

Certificate of Conformity

VWR Catalogue Number	See List
Description	VWR®, Confocal Dishes for Microscopy
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2023-05-01

Catalogue Number	Description
734-2905	Glass bottom dish, Ø15 mm centre, non treated
734-2906	Glass bottom dish, Ø20 mm centre, non treated
734-2904	Glass bottom dish, Ø20 mm centre, TC-treated

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	Dish:	GPPS (General polystyrene) Compliance with USP Class VI.
	Lid:	GPPS (General polystyrene) Compliance with USP Class VI
	Glass bottom:	D263M Borosilicate glass

Sterilization	Product labeled as sterile are EB (Electron beam) irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Products labeled sterile meets a minimum requirement of 10 ⁻⁶ SAL with a specified dose range of 15-30 kGy.
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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 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.
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.
This document has been produced electronically and is valid without a signature.

Version History

Sl.no	Version number	Description	Month & Year
1	1.0	Created General CoC using new layout	05-2023