

Certificate of Conformity

VWR Catalogue Number	See List
Description	Cell Culture Plates, 3D Scaffold, Sterile
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2022-06-08

Catalog Number	Description	Culture area [cm ²]
734-2970	Standard 6-well plate, 3x surface treated scaffold inserts (33.5 x 1.6 mm)	143
734-2971	Standard 12-well plate, 6x surface treated scaffold inserts (21.0 x 1.6 mm)	113
734-2972	Standard 24-well plate, 12x surface treated scaffold inserts (15.0 x 1.6 mm)	115

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

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

Material

Polystyrene(PS).

The composition of the product complies with the requirement of the 21 CFR 177.1640 "Polystyrene and rubber modified polystyrene".

Sterilization	Product labelled as sterile is gamma irradiated and dose released upon ISO 11137 recommended practices at the time of validation and meets a minimum requirement of 10 ⁻⁶ SAL with a specified dose range of 12-24 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	This product is not made from natural rubber latex.
BPA Statement	Bisphenol are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Please see RoHS information below.
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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