epredia Enhancing precision cancer diagnostics

TDS#: QSH-CG-0004

Date: March 23, 2023

Technical Data Sheet

1. Product Identification

- Item/Ref.: **BB02400500S113MNZ0**
- Description: CVG 24x50mm no. 1 100/bx 1000/cs
- Application: Microscope slide coverslips, for in-vitro-diagnostic use

2. Traceability

- LOT Number: 5 digits
- Position: Outer carton labels

3. Specification

- Usage: Ready to use, single use only
- Raw material: D 263 M Borosilicate glass
- Refractive Index: ne (λ=546,1nm): 1,5255 +/- 0,0015
  nd (λ=589,3nm): 1,5230
- Dimensions: 24x50mm (+0,20 / -0,50mm)
- Thickness: #1: 0,13 – 0,16mm

4. Quality

- Standards and directive
  - IVDR: Regulation 2017/746/EU – In Vitro Diagnostic Medical Regulation
  - ISO 13485:2016 Medical devices — Quality management systems
  - ISO 14971:2019 Medical devices — Application of risk management to medical devices
  - ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
  - ISO 18113-1:2009 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
  - ISO 8255-1:2017 Microscopes — Cover glasses — Part 1: Dimensional tolerances, thickness and optical properties
- Quality assurance by checking random samples on
  - Dimensions
  - Stain
  - Broken
  - Chips
  - Stuck
  - Count

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5. Instructions for Use

- General Information
  - Microscope slide coverslips are suitable for the preparation of cellular and tissue specimen
  - Microscope slide coverslips should be brought to room temperature before they are used
  - Microscope slide coverslips are for single use only
  - If for any reason you believe that your test result is equivocal, you should follow your laboratory standard operating procedures
  - When using the microscope slide coverslips in instruments, the usage instructions from the manufacturer regarding the safe operation of their instrument, dyes, and chemicals should be followed
- Storage, Archiving and Disposal
  - Store product under clean and dry conditions at ambient temperature (15-30 °C)
  - The product should be kept off floors, away from doors and heating/air conditioning ducts to minimize temperature and humidity changes
  - Avoid large variations in temperature during both storage and usage. Cooling of the microscope slide coverslips can lead to formation of condensation between the pieces of glass which may impact performance
  - Microscope slide coverslips should be allowed to come to room temperature in the lab before they are opened
  - Product stock should be rotated. Rotation is the first line of defense against temperature and humidity changes resulting in moisture contamination. Use older products in storage first by using FIFO principle (First In, First Out)
  - Archive, store and dispose of microscope slide coverslips per established laboratory protocols

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