epredia Enhancing precision cancer diagnostics

TDS#: QSH-MS-0001

Date: March 23, 2023

Technical Data Sheet

1. Product Identification

- Item/Ref.: **AB00000112E01MNZ10**
- Description: Slides 45° frosted 20 mm
- Application: Microscope slides, Non Adhesion, 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: Float glass, extra clear glass
- Refractive Index: n (λ = 546 nm): 1,53 ± 0,02
- Dimensions: Length: 76,0 mm (+0 / -1 mm)
  Width: 26,0 mm (+0 / -1 mm)
- Thickness: 1,0 mm = 0,95 - 1,05 mm

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 8037-1:1986 Optics and optical instruments — Microscopes — Slides — Part 1: Dimensions, optical properties and marking
- Quality assurance by checking random samples on
  - Dimensions
  - Cleanliness
  - Dirty/Spotty
  - Cloudy/Hazy
  - Scratch/Pits
  - Chips
  - Stuck

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- Finish
- Count
- Wettability

5. Instructions for Use

- General Information
  - Microscope slides are suitable for the preparation of cellular and tissue specimen
  - Microscope slides should be brought to room temperature before they are used
  - Microscope slides are for single use only
  - Microscope slides should be used on the working surface
  - If for any reason you believe that your test result is equivocal, you should follow your laboratory standard operating procedures
  - When using the microscope slides 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 slides can lead to formation of condensation between the pieces of glass which may impact performance
  - Microscope slides 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 slides per established laboratory protocols
  - Storage period for slides: refer to expiration date

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