

Certificate of Conformity

VWR Catalogue Number	391-0283
Description	VWR ® Media Bottles with screw Cap, Sterile, 250 L Capacity
Lot Number	22-1398CR
Date of Manufacture (yyyy-mm-dd)	2022-07
Date of Sterilization (yyyy-mm-dd)	2022-07
Sterilization Expiry Date (yyyy-mm-dd)	2027-07
Country of Origin	Manufactured in USA
Date of Issue (yyyy-mm-dd)	2023-03-31

Quality System Compliance

Products are manufactured under **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

These Products are manufactured in 100,000 Clean facility that is certified to ISO 13485 Device.

Material	Bottle: Polystyrene (PS), Copolyester (PETG), Polycarbonate (PC) Cap: Polypropylene.
Sterilization	Product are gamma irradiated and meets VD Max SAL 10^{-6} with a specified dose range of 25-40 kGy.
ATP Assay	Not Applicable.
DNase & RNase Free	Not Applicable.

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	Plastic Component materials are non-cytotoxic and meet the Elution Test 10993-5, 1999.
Non-Pyrogenic Statement	The acceptance level for product is less than 20 EU/Device. (LAL Gel Clot Method).
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenol are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Phthalates are not deliberately added to the product. This includes di (2-ethylhexyl) phthalate (DEHP), di butyl phthalate (DBP), benzyl butyl phthalate (BBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP) and di-n-octyl phthalate (DNOP).
RoHS	Not Applicable.
REACH Statement	Not Applicable.
Storage Conditions	Ambient temperature.

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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