Regulatory Compliance

Description	**See List**
Country of Origin	**Manufactured in India**
Date of Issue (yyyy-mm-dd)	**2023-05-15**

VWR Catalogue Number	Product Description
VWRI210-000043	VWR PETG SAMPLE BTTL 5ML ST CS100
VWRI210-000044	VWR PETG SAMPLE BTTL 10ML ST CS100
VWRI210-000045	VWR PETG SAMPLE BTTL 20ML ST CS100
VWRI210-000046	VWR PETG SAMPLE BTTL 5ML ST BULK CS500
VWRI210-000047	VWR PETG SAMPLE BTTL 10ML ST BULK CS500
VWRI210-000048	VWR PETG SAMPLE BTTL 20ML ST BULK CS500
VWRI210-000055	VWR PETG SQ BTTL 30ML ST CS96
VWRI210-000056	VWR PETG SQ BTTL 60ML ST CS96
VWRI210-000057	VWR PETG SQ BTTL 125ML ST CS48
VWRI210-000058	VWR PETG SQ BTTL 250ML ST CS48
VWRI210-000059	VWR PETG SQ BTTL 500ML ST CS24
VWRI210-000060	VWR PETG SQ BTTL 1L ST CS24
VWRI210-000061	VWR PETG SQ BTTL 2L ST CS12
VWRI210-000062	VWR PETG SQ BTTL 30ML NS CS96
VWRI210-000063	VWR PETG SQ BTTL 60ML NS CS96
VWRI210-000064	VWR PETG SQ BTTL 125ML NS CS48
VWRI210-000065	VWR PETG SQ BTTL 250ML NS CS48
VWRI210-000066	VWR PETG SQ BTTL 500ML NS CS24
VWRI210-000067	VWR PETG SQ BTTL 1L NS CS24
VWRI210-000068	VWR PETG SQ BTTL 2L NS CS12
VWRI210-000069	VWR PETG SQ BTTL 30ML ST BULK CS280
VWRI210-000070	VWR PETG SQ BTTL 60ML ST BULK CS200
VWRI210-000071	VWR PETG SQ BTTL 125ML ST BULK CS96

VWRI210-000072	VWR PETG SQ BTTL 250ML ST BULK CS60
VWRI210-000073	VWR PETG SQ BTTL 500ML ST BULK CS40
VWRI210-000074	VWR PETG SQ BTTL 30ML NS BULK CS280
VWRI210-000075	VWR PETG SQ BTTL 60ML NS BULK CS200
VWRI210-000076	VWR PETG SQ BTTL 125ML NS BULK CS96
VWRI210-000077	VWR PETG SQ BTTL 250ML NS BULK CS60
VWRI210-000078	VWR PETG SQ BTTL 500ML NS BULK CS40
VWRI210-000079	VWR PETG SQ BTTL ONLY 30ML ST BULK CS280
VWRI210-000080	VWR PETG SQ BTTL ONLY 60ML ST BULK CS200
VWRI210-000081	VWR PETG SQ BTTL ONLY 125ML ST BULK CS96
VWRI210-000082	VWR PETG SQ BTTL ONLY 250ML ST BULK CS60
VWRI210-000083	VWR PETG SQ BTTL ONLY 500ML ST BULK CS40
VWRI210-000084	VWR PETG SQ BTTL ONLY 1L ST BULK CS24
VWRI210-000111	VWR HDPE NATURAL CAP 20-415 ST CS280
VWRI210-000112	VWR HDPE NATURAL CAP 24-415 ST CS200
VWRI210-000113	VWR HDPE NATURAL CAP 38-415 ST CS96
VWRI210-000118	VWR HDPE TE CAP 20-415 ST CS280
VWRI210-000119	VWR HDPE TE CAP 24-415 ST CS200
VWRI210-000120	VWR HDPE TE CAP 38-415 ST CS 96

Based on the information provided by our supplier we hereby declare the following regulatory compliances for product PETG Sterile Diagnostic and Media Bottles with HDPE Closure (Raw Material - 100% virgin PETG -Polyethylene terephthalate glycol and HDPE- High Density Polyethylene) is based on documentation of our raw material vendor and standards of our manufacturing process.

Regulatory Requirements	Declarations
REACH Compliance	Raw materials do not contain or added any of the Annex XIV substances on the Authorization list or Annex XIV candidate chemicals proposed to be Substances of Very High Concern (SVHC) for Authorization (List as of January 17, 2022 and June 10, 2022) above the 0.1 % threshold as stated in REACH Article 57 and 59 (1907/2006/EC).
Food contact statement	FDA, CFR, Title 21 and also 3.1. of Union Guidance on Regulation (EU) No 10/2011, 1935/2004/EC, 2023/2006/EC .
Medical statement	USP VI, drug master file listed
Cytotoxicity	Non-cytotoxic.
RoHS Compliance	These products also meet the requirements specified in Restriction of Hazardous Substances (ROHS) Directive 2011/65/EU (recast, Directive 2002/95/EC repealed 3 January 2013).
BPA Statement	Bisphenols (A, AP, AF, B, BP, C, C 2, E, F, G, M, S, P, PH, TMC, Z) are absent.
Phthalates Statement	DEHP, DBP, BBP, DINP, DIDP, DNOP content < 0.1% by weight. The raw material complies the Directive 2005/84/EC, Commission Decision 1999/815/EC (Phthalates)
Residual solvents (conformance with ICH Q3)	During the manufacturing process of this product, we neither use nor intentionally incorporate any Class 1, 2A, 2B or 3 elements as listed in the ICH Q3D Guideline on Elemental Impurities (22 March 2019)- For Closure.
BSE-TSE	The Raw material of bottle does not contain any substances (Substances of Animal Origin Regulation EC 999/2001, as amended; 21 CFR 189.5; 21 CFR 700.27) of animal derived materials.
Allergen statement	The raw material does not contain any food allergens.
Extractables / leachable	Lead (Pb), cadmium (Cd), mercury (Hg), chromium VI (Cr(VI)), polybrominated biphenyl (PBB), and polybrominated diphenyl ethers (PBDE) were not detected within the detection limit (<1.0mg/kg). It complies with 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment. No detectable leachable/extractable found in testing of moulded products
Latex Free	No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for these 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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