Certificate of Conformity

VWR Catalogue Number	734-2972
Description	Cell Culture Plates, 3D Scaffold, Sterile, Standard 24-well plate, 12x surface treated scaffold inserts (15.0 x 1.6 mm), 115 cm^2 Culture area
Lot Number	2511101522F
Date of Manufacture (yyyy-mm-dd)	2025-11-10
Date of Sterilization (yyyy-mm-dd)	2025-11-13
Expiry Date (yyyy-mm-dd)	2028-11-10
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2026-02-02

Quality System Compliance

This certificate confirms that the product has been sourced from a supplier or manufacturer who has declared their Quality Management System (QMS) complies with **ISO 9001:2015 & ISO 13485:2016.**

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). Compliance with USP Class VI. 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 EB (Electron beam) 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 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	This product is not made from natural rubber latex.
BPA Statement	Bisphenols 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's Quality Management System (QMS) is ISO 9001:2015 certified as a wholesale distributor of finished products, ensuring effective oversight of finished product handling, traceability, and distribution processes. VWR is not a manufacture and does not engage in manufacturing, co-manufacturing or processing activities such as design, packaging, labeling, testing or quality release. Consequently, the supplier or manufacturer's QMS certification may differ from VWR's.

VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. This product is intended for research use only. It is not for use in diagnostic procedures, therapeutic applications, or any human or clinical use.

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