



PARTER MEDICAL PRODUCTS, INC.  
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## CERTIFICATE OF COMPLIANCE AND STERILITY

<b>Customer Name:</b> DEPENDABLE SCIENTIFIC	<b>Mfg. Batch No.:</b> <input type="text" value="N/A"/>
<b>Customer PO No.:</b> P4941	<b>Trailer No.:</b>
<b>Total Cases:</b> 90 cases	<b>Ship Date.:</b> 102418
<b>Country of Origin:</b> United States of America	

### Quality System Compliance:

This is to certify that the below shipment has been manufactured by Parter Medical Products, Inc. (PMP) in Carson, California. PMP is a registered manufacturing facility with Food and Drug Administration (FDA) under registration number 2024311.

Products are manufactured under FDA and ISO guidelines. Products are inspected and controlled through the entire production processing in accordance with the current applicable product specifications and quality inspections procedures. Inspection records are reviewed and signed off by qualified personnel for product release.

### Product Specification:

The below listed products are Class I category device as defined by the FDA in 21CFR Parts 862-892.

### Sterilization Process:

The Sterile products, when applicable, as listed below have been processed for sterility by irradiation method in order to achieve a minimum Sterility Assurance Level (SAL) of 10<sup>-3</sup>, in accordance with the following guidelines and standards:

- Title 21 CFR Part 820 US FDA GMP – Quality System Regulations (June 1997)
- ISO 13485:2003 Quality management System for Medical Devices
- ISO 11137:2006 Sterilization of Healthcare Products

### Material:

**Latex Free:** The resins used to manufacture the below products are from prime virgin medical grade materials, which meet the FDA requirements of 21CFR 177.1520. Such resins do not contain latex, BPA, DEHP and any other Phthalates. Thus, they are recommended for use in food, beverage and medical applications.

**BSE/TSE:** The goods manufactured by Parter Medical Products do not contain products from animal origin. These products do not contain, make use of, or involve, at any point of their respective manufacturing process, raw materials of animal origin (including animal proteins). Parter Medical Products do not store products of animal origin (including animal proteins) in its manufacturing and warehouses facilities.

**DNase/RNase:** Using prime virgin FDA compliant resin, without use of any mold release or additive through the molding process, should allow the below products to be free of DNase/RNase contaminants.

**Pyrogenicity:** The above products have been manufactured under very low bioburden conditions and as a result, the inner surface of these products should remain free of progenic contaminant.

### Responsibility and Awareness:

It is the responsibility of the customer to determine that above listed products as manufactured by Parter Medical Products or products/articles produced from the above are acceptable and suitable for use in the customer intended applications.

Signature:  Quality Manager or Designee:  Date: 10-24-18

Cat. No.	Product Description	PMP Sterility Lot No.	PMP Mfg Lot No.	Shelf Life	Case Qty
242020	SC - 120mLx53mm - Natural Lid Duo-click Sterile label	G1016182B	J16A2182	n/a	20
Sub Total Cases:					20
Cat. No.	Product Description	PMP Sterility Lot No.	PMP Mfg Lot No.	Shelf Life	Case Qty
3565	Mono (Undivided Bottom) - Fully Stackable - NO Logo,	G0806182	H0426181 H0326183 H0326181 H0226181 H0126183	n/a n/a n/a n/a n/a	23 7 11 10 19
Sub Total Cases:					70
Total Cases:					90