

# **Quality Certificate**

## **VWR® POLYPROPYLENE SPECIMEN CONTAINERS**

As per the manufacturer, the below product meets the following criteria:

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North American Catalog No:	89125-850
Lot Number:	43030 20200727
Description:	VWR Lid Only Steri 5-8OZ CS500
Date of Manufacture:	March 13, 2020
Date of Sterilization:	August 07, 2020
Sterilization Lot Number:	ML07272020
Sterilization Expiration Date:	August 07, 2023
Country of Origin:	USA
Country of Sterilization:	USA

### **Quality System Compliance**

Products are manufactured under the ISO 9001:2015 & ISO13485:2003 standard. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.

#### QC Testing:

Representative production samples are collected and inspected in accordance with current applicable standard protocols.

Dimensional Analysis: ASQ Z1.4-2003, General Insp. Level- II, AQL- 0.65. Result: Within tolerance

#### **Product Specifications**

This product is Class I category device as defined by the FDA in 21CFR Parts 862-892.

Material: Container: Polyethylene, 100 % Virgin, FDA 21 CFR Compliance, USP Class VI passed

Lid: Low-Density Polyethylene, 100 % Virgin, FDA 21 CFR Compliance, USP Class VI passed

Sterilization Process: Sterilization by B/C Gamma Process at 20–50 kGy. Result: 24.6 kGy

**Expiration Date**: Expiration date (Shelf life) is based on product and packaging shelf life, provided the product wrapper is

not damaged.

BSE/TSE Statement: All materials used and contact materials are of fully synthetic origin.

Non-Pyrogenic: N/A
BPA Statement: N/A
DEHP Statement: N/A
DNase & RNase Free: N/A
Cytotoxicity: N/A
Latex-free Statement: N/A

Signed:

Jamie Ethier VP Global Quality VWR, Part of Avantor

James Techie

Date: October 15, 2020