

Certificate of Conformity

VWR Catalogue Number	See List
Description	HDPE Bottle with EP liner
Country of Origin	Manufactured in India
Date of Issue (yyyy-mm-dd)	2023-04-28

Catalogue Number	Capacity [mL]	Bottle Shape	Sterility	Cap Colour	Neck Size & finish [mm]	Length [mm]	Width [mm]
215-4506	150	Square	Sterile	Red	45/400	50.5	50.5
215-4507	250	Square	Sterile	Red	45/400	57	57
215-4508	500	Square	Sterile	Red	63/410	76.5	76.5
215-4509	1000	Rectangle	Sterile	Red	63/410	94.9	76.3
215-4510	2000	Rectangle	Sterile	Red	63/410	108	97
215-4516	150	Square	Non-Sterile	White	45/400	50.5	50.5
215-4524	250	Square	Non-Sterile	White	45/400	57	57
215-4525	500	Square	Non-Sterile	White	63/410	76.5	76.5
215-4526	1000	Rectangle	Non-Sterile	White	63/410	94.9	76.3
215-4527	2000	Rectangle	Non-Sterile	White	63/410	108	97

Quality System Compliance

Products are manufactured under the **ISO 9001:2015 & ISO 15378:2017** 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.

Test Name	Test Reference	Accuracy	Result
Leak Test	SOP/QA/07A	General Insp. Level-1, AQL -1.5	Leak Proof
Ethylene Oxide Dose	SOP/PRO/21	NA	PASS
Dimensional	SOP/QA/01	General Insp. Level-1, AQL -1.5	Within Tolerance

Product Specifications

Material

Bottle: High Density Polyethylene, 100% Virgin, FDA 21 CFR Compliance, USP Class VI Passed, Colour: Natural.

Closure with EP Liner: Polypropylene, 100% Virgin, FDA 21 CFR Compliance, USP Class VI Passed.

Monomers and additives used to produce the products are listed in List of Authorised Substances of Regulation EU/10/2011.

The material grades conform to EU Directive 1935/2004 on materials and articles intended to come into contact with food.

Application Temperature

76°C to +75° C

Sterilization

Product labelled as sterile is ETO (Ethylene Oxide) irradiated as per ISO 11135:2014 and meets SAL 10⁻³. (Which is not applicable for non-sterile products).

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

This product is free of cytotoxicity effects.

Non-Pyrogenic Statement

Not Applicable.

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

Please see RoHS information below.

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	No substances as listed on >Substance of Very High Concern< candidate list published 2022-01-17 are used in manufacturing of the raw materials used to produce this product. No routinely analyse is performed.
Storage Conditions	Store at 25 + 3 / - 8 °C, Relative Humidity 50 ± 10 % RH.
Shelf Life	2 years. (Which is not applicable for non-sterile products).

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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