

Certificate of Quality



454228P



B18113DS

Product description: VACUETTE® TUBE 3.5 ml Z Serum Separator Clot Activator 13x75 gold cap-gold ring, black label, non-ridged, USA

Following inspections were carried out and passed:

| visual | \mathbf{X} | passed |
|----------|--------------|--------|
| physical | \boxtimes | passed |
| chemical | X | passed |

We hereby certify that our products were manufactured and tested in accordance with the following international standards and meet the required specifications:

98/79/EC "Directive 98/79/EC of the European Parliament and of the Council of 27th Oct 1998 on in vitro diagnostic medical devices"

ISO 6710 "Single-use containers for venous blood specimen collection"

ISO 11137 "Sterilization of health care products - Radiation"

EN 14820 "Single-use containers for human venous blood specimen collection"

ISO 9001 "Quality management systems - Requirements"

ISO 13485 "Medical devices - Quality management systems - Requirements for regulatory purposes"

2

2020-02-12 **STERILE**

SAL 10⁻⁶

This certificate is valid for the above mentioned lot and has no validity if no lot number is provided.



Certificate creation date: 2018-12-26

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