# TECHNICAL INFORMATION SHEET

## BD Microtainer® SST™ with Microgard™ Closure

## Product Catalogue Number: 365968

### Product Description

Single use, non-sterile capillary blood collection tube, containing an inert gel barrier and a clot activator coating, intended for the primary containment and preservation of specimens for the purposes of in-vitro diagnostic examination. Used to obtain and separate a serum sample. These products are intended for use by healthcare professionals.

### Manufacturing Information

| | |
|---|---|
| (Legal) Manufacturer: | Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417, USA |
| Standards & Certificate Numbers: | EN ISO 13485:2016, MD19.2137 |
| Country of origin: | USA |
| Certification body: | NSAI (0050) |
| Notified Body: | N/A |
| EU Authorised Representative: | BD Switzerland Sarl, Terre Bonne Park - A4, Route de Crassier 17, 1262 Eysins, Switzerland |

### Sterilisation

| | |
|---|---|
| Method: | Not sterile |

### Compliance

| | |
|---|---|
| Directive: | European In Vitro Diagnostic Medical Devices Directive 98/79/EC |
| Classification: | Non Annex II / General IVD |

### Product Specification

| | |
|---|---|
| Tube material: | Polypropylene (PP) |
| Tube size (mm): | 10 x 45 |
| Maximum fill volume (mL): | 0.6 |
| Additives: | Silica: 0.10 – 2.56 mg/mL blood |
| Separator: | Polyester Gel: 0.90 – 3.50 g |
| Collector material: | Not Applicable |
| Closure material (cap): | High Density Polyethylene Resin (HDPE) |
| Closure material (stopper): | N/A |
| Closure colour: | Gold |
| Product Storage: | Do not expose to direct sunlight<br>Store product at less than 25°C |
| Label type: | None |
| Shelf-life: | 15 months |
| Global medical device nomenclature (GMDN): | 58138 |
| Material Safety Data Sheet (MSDS): | VS60313-11 |
| Fill line indicator (µL): | 400 & 600 µL |



**Materials**

| | |
|---|---|
| Latex (NRL): | No |
| Dry Natural Rubber (DNR): | No |
| Phthalates: | No |
| Material of animal origin: | Gel barrier: Contains Component from Bovine Origin. |

### Packaging Specifications

| | | | |
|---|---|---|---|
| 50 unit pack weight (kg): | 0.1587 | 50 unit packaging material: | Polyethylene |
| 50 unit pack volume ($m^3$): | 0.000950 | 50 unit packaging weight (kg): | 0.01 |
| 50 unit pack dimensions LxHxW (mm): | 215 x 25 x 177 | 50 unit packaging volume ($m^3$): | Not Available |
| 200 unit pack weight (kg): | 0.69 | 200 unit packaging material: | Cardboard |
| 200 unit pack volume ($m^3$): | 0.004000 | 200 unit packaging weight (kg): | 0.126 |
| 200 unit pack dimensions LxHxW (mm): | 177 x 143 x 158 | 200 unit packaging volume ($m^3$): | Not Available |

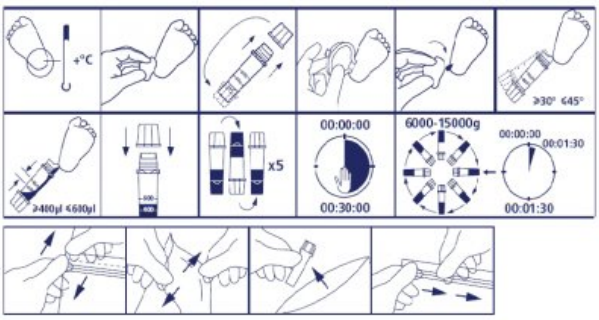
Product Catalogue Number: **365968**

## Labelling Information

All labelling complies with the requirements of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC and includes the CE marking.

| | Unit Pack | Shelf Pack | Case Pack |
|---|---|---|---|
| Company name | | • | • |
| Manufacturer address | | • | • |
| Product Catalogue Number (PCN) | | • | • |
| Colour Coding | • | • | • |
| CE marking | | • | • |
| Single use symbols | | • | • |
| Lot number | • | • | • |
| Expiry date | • | • | • |
| Instructions for Use (pictorials) | | • | |
| Draw Volume | • | | |
| Storage instructions | | • | • |
| Quantity in package | | • | • |
| Secondary barcode (GS1-128) quantity, expiry, lot number | | • | |
| Product name & short description | • | • | • |
| Authorised Representative | | • | • |

## Instructions For Use




## Further Reading

1. Guder WG, Narayanan S, Wisser H and Zawta B. Samples: From the Patient to the Laboratory: the Impact of Preanalytical Variables on the Quality of Laboratory Results (4th Edition). Darmstadt, Germany: Wiley-VCH; 2009.
2. Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS): Procedures for the Handling and Processing of Blood Specimens; 7th ed. CLSI standard GP42. Clinical and Laboratory Standards Institute, 2020.
3. BD White Paper VS5866: "Comparison of BD Microtainer™ SST™ Tubes with BD Microgard™ Closure and the BD Microtainer™ SST™ Tubes with FloTop Collector for Visual Hemolysis, Clotting Time and Chemistry Analytes". 2001.

## Sample Storage & Stability

Stability depends on the analyte (see specific analyte).[1,2]

## References

1. Guder WG, et al. Recommendations of the Working Group on Preanalytical Quality of the German Society for Clinical Chemistry and Laboratory Medicine for Quality of Diagnostic Samples (3rd Edition). Darmstadt, Germany: GIT, 2010.
2. Tietz NW. Clinical Guide to Laboratory Tests (4th Edition). W.B. Saunders, USA: 2006.

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