

Certificate of Quality



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

North American Catalog No:	414004-450
Lot Number:	A1191601
Description:	VWR COVERALL IRRDTD H/B M CS25
Date of Manufacture:	November 02, 2019
Sterilization Lot Number:	20191109
Date of Sterilization:	November 09, 2019
Sterilization Expiration Date:	November 09, 2024
Country of Origin:	China

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

Inspected according to AQL level II 4.0 sampling plan per MIL-STD-105E

-Break Tensile Properties (N): CD= 84.17 ASTM D5034 standard MD=85.03 -Elongation Rate (%): ASTM D5034 standard MD=54.02 CD= 55.10 -Trapezoid Tearing Strength (N): FZ/T 01085-1999 standard MD=351.00 CD= 322.00

Product Specifications

SF 56g/m² White (breathable fibre) (Spunbonded Polypropylene fabric coated with breathable Material:

Polyethylene film)

Sterilization Process: Gamma-ray irradiated according to ISO 11137:2006, Dose set meets SAL 10⁻⁴, With the dose

range of: MINIMUM DOSE: 17.3Gy; MAXIMUM DOSE: 23.9kGy

The above product contains no ingredients of animal origin and no material derived from, or exposed to animals affected by or under quarantine for Transmitting, Animal Spongiform **BSE/TSE Statement:**

Encephalopathy (TSE)/ Bovine Spongiform Encephalopathy (BSE).

Non-Pyrogenic: N/A **DNase & RNase Free:** N/A Cytotoxicity: N/A

Latex Free Statement: The above product is latex free.

Signed:

Jamie Ethier VP Global Quality

James TEchie

VWR, Part of Avantor **Date:** January 04, 2020