

Certificate of Conformity

VWR Catalogue Number	See List
Description	Vacuum Urine Containers, 120 mL Capacity
Country of Origin	Manufactured in Italy
Date of Issue (yyyy-mm-dd)	2022-04-20

Catalogue Number	Type
216-1080	Non-sterile
216-1161	Sterile
216-2200	Sterile

Quality System Compliance

Products are manufactured under the **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 in compliance with CE IVD Directive 98/79/EC.

Material	Cup – Polypropylene. Cap – Polyethylene.
Sterilization	Products are sterilized using Beta rays and meets SAL 10 ⁻⁶ with a specified dose range of 17.8-20.4 kGy. (which is not applicable for Non-sterile products)
ATP Assay	Not tested.
DNase & RNase Free	Not tested.

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	Not tested.
Non-Pyrogenic Statement	Not tested.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenol is not used in the manufacture of the raw material and are not expected to be present
DEHP Statement	DEHP has not been intentionally incorporated in the manufacturing of the product.
RoHS	Not Applicable.
REACH Statement	Not Applicable.
Storage Conditions	Store in a dry place, away from sunlight.
Shelf Life	60 months.

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.