**RICCA CHEMICAL COMPANY**®

## **Certificate of Analysis**

## Sodium Chloride, 0.9% (w/v), Isotonic Saline Suitable for Use as Blood Bank Saline

## Manufacture Date: DEC 18, 2023 Expiration Date: DEC 2025

Lot Number: 4312G18

Product Number: 7210

For In Vitro Diagnostic Use. Suitable for use as isotonic Blood Bank Saline, as a general purpose red blood cell washing fluid to remove plasma proteins, and as a cell diluent. May be suitable for other laboratory applications.

Manufacturing controls, including submicron filtration, are in place to minimize particle count, fungal and bacterial content, and heavy metal contamination. There is no observable hemolysis with human red blood cells. This product is non-sterile and contains no preservatives or inhibitors. Low temperature storage (1 - 8°C) will minimize increase in microbiological content as this product ages.

| Name            | CAS#      | Grade           |
|-----------------|-----------|-----------------|
| Water           | 7732-18-5 | ACS/ASTM/USP/EP |
| Sodium Chloride | 7647-14-5 | ACS             |

| Test  | Specification    | Result   | NIST SRM# |
|---|------------------|----------|-----------|
| Appearance                                    | Colorless liquid | Passed   |           |
| Assay (vs. Silver Nitrate/Potassium Chromate) | 8.98-9.00 g/L    | 9.00 g/L | 999       |

| Specification  | Reference        |  |
|--|------------------|--|
| Standard Isotonic Sodium Chloride Solution for   | NCCLS (ASI/BB-1) |  |
| Immunohematologic Testing  |                  |  |
| Saline TS  | USP (N/A)        |  |
| Volumetric glassware complies with Class A tolerance requirements of ASTM E 288 and NIST Circular 434; it is calibrated before first use and |                  |  |

recalibrated regularly in accordance with ASTM E 542 and NIST Procedure NBSIR 74-461. Balances are calibrated regularly with weights certified traceable to the NIST national mass standard. Thermometers and temperature probes are calibrated before first use and recalibrated regularly with a thermometer traceable to NIST standards. All products are prepared according to master documents that assure manufacture according to validated methods. Batch records document raw material traceability and production and testing history for each lot manufactured.

| Part Number | Size / Package Type | Shelf Life (Unopened Container) |
|-------------|---------------------|---------------------------------|
| 7210-1      | 4 L natural poly    | 24 months                       |
| 7210-16     | 500 mL natural poly | 24 months                       |

Recommended Storage: 15°C - 30°C (59°F - 86°F)

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Paul Brandon (12/18/2023) **Production Manager** This document is designed to comply with ISO Guide 31 "Reference Materials --Contents of Certificates and Labels.

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