

Certificate of Conformity

VWR Catalogue Number	See List
Description	Disposable Spatulas
Country of Origin	Manufactured in China, Sterilized and Packaged in USA (for sterile items)
Date of Issue (yyyy-mm-dd)	2025-10-16

Non-sterile spatulas

Catalogue Number	Type	Length [mm]	Blade width [mm]	Colour
231-0106	Micro	140 mm	3 mm	Natural
231-0416	Eco	140 mm	7 mm	Natural
231-0103	Standard	210 mm	7 mm	Blue
231-0104	Standard	210 mm	7 mm	Opaque
231-0105	Macro	310 mm	13 mm	Green

Sterile spatulas

Catalogue Number	Properties	Length [mm]	Blade width [mm]	Colour
231-0369	Sterile	210 mm	7 mm	Natural
231-0593	Sterile, Non pyrogenic	210 mm	7 mm	Natural

Quality System Compliance

This certificate confirms that the product has been sourced from a supplier or manufacturer who has declared that the products are manufactured, inspected, and controlled in accordance with current applicable product specifications and internal quality system.

QC Testing

Representative products samples are collected and inspected in accordance with current applicable QC requirements.

Product Specifications

Material Standard, Macro, Sterile Spatulas - 100 % Food Grade Polypropylene Homopolymer.

Eco Spatulas - 99 % Virgin Food Grade Polypropylene , 1 % by weight, EcoPure® Additive.

Micro Spatulas - 96 % Virgin Food Grade Polypropylene, and 4% by volume, AMPACET 40390 Hostat 10 BOPP Masterbatch, an internal antistatic agent.

Product complies with the FDA Regulations 21CFR 177.1520.

Sterilization The original product which meets food contact standards is sent to a 3rd party processor in the USA for repackaging and sterilization. The products are sterilized to an SAL of 10^{-6} using ethylene oxide as the sterilant in compliance with ISO 11135 requirements.

Acceptance Criteria: Random samples of each batch from China are tested for adherence to manufacturing specifications. The spatulas used to create this sterile product met the specifications supplied to the manufacturer. This lot of sterile product was assembled, packaged and sterilized in full accordance with the requirements and specifications provided to our sub-contractors; the following processing and testing acceptance criteria were met.

Sterility Assurance Level (SAL)	10^{-6} Using Biological Indicator Testing as acceptance	
EO Residual Limits per ISO 10993-7	EO <4 mg/device	ECH <9 mg/device

Accuracy: Sterile Barrier testing was performed per ISO 11607-1 requirements along with Distribution Simulation testing. The repackaged sterilized spatulas will remain sterile as long as the inner pouch containing the 10 sterile spatulas remains visually intact. The seals on this product are certified to remain intact for a minimum of 72 months.

Autoclave: Autoclaving polypropylene at 121°C at 15 psi for 20minutes is standard.

ATP Assay Not Applicable.

DNase & RNase Free Not Applicable.

BSE/TSE	Standard, Macro, Eco, Sterile Spatulas - 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). Micro spatula – This product contains one or more ingredients formulated with animal derived substances that complies with USDA/APHIS Title 9 CFR, EMEA/410/01, EU regulation 1774/2002/EC, Directive 2000/6/EC and Commission Directive 2003/32/EC.
Cytotoxicity	For the product that is marked Sterile, Non-pyrogenic, Testing is conducted to quality all material resins using ISO 10993-7 standards for cytotoxicity and found to be EO <4 mg/device, ECH <9 mg/device ,which is not applicable for micro, macro, eco, standard and sterile spatulas.
Non-Pyrogenic Statement	For the product that is marked Sterile, Non-pyrogenic, The acceptance level for the non pyrogenic product is ≤ 0.5 EU/ml or 20 EU/device per USP <85> requirements, ,which is not applicable for micro, macro, eco, standard and sterile spatulas.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	The product does not contain Di(2-Ethyhexyl) Phthalate (DEHP).
RoHS	Not Applicable.
REACH Statement	Not Applicable.
Storage Conditions	Storage of the spatulas out of direct sunlight in a cool, dry locations (normal lab conditions).
Shelf Life	Non-sterile spatulas - No Limit. Sterile spatuls – 72 months.

Disclaimer: VWR's Quality Management System (QMS) is ISO 9001:2015 certified as a wholesale distributor of finished products, ensuring effective oversight of finished product handling, traceability, and distribution processes. VWR is not a manufacture and does not engage in manufacturing, co-manufacturing or processing activities such as design, packaging, labeling, testing or quality release. Consequently, the supplier or manufacturer's QMS certification may differ from VWR's.

VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. This product is intended for research use only. It is not for use in diagnostic procedures, therapeutic applications, or any human or clinical use.

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Version History

Sl.no	Version number	Description	Month & Year
1	1.0	Created General CoQ using new layout	04-2022
2	2.0	Modified Country of Origin. Modified Quality system compliance and disclaimer. Sterility Statement updated. Included Acceptance Criteria and Accuracy statement	10-2025