

## **Certificate of Quality**



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

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VWR Catalog Number	470210-568
Manufacturing Lot Number	J2024173
Description	PETRI DISH VWR 100X15MM GMA STERILE PK20
Sterilization Lot Number	G1019172D
Shelf Life	Not Applicable
Country of Origin	United States of America

## **Quality System Compliance**

The manufacturing facility is registered with Food and Drug Administration (FDA). 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 Specifications**

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

Material: Latex Free. The resins used to manufacture the product is 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.

Sterilization Process: The product 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:

-Tile 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

BSE/TSE Statement: The products manufactured 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). The manufacturer does not store products of animal origin (including Animal proteins) in their manufacturing and

warehouse facilities.

Pyrogenicity: The product has been manufactured under very low bio-burden conditions and as a result, the inner surface of the product

should remain free of pyrogenic contaminant.

DNase & RNase Free: Using prime virgin FDA compliant resin, without use of any mold release or additive through the molding process, should

allow the above product to be free of DNase/RNase contaminants.

Responsibility and Awareness: It is the responsibility of the customer to determine that above product or products/articles produced from the above are acceptable and suitable for use in the customer intended applications.

Signed:

Linda K. Shine

Manager - Supplier Qualification Global Compliance

Lyda K. Shine

VWR International LLC

Date: October 27, 2017