

## LVS-95XX



## Series IQ/OQ Overview

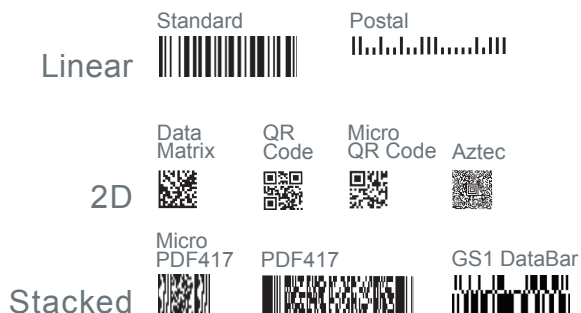
The “LVS-95XX Series Installation Qualification (IQ) and Operational Qualification (OQ) Guideline” assists in validating an LVS-95XX Series system. The document provides guidelines to determine if an LVS-95XX Series system meets IQ and OQ specifications and fulfills its intended purpose. The document can be modified to fit the specifications of the client’s validation protocol.

### LVS-95XX Series: At a Glance

- Offline verification of bar codes to ISO/IEC standards.
- Inspects all nine of the ISO (ANSI) parameters, plus added features of determining blemishes, opacity, and human readable validation.
- Verifies 1D & 2D codes and reports all parameters as specified in the applicable symbology specification.

For more information on this product, visit [www.microscan.com](http://www.microscan.com).

### LVS-95XX: Available Symbolobies



Please see the second page for a complete list of supported symbologies.

### Installation Qualification (IQ)

The purpose of IQ is to confirm that the LVS-95XX system was installed correctly. A series of questions are provided pertaining to the installation of the system. In addition, a Calibrated Conformance Standard Test Card for GS1 Symbols accompanies an LVS-95XX system purchase. The Test Card reports on several certified parameters. The LVS-95XX system must demonstrate its ability to stay within +/- 5 percentage points of the parameters listed on the Test Card. The IQ section provides a chart to document and verify each Test Card parameter.

### Operational Qualification (OQ)

The purpose of OQ is to demonstrate that LVS-95XX system components operate correctly within established limits and tolerances. OQ sections include:

- **Testing:** This section is designed to certify that the

system is working according to factory specifications and according to the following test methods:

- **Linear codes (1D):**  
ISO/IEC 15426-1:2000(E)
- **Two-dimensional codes (2D):**  
ISO/IEC 15426-2:2004(E)

To pass the OQ test, each test label supplied with the package is graded twice. The First Test Overall Grade and Second Test Overall Grade must measure within +/- 0.3 of each other’s grade point average. The labels to be tested can be taken from the “LVS-95XX Series IQ and OQ Validation Guidelines,” supplied by the client, or a combination of both. The labels must have at least a 1.4 grade point average.

- **Operational Status:** This section provides a series of questions about the operational status of the system.

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# LVS-95XX SPECIFICATIONS AND OPTIONS

- **Support Documentation:** This section verifies that supporting documentation is supplied with the system. Sample documents include the "LVS-95XX Series Operations Manual," Preventive Maintenance Schedule, and Certificate of Training Documentation.
- **Electronic Records and Signatures:** This section provides a list of questions associated with the criteria of using Electronic Records and Electronic Signatures with the LVS-95XX system; this pertains to FDA regulations required under 21 CFR Part 11.
- **Training Documentation:** This section provides a place for training instructors to document operational training session information pertaining to the calibration process; calibration test card replacement process; setup screen functions; system verification methods; printing and archiving reports; and software upgrades.

## Items Included with Purchase

- Microsoft® Word version of the "LVS-95XX Series IQ and OQ Guidelines"
- Microsoft® Word version of the "LVS-95XX Series Operations Manual"
- One set of twenty five (25) challenge bar code labels (1D and 2D bar codes) for testing (see example images)



Example 1D (Code 39) Bar Code



Example 2D (Data Matrix) Bar Code



Example 2D (Data Matrix) Bar Code

## SAFETY CERTIFICATIONS DESIGNED FOR

FCC, CE, UL (Pending)

## ROHS COMPLIANT

## QMS CERTIFICATION

[www.microscan.com/quality](http://www.microscan.com/quality)

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Warranty – For current warranty information about this product, please visit [www.microscan.com/warranty](http://www.microscan.com/warranty).



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