

Certificate of Conformity

VWR Disposable Spatula, Sterile

VWR International certifies that the specified products meet all VWR specifications and quality criteria for release. The products comply in every respect with the relevant particular specifications, drawings, relevant standards and regulations in force.

VWR International certifie que les produits mentionnés respectent toutes les spécifications et critères de qualité VWR. Les produits satisfont aux spécifications particulières, aux plans, aux normes et règlements en vigueur s'y rapportant.

VWR International bestätigt hiermit, daß die angegebenen Produkte alle VWR Spezifikationen und Qualitätskriterien zur Freigabe erfüllen. Die Produkte entsprechen in jeder Hinsicht den maßgeblichen Spezifikationen, den Zeichnungen sowie den relevanten Normen und gültigen Vorschriften.

VWR Cat.No	Lot No	Description	Length	Blade Width	Colour	Pk
231-0593	040620	Sterile disposable spatulas, non-pyrogenic	210 mm	7 mm	Natural	100

Date of Manufacture: Apr 2020

Product Shelf Life: 72 months

Sterilization Lot Number: 040620

Date of Sterilization: Apr 2020

Sterilization Expiration Date: Apr 2026

Material: 100% Food grade Virgin Polypropylene

Quality System Compliance & QC Testing:

Random samples of each batch are tested for adherence to size, weight and other manufacturing specifications. The spatulas used to create this sterile product met the specifications are supplied. Product was assembled, packaged and sterilized in full accordance with the requirements and specifications provided and the following processing and testing acceptance criteria were met:

Acceptance Criteria:

Sterility Assurance Level (SAL)	10 ⁻⁶ Using Biological Indicator Testing as acceptance	
Endotoxin Limits per USP 85 Requirements	≤ 0.5 IU/ml or 20 IU/device / Non-Pyrogenic	
EO Residual Limits per ISO 10993-7	EO <4 mg/device	ECH <9 mg/device

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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.

Sterilization Process: The products are sterilized to a SAL of 10^{-6} using ethylene oxide as the sterilant in compliance with ISO 11135 requirements.

BSE/TSE Statement: No raw materials that contain, or are derived from, animals are specified in the manufacture of this product.

Melamine Statement: No Melamine is specified in the manufacture of this product

Non-Pyrogenic: Yes (see above Acceptance Criteria)

DNase & RNase Free: Not tested

Cytotoxicity: Non-toxic (see above Acceptance Criteria)

Latex Free Statement: No latex is specified in the manufacture of this product

This document has been produced electronically and is valid without a signature

Date of issue: **December 2020**