**ZHEJIANG AIJIREN TECHNOLOGY, INC.**

浙江爱吉仁科技股份有限公司

No. 8, Jiangnan Road, Quzhou, Zhejiang, China · www.hplcvials.com · Boonemi@aijirenvial.com

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# CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| **Certificate No.** | COA-26-11-0417 | **Batch No.** | B261104-09 |
| **Product** | 9mm Short Thread Screw Cap, bonded, PTFE/Silicone | **Part No.** | SC9191 |
| **Quantity** | 100 pcs / pack | **Manufacture date** | 2026-11-04 |
| **Release date** | 2026-11-06 | **Retest / shelf life** | 36 months from manufacture |

| Parameter | Method | Specification | Result | Verdict |
|---|---|---|---|---|
| Appearance | Visual, light table | Blue PP cap, clean, no flash or deformation | Conforms | **PASS** |
| Cap outer diameter | Micrometer | Φ 9.00 ± 0.15 mm | 8.97 mm | **PASS** |
| Cap height | Micrometer | 6.20 ± 0.15 mm | 6.24 mm | **PASS** |
| Centre hole diameter | Vision measurement | 5.50 ± 0.15 mm | 5.46 mm | **PASS** |
| Septa diameter | Micrometer | Φ 9.00 ± 0.10 mm | 9.02 mm | **PASS** |
| Septa thickness | Micrometer | 1.00 ± 0.10 mm | 1.02 mm | **PASS** |
| Septa hardness | Shore A, ASTM D2240 | 45 – 60 Shore A | 52 | **PASS** |
| Bonding force | Tensile pull, in-house method | ≥ 40 N on assembled unit | 47.3 N | **PASS** |
| Extractable particulate | Light table, 100,000-class cleanroom | No visible particulate | None | **PASS** |

**Remark.** Bonding force is measured on the assembled cap-and-septa unit by tensile pull at a constant rate; the value reported is the mean of ten specimens. Full raw data is available on request (see Bonding Force Report, DOC 04).

**Declaration.** This batch was manufactured and released in accordance with the Aijiren quality management system certified to ISO 9001:2015. Retain under dry conditions, 15–30 °C, away from direct sunlight.

**Tested by**
Analyst, QC Laboratory

**Reviewed by**
QC Supervisor

**Released by**
Quality Manager



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# DIMENSIONAL INSPECTION REPORT

| | | | |
|---|---|---|---|
| **Report No.** | DIM-26-11-0417 | **Batch No.** | B261104-09 |
| **Product** | 2mL Clear 9mm Short Thread Vial, Type I glass | **Part No.** | V913 |
| **Sample size** | 5 pcs, random from batch | **Instrument** | Digital micrometer 0.001 mm / vision system |

| Dimension | Nominal | Tolerance | S1 | S2 | S3 | S4 | S5 | Mean | Verdict |
|---|---|---|---|---|---|---|---|---|---|
| Body outer diameter | 11.60 | ± 0.20 | 11.58 | 11.61 | 11.59 | 11.62 | 11.60 | 11.60 | **PASS** |
| Body height | 32.00 | ± 0.30 | 32.05 | 32.02 | 32.08 | 31.98 | 32.04 | 32.03 | **PASS** |
| Neck outer diameter | 9.00 | ± 0.15 | 8.98 | 9.01 | 8.99 | 9.02 | 9.00 | 9.00 | **PASS** |
| Neck height | 6.20 | ± 0.20 | 6.22 | 6.19 | 6.24 | 6.21 | 6.20 | 6.21 | **PASS** |
| Wall thickness | 1.00 | ± 0.10 | 1.02 | 0.99 | 1.01 | 1.00 | 1.03 | 1.01 | **PASS** |
| Bottom thickness | 1.00 | ± 0.15 | 1.05 | 1.02 | 0.98 | 1.01 | 1.03 | 1.02 | **PASS** |
| Neck concentricity | — | ± 0.20 | 0.06 | 0.08 | 0.05 | 0.09 | 0.07 | 0.07 | **PASS** |
| Verticality | — | ≤ 0.25 | 0.10 | 0.12 | 0.09 | 0.11 | 0.10 | 0.10 | **PASS** |

**Note.** All dimensions in millimetres. Concentricity and verticality measured on the vision system with the vial seated on a calibrated V-block. Dimensions are verified per batch on a sampling basis; a full dimensional layout on every cavity is available on request.

## Glass specification

- Material: borosilicate glass, Type I, hydrolytic resistance per USP <660> / ISO 719
- Colour: clear (amber available as separate part number)
- Thermal expansion coefficient: $5.0 \times 10^{-6}\ K^{-1}$ (20–300 °C)
- Surface: unsilanised (deactivated grades available as separate part numbers)

**Measured by**
QC Laboratory

**Reviewed by**
QC Supervisor

**Approved by**
Quality Manager



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# MATERIAL DECLARATION

| | | | |
|---|---|---|---|
| **Declaration No.** | MAT-26-11-0417 | **Product family** | 9mm short thread vials and closures |
| **Part numbers covered** | V913 / V917 / SC9191 / SC9193 | **Issue date** | 2026-11-06 |

| Component | Material | Grade / reference | Supplier declaration |
|---|---|---|---|
| Vial body | Borosilicate glass, Type I | USP <660> / ISO 719, expansion 5.0 × $10^{-6}$ $K^{-1}$ | On file, per glass lot |
| Cap | Polypropylene, virgin | No recycled content, no halogenated flame retardant | On file |
| Septa — face layer | PTFE | Pharmaceutical grade, unsintered | On file |
| Septa — core | Silicone rubber | Platinum cured, Shore A 52 | On file |
| Bonding | Thermal, moulded-in | No adhesive used | — |
| Packaging | PE bag + carton | No PVC, no expanded polystyrene | On file |

## Statements

- **RoHS.** Products do not contain the restricted substances listed in Directive (EU) 2015/863 above the permitted thresholds.
- **Phthalates.** No phthalate plasticisers are intentionally added to any component.
- **Heavy metals.** No lead, cadmium or mercury is intentionally added.
- **PFAS — important.** PTFE is classified as a PFAS under the OECD 2021 definition. **Products containing a PTFE face layer are therefore not PFAS-free and must not be described as such.** Where a fluorine-free wetted path is required, silicone-only, butyl or EPDM septa with PP or PE caps are supplied as separate part numbers, with total fluorine tested on request.
- **Animal-derived material.** Silicone and polypropylene components contain no animal-derived material.

**Scope.** This declaration covers the part numbers listed above as currently manufactured. Any change in raw material source or formulation is notified to affected customers before shipment, in line with the Aijiren change control procedure.

| Prepared by | Reviewed by | Approved by |
|---|---|---|
| Quality Department | Technical Manager | Quality Manager |

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# BONDING FORCE TEST REPORT

| | | | |
|---|---|---|---|
| **Report No.** | BND-26-11-0417 | **Batch No.** | B261104-09 |
| **Part No.** | SC9191 — 9mm bonded cap with PTFE/silicone septa | **Sample size** | n = 10, random from batch |
| **Equipment** | Tensile tester, 500 N load cell, calibrated | **Test speed** | Constant rate, cap restrained, septa pulled axially |

| 47.3 N | 43.1 N | 51.8 N | 2.7 N | ≥ 40 N |
|---|---|---|---|---|
| Mean peak force | Minimum | Maximum | Std. deviation | Release limit |

| Specimen | Peak force (N) | Extension at peak (mm) | Failure mode | Verdict |
|---|---|---|---|---|
| 1 | 45.6 | 1.82 | Septa shear at bond line | **PASS** |
| 2 | 48.9 | 1.94 | Septa shear at bond line | **PASS** |
| 3 | 43.1 | 1.71 | Septa shear at bond line | **PASS** |
| 4 | 50.2 | 2.03 | Septa shear at bond line | **PASS** |
| 5 | 46.8 | 1.88 | Septa shear at bond line | **PASS** |
| 6 | 47.5 | 1.90 | Septa shear at bond line | **PASS** |
| 7 | 44.9 | 1.79 | Septa shear at bond line | **PASS** |
| 8 | 51.8 | 2.11 | Septa shear at bond line | **PASS** |
| 9 | 49.3 | 1.97 | Septa shear at bond line | **PASS** |
| 10 | 44.9 | 1.76 | Septa shear at bond line | **PASS** |

## Method summary

- The assembled cap-and-septa unit is clamped by the cap skirt; the septa is gripped axially and pulled at a constant rate until separation.
- Peak force is recorded as the bonding force. The test is performed on the finished part, not on the raw septum.
- Release limit: **≥ 40 N**. A batch is held if any specimen falls below the limit, and the batch is re-sampled at double size before release.
- Equipment is calibrated on a 12-month cycle with traceable load cells; calibration certificates are available on request.

**Why this test.** A septum that separates mid-sequence causes lost runs and, in LC-MS, contamination of the source. Bonding force is the parameter that predicts separation, which is why it is measured on every batch rather than only at design validation.

**Tested by**
QC Laboratory

**Reviewed by**
QC Supervisor

**Approved by**
Quality Manager



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