

Certificate of Conformity

VWR Catalogue Number	See List
Description	Pestles for Cell Strainers, Sterile, Purple Colour
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2022-06-08

Catalog Number	Description
734-2819	Pestle, sterile, individually packaged
734-2820	Pestle, sterile, bulk packaging

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	Polypropylene(PP).
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. Autoclavable Temperature – 121 °C for 30 min.
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	Not Applicable.
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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