



**Certificate No. 10893-7-2025-1**

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from July 28, 2025 to July 27, 2027.**



To verify the authenticity of the information on this certificate, you may scan the QR code or visit [www.access.fda.gov/fecv/CDRH](http://www.access.fda.gov/fecv/CDRH).



**Certificate No. 10893-7-2025-1**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-01017, miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-00120-SYS, iSED Pro Series S Erythrocyte Sedimentation Rate (ESR) Analyzer
  - DSC01, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - EQC02, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - 112-12-001, iWASH™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-002, iWASTE™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer (24 per case)
  - 112-12-005, iWASTE for iSED ESR Analyzer (4/pk)
  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
  - 112-12-022, DeepCLEAN Pro
  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-00500, iSED Test Card, 500 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-01000, iSED Test Card, 1000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers,
  - 112-02000, iSED Test Card, 2000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-03000, iSED Test Card, 3000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-05000, iSED Test Card, 5000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-10000, iSED Test Card, 10000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-20000, iSED Test Card, 20000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-04000, iSED PRO Test Card, 4000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-07500, iSED PRO Test Card, 7500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-12500, iSED PRO Test Card, 12500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-25000, iSED PRO Test Card, 25000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----





**Certificate No. 10893-7-2025-2**

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See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

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Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

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**Certificate No. 10893-7-2025-2**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-01017, miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-00120-SYS, iSED Pro Series S Erythrocyte Sedimentation Rate (ESR) Analyzer
  - DSC01, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - EQC02, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - 112-12-001, iWASH™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-002, iWASTE™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer (24 per case)
  - 112-12-005, iWASTE for iSED ESR Analyzer (4/pk)
  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
  - 112-12-022, DeepCLEAN Pro
  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-00500, iSED Test Card, 500 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-01000, iSED Test Card, 1000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers,
  - 112-02000, iSED Test Card, 2000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-03000, iSED Test Card, 3000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-05000, iSED Test Card, 5000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-10000, iSED Test Card, 10000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-20000, iSED Test Card, 20000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-04000, iSED PRO Test Card, 4000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-07500, iSED PRO Test Card, 7500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-12500, iSED PRO Test Card, 12500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-25000, iSED PRO Test Card, 25000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----





**Certificate No. 10893-7-2025-3**

CERTIFICATE TO FOREIGN GOVERNMENT

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**Name of Product(s)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

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Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

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**Certificate No. 10893-7-2025-3**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-01017, miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-00120-SYS, iSED Pro Series S Erythrocyte Sedimentation Rate (ESR) Analyzer
  - DSC01, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - EQC02, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - 112-12-001, iWASH™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-002, iWASTE™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer (24 per case)
  - 112-12-005, iWASTE for iSED ESR Analyzer (4/pk)
  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
  - 112-12-022, DeepCLEAN Pro
  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-00500, iSED Test Card, 500 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
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  - 112-03000, iSED Test Card, 3000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-05000, iSED Test Card, 5000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-10000, iSED Test Card, 10000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-20000, iSED Test Card, 20000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-04000, iSED PRO Test Card, 4000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
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  - 120-25000, iSED PRO Test Card, 25000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----





**Certificate No. 10893-7-2025-4**

CERTIFICATE TO FOREIGN GOVERNMENT

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(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

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Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

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**Certificate No. 10893-7-2025-4**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-01017, miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-00120-SYS, iSED Pro Series S Erythrocyte Sedimentation Rate (ESR) Analyzer
  - DSC01, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - EQC02, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - 112-12-001, iWASH™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-002, iWASTE™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer (24 per case)
  - 112-12-005, iWASTE for iSED ESR Analyzer (4/pk)
  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
  - 112-12-022, DeepCLEAN Pro
  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
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  - 112-02000, iSED Test Card, 2000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-03000, iSED Test Card, 3000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-05000, iSED Test Card, 5000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-10000, iSED Test Card, 10000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-20000, iSED Test Card, 20000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-04000, iSED PRO Test Card, 4000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-07500, iSED PRO Test Card, 7500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-12500, iSED PRO Test Card, 12500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-25000, iSED PRO Test Card, 25000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----





**Certificate No. 10893-7-2025-5**

CERTIFICATE TO FOREIGN GOVERNMENT

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(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

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Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

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**Certificate No. 10893-7-2025-5**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
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  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - EQC02, Erythrocyte Sedimentation Rate (ESR) Quality Control
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  - 112-12-002, iWASTE™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer (24 per case)
  - 112-12-005, iWASTE for iSED ESR Analyzer (4/pk)
  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
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  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
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  - 120-07500, iSED PRO Test Card, 7500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-12500, iSED PRO Test Card, 12500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
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  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----





**Certificate No. 10893-7-2025-6**

CERTIFICATE TO FOREIGN GOVERNMENT

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**Name of Product(s)**

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(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

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Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

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**Certificate No. 10893-7-2025-6**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-01017, miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-00120-SYS, iSED Pro Series S Erythrocyte Sedimentation Rate (ESR) Analyzer
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  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
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  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
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  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-00500, iSED Test Card, 500 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-01000, iSED Test Card, 1000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers,
  - 112-02000, iSED Test Card, 2000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-03000, iSED Test Card, 3000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-05000, iSED Test Card, 5000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-10000, iSED Test Card, 10000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-20000, iSED Test Card, 20000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-04000, iSED PRO Test Card, 4000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-07500, iSED PRO Test Card, 7500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-12500, iSED PRO Test Card, 12500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-25000, iSED PRO Test Card, 25000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----





**Certificate No. 10893-7-2025-7**

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from July 28, 2025 to July 27, 2027.**



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**Certificate No. 10893-7-2025-7**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-01017, miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-00120-SYS, iSED Pro Series S Erythrocyte Sedimentation Rate (ESR) Analyzer
  - DSC01, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - EQC02, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - 112-12-001, iWASH™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-002, iWASTE™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer (24 per case)
  - 112-12-005, iWASTE for iSED ESR Analyzer (4/pk)
  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
  - 112-12-022, DeepCLEAN Pro
  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-00500, iSED Test Card, 500 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-01000, iSED Test Card, 1000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers,
  - 112-02000, iSED Test Card, 2000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-03000, iSED Test Card, 3000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-05000, iSED Test Card, 5000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-10000, iSED Test Card, 10000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-20000, iSED Test Card, 20000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-04000, iSED PRO Test Card, 4000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-07500, iSED PRO Test Card, 7500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-12500, iSED PRO Test Card, 12500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-25000, iSED PRO Test Card, 25000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----





**Certificate No. 10893-7-2025-8**

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from July 28, 2025 to July 27, 2027.**



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**Certificate No. 10893-7-2025-8**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-01017, miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-00120-SYS, iSED Pro Series S Erythrocyte Sedimentation Rate (ESR) Analyzer
  - DSC01, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - EQC02, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - 112-12-001, iWASH™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-002, iWASTE™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer (24 per case)
  - 112-12-005, iWASTE for iSED ESR Analyzer (4/pk)
  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
  - 112-12-022, DeepCLEAN Pro
  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-00500, iSED Test Card, 500 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-01000, iSED Test Card, 1000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers,
  - 112-02000, iSED Test Card, 2000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-03000, iSED Test Card, 3000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-05000, iSED Test Card, 5000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-10000, iSED Test Card, 10000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-20000, iSED Test Card, 20000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-04000, iSED PRO Test Card, 4000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-07500, iSED PRO Test Card, 7500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-12500, iSED PRO Test Card, 12500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-25000, iSED PRO Test Card, 25000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----





**Certificate No. 10893-7-2025-9**

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from July 28, 2025 to July 27, 2027.**



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**Certificate No. 10893-7-2025-9**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-01017, miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-00120-SYS, iSED Pro Series S Erythrocyte Sedimentation Rate (ESR) Analyzer
  - DSC01, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - EQC02, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - 112-12-001, iWASH™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-002, iWASTE™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer (24 per case)
  - 112-12-005, iWASTE for iSED ESR Analyzer (4/pk)
  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
  - 112-12-022, DeepCLEAN Pro
  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-00500, iSED Test Card, 500 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-01000, iSED Test Card, 1000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers,
  - 112-02000, iSED Test Card, 2000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-03000, iSED Test Card, 3000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-05000, iSED Test Card, 5000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-10000, iSED Test Card, 10000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-20000, iSED Test Card, 20000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-04000, iSED PRO Test Card, 4000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-07500, iSED PRO Test Card, 7500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-12500, iSED PRO Test Card, 12500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-25000, iSED PRO Test Card, 25000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----





**Certificate No. 10893-7-2025-10**

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
20 Thurber Blvd  
Smithfield, RI USA 02917

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

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Sincerely,

CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

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**Certificate No. 10893-7-2025-10**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

**Name of Manufacturer/Distributor**

ALCOR SCIENTIFIC LLC  
 20 Thurber Blvd  
 Smithfield, RI  
 USA 02917

**Name of Product(s)**

- 112-00101, iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-01017, miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-00120-SYS, iSED Pro Series S Erythrocyte Sedimentation Rate (ESR) Analyzer
  - DSC01, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - DSC06, Seditrol®, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - EQC02, Erythrocyte Sedimentation Rate (ESR) Quality Control
  - 112-12-001, iWASH™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-002, iWASTE™ for iSED® Erythrocyte Sedimentation Rate (ESR) Analyzer (24 per case)
  - 112-12-005, iWASTE for iSED ESR Analyzer (4/pk)
  - 112-12-003, miniiWASH™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-004, miniiWASTE™ for miniiSED® Erythrocyte Sedimentation Rate (ESR) Analyzer
  - 112-12-006, iWASH Pro
  - 112-12-009, iWASTE Pro
  - 112-12-022, DeepCLEAN Pro
  - 112-12-020, deepCLEAN (3x2.0mL) for iSED and miniiSED ESR Analyzers
  - 112-00250, iSED Test Card, 250 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-00500, iSED Test Card, 500 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
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  - 112-02000, iSED Test Card, 2000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-03000, iSED Test Card, 3000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-05000, iSED Test Card, 5000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-10000, iSED Test Card, 10000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 112-20000, iSED Test Card, 20000 Tests for Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-04000, iSED PRO Test Card, 4000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-07500, iSED PRO Test Card, 7500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-12500, iSED PRO Test Card, 12500 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-25000, iSED PRO Test Card, 25000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - 120-50000, iSED PRO Test Card, 50000 Tests for iSED PRO Erythrocyte Sedimentation Rate (ESR) Analyzers
  - DS-05240, Thermal Printer
  - DS-05233, Alcor Thermal Printer Paper for Erythrocyte Sedimentation Rate (ESR) Analyzers
- END OF PRODUCT LIST-----

