FLOWLINX® BETA BAG VALIDATION GUIDE

When material transfer integrity matters, FlowLinX® delivers flexible, high performance solutions engineered for modern biopharmaceutical manufacturing. The FlowLinX® Beta Bag is a single use transfer bag designed to support contamination controlled movement of materials in conjunction with rapid transfer port systems, while minimizing cleaning, revalidation, and operational downtime.

1. INTRODUCTION

The FlowLinX® Beta Bag is a single-use transfer bag designed for contamination-controlled transfer of components and materials into or out of controlled environments including isolators, restricted access barrier systems (RABS), and classified cleanrooms.

The system provides a closed transfer solution compatible with rapid transfer port (RTP) systems and is intended for use in pharmaceutical manufacturing environments including:

- Sterile drug product filling
- Aseptic processing
- Sterile component transfer
- Cell and gene therapy manufacturing
- Biologics manufacturing
- Sterile compounding
- Containment transfer applications

The FlowLinX® Beta Bag is manufactured under controlled conditions and undergoes routine quality testing to ensure mechanical integrity, containment performance, and product traceability.

This document provides guidance for qualification and validation of the FlowLinX® Beta Bag and may be used by pharmaceutical manufacturers, contract development and manufacturing organizations (CDMOs), and equipment integrators as part of facility validation programs. Final suitability for use should be determined by the end user within the intended process conditions.

2. SCOPE

This validation guide provides recommended qualification approaches for the FlowLinX® Beta Bag covering:

- Product design qualification
- Materials of construction
- Mechanical performance
- Containment integrity
- Cleanliness and microbiological control
- Sterilization compatibility
- Packaging and storage validation
- Traceability and documentation

3. PRODUCT DESCRIPTION

3.1 Intended Use

FlowLinX® Beta Bags are designed for:

- Controlled transfer of components, materials, and process intermediates
- Material transfer into/out of isolators, RABS, and cleanrooms
- Integration with single-use assemblies, including tubing sets and filling needles

FlowLinX® Beta Bags are supplied non-sterile and are intended for integration into validated transfer processes.

3.2 Key Features

- 190 mm alpha-port compatible interface
- Enhanced puncture-resistant multilayer barrier film
- Manufactured in ISO 7 cleanroom
- 100% pressure-differential leak testing
- Lot-level traceability with Certificate of Conformance (CoC)
- Available with optional bag ports (hose barb or tri-clamp style port)

3.3 System Components

The FlowLinX® Beta Bag system consists of the following primary components:

COMPONENT	DESCRIPTION
Beta flange	Rigid docking interface designed for RTP alpha port connection
Beta door	Integrated door mechanism enabling controlled transfer
Gasket seal	Elastomeric sealing component ensuring containment integrity
Flexible bag body	Multilayer barrier film bag
Optional ports	Hose barb or TC transfer connections (configurable)
Protective cover	Dust cover that seats over door

4. PRODUCT CONFIGURATION

4.1 Standard Versions (Non-Ported)

PART NUMBER	DESCRIPTION	BAGS PER BOX
F-BB-190-30L	FlowLinX® Beta Bag, 30 L, Non-Sterile	8
F-BB-190-50L	FlowLinX® Beta Bag, 50 L, Non-Sterile	8

4.2 Ported Versions

PART NUMBER	DESCRIPTION	BAGS PER BOX
F-BBG-190-30L-0188	30 L, NS, with 3/16" ID opposing barb	8
F-BBG-190-30L-0250	30 L, NS, with 1/4" ID opposing barb	8
F-BBG-190-30L-0375	30 L, NS, with 3/8" ID opposing barb	8
F-BBG-190-30L-0500	30 L, NS, with 1/2" ID opposing barb	8
F-BBG-190-30L-MAXITC	30 L, NS, with 1.5" TC port	8
F-BBG-190-30L-3TC	30 L, NS, with 3" TC port	8
F-BBG-190-50L-0188	50 L, NS, with 3/16" ID opposing barb	8
F-BBG-190-50L-0250	50 L, NS, with 1/4" ID opposing barb	8
F-BBG-190-50L-0375	50 L, NS, with 3/8" ID opposing barb	8
F-BBG-190-50L-0500	50 L, NS, with 1/2" ID opposing barb	8
F-BBG-190-50L-MAXITC	50 L, NS, with 1.5" TC port	8
F-BBG-190-50L-3TC	50 L, NS, with 3" TC port	8

Box Size = 508 mm x 508 mm x 508 mm (20 in x 20 in x 20 in)

5. PRODUCT SPECIFICATIONS

5.1 Summary Specifications

SPECIFICATIONS	
Nominal Diameter	190 mm
Available Volumes	30 L, 50 L
Sterility	Non-sterile
Bag Film Material	Nylon/EVOH/PE
Flange / Door Material	HDPE
Gasket Material	Platinum-cured silicone
Operating Temperature	16–24 °C
Maximum Differential Pressure	≥ 0.200 psi (1379 Pa)
Load Rating	Up to 10 kg (30–50 L)
Seal Strength	≥ 15 N / 15 mm (ASTM F88)
Endotoxin	Tested per USP <85>
Bioburden	Tested per ISO 11737-1
Integrity Testing	100% pressure-differential leak test
Sterilization Compatibility	Gamma & X-ray compatible (25–50 kGy); sterilization indicator on door
Packaging	Individually double bagged
Shelf Life	5 years from date of manufacture

6. MATERIALS OF CONSTRUCTION

6.1 Film Properties

The FlowLinX® Beta Bag utilizes a multilayer barrier film (Nylon/EVOH/PE) designed for high strength, impact resistance, and enhanced durability for modern single-use assemblies.

PROPERTY	TEST METHOD	UNITS	TYPICAL VALUE
Film thickness		mil	5.0
Water vapor transmission (WVTR)	ASTM F1249	g/100 in^2/24 hr (g/m2 · day)	0.024 (3.72)
Oxygen transmission (OTR)	ASTM 3985	cc/100 in^2/24 hr (cm3/m2 · day)	0.03 (4.65)
Tensile (MD) at break	ASTM D882	Lb (MPa)	33.5 (36)
Tensile (XMD) at break	ASTM D882	Lb (MPa)	35 (38)
Tear (MD)	ASTM D689	g	65
Tear (XMD)	ASTM D689	g	65

6.2 Rigid Flange / Door

The flange and door are manufactured from HDPE selected for durability and dimensional stability.

PROPERTY	TEST METHOD	UNITS	TYPICAL VALUE
Density	ISO 1183	kg/m^3	954
Melt flow rate (190°C / 2.16 kg)	ISO 1133	g/10 min	4
Flexural modulus	ISO 178	MPa	1,250
Tensile modulus	ISO 527-2	MPa	1,150
Tensile stress at yield	ISO 527-2	MPa	26
Tensile strain at yield	ISO 527-2	%	9
Heat deflection temperature (0.45 MPa)	ISO 75-2	°C	71
Hardness	ISO 868	Shore D	61

6.3 Gasket Seal

The gasket seal is manufactured from platinum-cured silicone elastomer.

PROPERTY	UNITS	TYPICAL VALUE
Hardness	Shore A	50
Tensile strength	psi (MPa)	1250 (8.6)
Elongation at break	%	575
Tear strength	ppi (kN/m)	250 (43.9)
Compression set (22 hr @ 350°F)	%	35

6.4 Protective Cover

The protective cover for the door is manufactured from polycarbonate.

7. MATERIALS OF CONSTRUCTION AND REGULATORY COMPLIANCE

7.1 Film

REGULATION	STATUS
FDA 21 CFR 177.1520	Meets
USP <85>, Bacterial Endotoxin	Meets
TSE/BSE/EMEA 4.10	Meets
RoHS Compliance	Meets
REACH Compliance	Meets
Conflict Minerals	None Used
Allergens	None Used
Non GMO	Meets
Phthalate Free	Meets
Melamine Free	Meets
Nitrosamines Free	Meets
Parabens Free	Meets
PFAS Free	Meets
Latex Free	Meets
BPA Free	Meets

7.2 Flange / Door

REGULATION	STATUS
USP <88>, Biological Reactivity Tests, Class VI	Meets
USP <87>, Biological Reactivity Tests, In Vitro	Meets
ISO 10993-4, Interactions with Blood	Meets
ISO 10993-5, In Vitro Cytotoxicity	Meets
ISO 10993-10, Skin Sensitization	Meets
ISO 10993-11, Systemic Toxicity	Meets
USP <85>, Bacterial Endotoxin	Meets
EP 3.1.3, Polyolefins	Meets
EP 3.1.5, Polyethylene with Additives for Containers	Meets
USP <661>, Plastic Packaging Systems	Meets
TSE/BSE/EMEA 4.10	Meets
RoHS Compliance	Meets
REACH Compliance	Meets
Conflict Minerals	None Used
Allergens	None Used
Elemental Impurities per ICH Q3D(R2)	None Used
Non GMO	Meets
Phthalate Free	Meets
Melamine Free	Meets
Nitrosamines Free	Meets
Parabens Free	Meets
PFAS Free	Meets
Latex Free	Meets
BPA Free	Meets

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7.3 Gasket Seal

REGULATION	STATUS
USP <88>, Biological Reactivity Tests, Class VI	Meets
ISO 10993-4, Interactions with Blood	Meets
ISO 10993-5, In Vitro Cytotoxicity	Meets
ISO 10993-10, Skin Sensitization	Meets
ISO 10993-11, Systemic Toxicity	Meets
USP <85>, Bacterial Endotoxin	Meets
EP 3.1.9	Meets
USP <661>, Plastic Packaging Systems	Meets
FDA 21 CFR 177.2600	Meets
TSE/BSE/EMEA 4.10	Meets
RoHS Compliance	Meets
REACH Compliance	Meets
Conflict Minerals	None Used
Allergens	None Used
Elemental Impurities per ICH Q3D(R2)	None Used
Phthalate Free	Meets
Melamine Free	Meets
Nitrosamines Free	Meets
Parabens Free	Meets
PFAS Free	Meets
Latex Free	Meets
BPA Free	Meets

8. MANUFACTURING ENVIRONMENT

The FlowLinX® Beta Bag is manufactured in controlled cleanroom environments to minimize particulate and microbial contamination.

MANUFACTURING STAGE	CLEANROOM CLASSIFICATION
Flange/Door Injection Molding	ISO Class 8
Bag Fabrication/Flange Integration	ISO Class 7
Gasket Seal	ISO Class 7
Integrity Testing	ISO Class 7
Packaging	ISO Class 7

Environmental monitoring and process controls are implemented to ensure manufacturing consistency and product quality.

9. MECHANICAL PERFORMANCE VALIDATION

Mechanical testing is performed to verify durability and robustness of the FlowLinX® Beta Bag. Testing is conducted according to recognized industry standards.

9.1 Seal Strength

Seal integrity testing was performed in accordance with the CCG SOP and testing verified that seal strength exceeded the acceptance criterion of ≥ 15 N/15 mm (≥ 6 lb/in) without premature film failure. All tested samples passed, with measured seal strengths ranging from approximately 71.2 to 76.7 N/15mm (27.1 to 29.2 lb/in.). No seal failures below the acceptance criteria were observed, confirming robust weld integrity and consistent seal performance.

Seal integrity is verified using peel testing methods.

PARAMETER	VALUE
Test method	ASTM F88
Seal strength acceptance criteria	≥ 15 N / 15 mm
Test sample size	3 seals per lot; 3 lots
Seal locations tested	Port seal; End seal

9.2 Film Mechanical Performance – Puncture Resistance (ASTM F1306-21)

Puncture resistance testing was performed in accordance with ASTM F1306-21 using a slow-rate penetration methodology. Testing evaluated film performance across the beginning, middle, and end of the film roll in both Inside-to-Outside and Outside-to-Inside orientations to assess laminate consistency, directional mechanical behavior, and sterilization compatibility.

The FlowLinX® Beta Bag film demonstrated consistent puncture resistance throughout the roll, with an overall average puncture force of approximately 4.8 kgf (47 N).

Directional testing confirmed expected laminate behavior, with average puncture forces of approximately 5.4 kgf (53 N) in the Inside-to-Outside direction and 4.1 kgf (40 N) in the Outside-to-Inside direction, while maintaining robust performance across all test conditions. Low standard deviation values across all test conditions support manufacturing consistency and uniform film performance throughout

the roll. Gamma-irradiated samples maintained comparable puncture resistance and displacement performance relative to non-irradiated controls, supporting compatibility with validated sterilization processes.

These results demonstrate strong resistance to puncture damage and reduced risk of film compromise during handling and transfer of modern single-use assemblies and process components.

TABLE 1: PUNCTURE FORCE BY CONDITION

CONDITION	DIRECTION	AVERAGE FORCE (KGF)	AVERAGE FORCE (N)
Beginning of Roll	Inside → Outside	5.55	54.4 N
Beginning of Roll	Outside → Inside	4.04	39.6 N
Middle of Roll	Inside → Outside	5.52	54.1 N
Middle of Roll	Outside → Inside	4.01	39.3 N
End of Roll	Inside → Outside	5.14	50.4 N
End of Roll	Outside → Inside	4.31	42.3 N

9.3 Load Testing

Load testing was performed to evaluate the ability of the FlowLinX® Beta Bag assembly to withstand mechanical loading during handling and transfer operations. A 10 kg (~22 lb) load was placed inside the finished assembly for a minimum of 24 hours, followed by a pressure differential leak test conducted for 2 minutes at ≥ 0.200 psi. No weld failures or loss of integrity were observed following testing. All samples passed acceptance criteria, supporting the ability of the assembly to withstand expected operational loading conditions.

PARAMETER	VALUE
Maximum recommended load	10 kg (22lb)
Test method	Static load suspension test, 24 hour dwell at rated load
Acceptance criteria	No seal failure, no film rupture, no flange deformation at Alpha Port integration

9.4 Dimensional Validation

Dimensional and visual inspection is performed per FlowLinX® quality procedures.

INSPECTION CATEGORY	EXAMPLES	ACCEPTANCE CRITERIA
Visual	Film defects, seal uniformity, foreign matter, delamination	No critical defects, cosmetic defects per ANSI/ASQ sampling plan
Dimensional	Flange interface dimensions, door engagement, port geometry	Conforms to released engineering drawings and tolerances

10. CONTAINMENT INTEGRITY TESTING

Integrity testing verifies that the FlowLinX® Beta Bag maintains containment during normal operating conditions.

10.1 Pressure Differential Leak Testing

Finished assemblies were subjected to pressure differential testing for 2 minutes at ≥ 0.200 psi to verify containment integrity and weld performance. All tested assemblies successfully maintained pressure with no evidence of weld failure or loss of containment. Recorded test pressuresaveraged 0.290 psi during testing.. These results demonstrate reliable pressure integrity and containment performance of the assembled system. All completed FlowLinX® Beta Bags undergo integrity testing using pressure-based leak detection methods.

PARAMETER	VALUE
Test method	ASTM F2338, Pressure decay leak test
Pressure level	≥ 0.200 psi (1379 Pa)
Test duration	60 seconds stabilization + 60 seconds measurement
Maximum allowable leak rate	≤ 10 Pa/min pressure loss

10.2 Interface Integrity

Interface integrity testing was conducted by attaching the full FlowLinX® Beta Bag assembly to a compatible 190mm alpha door interface for multiple docking cycles to evaluate gasket sealing performance and containment integrity. Acceptance criteria included no measurable pressure decay beyond allowable leak limits, uniform gasket compression without visible gaps, and no loss of containment. Following testing, FlowLinX® Beta Bags maintained an average pressure of 0.290 psi after 2 minutes with uniform gasket compression and no visible sealing defects. All beta bags passed acceptance criteria, confirming robust interface sealing performance under repeated docking conditions.

INSPECTION CATEGORY	EXAMPLES	ACCEPTANCE CRITERIA
Door seal integrity	Pressure hold test after door closure	No measurable pressure decay beyond allowable leak rate
Gasket compression seal	Compression set and visual verification	Uniform compression, no visible gaps
Interface leak test	Docked pressure decay test with alpha port	No loss of containment; leak rate within system limits

11. CLEANLINESS AND MICROBIOLOGICAL TESTING

Cleanliness and microbiological testing support contamination control requirements for pharmaceutical environments.

11.1 Bioburden

Bioburden testing evaluates microbial levels present on the product prior to sterilization or use.

PARAMETER	VALUE
Test standard	ISO 11737-1
Test frequency	Quarterly

11.2 Endotoxin and Particulates

Testing of the FlowLinX™ Beta Bag was performed under cGMP conditions using NIST-traceable methods in accordance with USP <85>, Endotoxins and USP <788>, Sub visible particulates.

All samples passed both endotoxin and particulate requirements with results below pharmacopeia limits:

- Endotoxins: <0.0105 EU/mL (limit: 0.125 EU/mL)
- Particulates ≥10 µm: 3.2–4.8 particles/mL (limit: 25 particles/mL for LVP)
- Particulates ≥25 µm: 0.2–0.6 particles/mL (limit: 3 particles/mL for LVP)

These results demonstrate exceptionally low bioburden and particulate contribution, supporting suitability for high-purity applications.

TABLE 1: ENDOTOXIN RESULT VS. USP LIMIT

SAMPLE	RESULT (EU/ML)	USP LIMIT (EU/ML)
Sample 1	<0.0105	0.125
Sample 2	<0.0102	0.125
Sample 3	<0.0100	0.125

TABLE 2: PARTICULATE RESULTS, ≥10 µM PARTICLES

SAMPLE	RESULT (PARTICLES/ML)	USP LIMIT
Sample 1	3.2	25
Sample 2	4.8	25
Sample 3	3.7	25

TABLE 2: PARTICULATE RESULTS, ≥25 µM PARTICLES

SAMPLE	RESULT (PARTICLES/ML)	USP LIMIT
Sample 1	0.2	3
Sample 2	0.6	3
Sample 3	0.5	3

12. STERILIZATION COMPATIBILITY

FlowLinX® Beta Bags are compatible with gamma irradiation in the range of 25–50 kGy.

13. DOCKING SYSTEM COMPATIBILITY

The FlowLinX® Beta Bag is designed to interface with compatible rapid transfer port (RTP) alpha systems. Docking system compatibility testing was performed using repeated attachment cycles between the FlowLinX® Beta Bag assembly and a compatible 190mm alpha door interface. The assembly was connected and disconnected mulitple times to evaluate mechanical engagement, gasket integrity, and sealing performance following repeated use. No degradation of sealing performance or mechanical integrity was observed throughout testing. Assemblies maintained an average pressure of 0.290 psi after 2 minutes during post-cycle integrity verification. These results support reliable compatibility with rapid transfer port (RTP) docking systems and demonstrate repeatable sealing performance during routine transfer operations.

TEST	ACCEPTANCE CRITERIA
Docking engagement	Positive mechanical engagement with compatible RTP alpha port; no misalignment or incomplete seating
Door opening/closing	Smooth actuation without binding; full travel achieved; door fully seats and seals when closed
Transfer containment	No measurable loss of containment during simulated transfer operations
Repeated connection cycles	Minimum 5 docking cycles with no degradation of sealing or mechanical performance

14. STORAGE CONDITIONS

Recommended storage conditions:

PARAMETER	REQUIREMENT
Temperature	16 – 24 °C
Relative humidity	< 70% RH
Light exposure	Protect from direct sunlight and UV

Products should remain in original packaging until use.

15. SHELF LIFE

Shelf life is determined through stability studies including accelerated and real-time aging.

PARAMETER	VALUE
Shelf life	5 Years
Aging method	Accelerated aging per ASTM F1980 and real-time aging studies
Verification tests	Seal strength, integrity leak testing, visual inspection, dimensional verification

16. TRACEABILITY

Each FlowLinX® Beta Bag is traceable through manufacturing documentation.

Traceability information includes lot number, manufacturing batch record, date of manufacture and product identification. Traceability records are maintained according to quality system procedures.

17. SUMMARY

The FlowLinX® Beta Bag provides a robust single-use solution for contamination-controlled material transfer in high-purity manufacturing environments. Mechanical testing, containment verification, and controlled manufacturing processes support reliable operation within isolator and RTP systems. The validation guidance provided in this document assists customers in integrating the FlowLinX® Beta Bag into validated manufacturing processes. Final suitability for use should be determined by the end user within the intended process conditions.