

Certificate of Conformity

VWR Catalogue Number	See List
Description	Cell culture insert plates, PC
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2022-03-07

Catalogue Number	Description	Pore Size [µm]	Membrane	Membrane Diameter [mm]
734-2715	6-well insert plate	0.1	Translucent	24
734-2720	6-well insert plate	0.4	Translucent	24
734-2716	6-well insert plate	1.0	Translucent	24
734-2721	6-well insert plate	3.0	Transparent	24
734-2722	6-well insert plate	8.0	Transparent	24
734-2717	6-well insert plate	12.0	Transparent	24
734-2726	12-well insert plate	0.1	Translucent	12
734-2731	12-well insert plate	0.4	Translucent	12
734-2727	12-well insert plate	1.0	Translucent	12
734-2732	12-well insert plate	3.0	Transparent	12
734-2733	12-well insert plate	8.0	Transparent	12
734-2728	12-well insert plate	12.0	Transparent	12
734-2737	24-well insert plate	0.1	Translucent	6.5
734-2742	24-well insert plate	0.4	Translucent	6.5
734-2738	24-well insert plate	1.0	Translucent	6.5
734-2743	24-well insert plate	3.0	Transparent	6.5
734-2744	24-well insert plate	8.0	Transparent	6.5
734-2745	24-well insert plate	5.0	Transparent	6.5
734-2739	24-well insert plate	12.0	Transparent	6.5

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	Plate – Polystyrene (PS) Insert - Polystyrene (PS) Insert Membrane – Polycarbonate (PC)
Temperature range	–20 to 50 °C.
Sterilization	Product labelled as sterile is gamma irradiated as per ISO 11137 and meets SAL 10 ⁻⁶ with a specified dose range of 12-24kGy.
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	Not Applicable.

DEHP Statement	Not Applicable.
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 analysis 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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