Certificate of Conformity

VWR CELL CHAMBERS

VWR International certifies that the specified products meet all VWR specifications and quality criteria for release. The products comply in every respect with the relevant particular specifications, drawings, relevant standards and regulations in force.

VWR International certifie que les produits mentionnés respectent toutes les spécifications et critères de qualité VWR. Les produits satisfont aux spécifications particulières, aux plans, aux normes et règlements en vigueur s'y rapportant.

VWR International bestätigt hiermit, daß die angegebenen Produkte alle VWR Spezifikationen und Qualitätskriterien zur Freigabe erfüllen. Die Produkte entsprechen in jeder Hinsicht den maßgeblichen Spezifikationen, den Zeichnungen sowie den relevanten Normen und gültigen Vorschriften.

VWR Catalog No: 734-2981

Lot No: 220212531A

Date of Manufacture: 12th Feb 2022

Expiry Date: 12th Feb 2025

Date of Sterilization: 22nd Feb 2022

Type	Recommended working volume (ml)	Growth area (cm^2)	Pk
2 level	260 - 400	1296	6

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

Material: Polystyrene (PS), Compliance with USP Class VI
Cap – High Density Polyethylene (HDPE), Compliance with USP Class VI
Membrane – 0.22 µ m Hydrophobic

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. Inspection records are reviewed and signed off by qualified personnel for product release.

Quality Testing: Representative production samples are collected and inspected in accordance with current applicable product specifications.

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Test Procedure	Results
Visual Attributes	Pass
Flatness	Pass
Cell Culture	Pass
Packaging	Pass

Sterility: Products labeled as sterile is Electron beam (EB) irradiated and dose released upon ISO11137 recommended practices meets a minimum requirement of 10^{-6} SAL with the specified dose range of 15 - 30 kGy.

BSE/TSE Statement: The above product contains no ingredients of animal origin and no material derived from, or exposed to animals affected by or under quarantine for Transmitting, Animal Spongiform Encephalopathy (TSE)/ Bovine Spongiform Encephalopathy (BSE)

Non-pyrogenic: The acceptance level of product is 0.5 EU/ml or less than 20 EU/device by TAL Gel Clot Method. Test passed.

DNase & RNase free : This product has been tested and is free of any detectable DNase/RNase contamination.

Cytotoxity: Testing is conducted to quality all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

Latex Free statement: Product is Latex Free

BPA Statement: Bisphenol-A (BPA) and Bisphenol-F (BPF) are not used in the manufacture or the formulation of the raw materials and are not expected to be present. However, tests have not been performed for these chemical materials.

DEHP Statement: Not Applicable.

Heavy metals - RoHS: Raw materials comply with the requirements of the Directive 2002/95/EC, as amended, and 2011/65/Eu concerning the limits of cadmium, lead, mercury, hexavalent chromium, Polybrominated Biphenyls (PBB) and Polybrominated Diphenyl Ethers (PBDE).

This document has been produced electronically and is valid without a signature

Date of Issue: **May 2022**