

VWR Catalogue Number	Description	Diameter	Pore size	Surface
76012-952	1 Scaffold Insert (32 x 1.6 mm)	3.5 cm	260 µm	43 cm <sup>2</sup>
76012-954	1 Scaffold Insert (51 x 1.6 mm)	6.0 cm	260 µm	109 cm <sup>2</sup>
76012-956	1 Scaffold Insert (67.5 x 1.6 mm)	7.0 cm	260 µm	191 cm <sup>2</sup>

## 3D Plates

VWR Catalogue Number	Description	No. of wells	Pore size	Surface
76012-958	3 Scaffold Inserts (33.5 x 1.6 mm)	6	260 µm	143 cm <sup>2</sup>
76012-960	6 Scaffold Inserts (21 x 1.6 mm)	12	260 µm	113 cm <sup>2</sup>
76012-962	12 Scaffold Inserts (15 x 1.6 mm)	24	260 µm	115 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.

**Food contact statement:** The composition of the product complies with the requirements of the 21 CFR 177.1640 "Polystyrene and rubber modified polystyrene".

## Product Specifications

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

**Material** Polystyrene (PS)

<b>Sterilization</b>	Product is EB (Electron beam) irradiated, and dose released upon ISO11137 recommended practices in effect at the time of validation. Products meets a minimum requirement of 10 <sup>-6</sup> SAL with a specified dose range of 15-30 kGy.
<b>ATP Assay</b>	Not applicable.
<b>DNase &amp; RNase Free</b>	This product is free of any detectable DNase/RNase contamination.
<b>BSE/TSE</b>	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).
<b>Cytotoxicity</b>	Testing is conducted to quality all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.
<b>Non-Pyrogenic Statement</b>	The acceptance level for product is 0.5 EU/ml or less than 20 EU/device. (TAL Gel Clot Method).
<b>Latex Statement</b>	The product is Latex free.
<b>BPA Statement</b>	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.
<b>DEHP Statement</b>	Not Applicable.
<b>RoHS</b>	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.
<b>REACH Statement</b>	Not applicable.
<b>Storage Conditions</b>	Store at room temperature.
<b>Shelf-Life</b>	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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