

# BPSA Quality Test Matrices 2023 Update

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# Agenda

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- Project Review
- Changes
- Path Forward

# Objective

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- Update the BPSA Quality Test Matrices (Last updated in 2015)
  - Add new standards and references
  - Remove obsolete standards and references
  - Prioritize tests to:
    - Required
    - Recommended
    - To Be Considered
- Complete for rollout with BPSA Summit in ~~July~~ **August 2023**

# Project

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- Gather community input from BPSA members and the industry in general.
- Survey.
- Combine information in in 5-6 teams-3-4 online meetings
  - Test Categories and/or
  - Component Categories
- Present to other teams at a face to face.
- Refine information in 5-6 teams-2-3 online meetings
- SAB approval
- Board approval
- Presentation to Membership-**Today**

# Team Members

Jim Sanford

Paul Priebe

Dan Nelson

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Robert "Bob" Huffman

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# QTM History

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- Purpose: “help guide users when making their selections and (to) facilitate qualification, validation and use of Single-Use products”
- Most accurate, up-to-date and emergent information

# QTM History

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- 2007-Initial
- 2015-Last Update
- 2023-Current Update



# 2015

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## Test Categories

- A. Physical
- B. Functional
- C. Biological
- D. Chemical
- E. Regulatory
- F. Sterilization/Sanitization

## Component Categories

1. Chromatography
2. Connectors, Valves and Retainers
3. Containers and Film
4. Sensors
5. Tubing
6. Filters



Bio-Process Systems Alliance  
*Advancing Single-Use Worldwide*



BPSA International  
Single-Use Summit



# 2023

## Test Categories

- A. Physical
- B. Functional
- C. Biological
- D. Chemical
- E. Regulatory
- F. Sterilization/Sanitization

## Component Categories

- 1. Chromatography
- 2. Connectors, Valves and Retainers
- 3. Containers and Film
- 4. Sensors
- 5. Tubing
- 6. Filters
- 7. Single-Use Assemblies



# 2023 Changes

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- Single-Use Assembly Sheet added
- Tests added
- Manufacturer defined methods
- Tests deleted
- Links Updated
- Component Categories added to Test Sheets
- Alphabetical Listings
- BPSA color scheme

# A. Physical Tests

- Updates
- Integrity
- Shelf life added

A. PHYSICAL TESTS				COMPONENTS		
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Com
Integrity (Leak) Test	Hydrostatic Pressure Test (Shell/Seat Test)	<a href="#">ASTM E 3251-20</a>	Final Article		<a href="#">ASTM E 3251-20</a>	
	Standard Test Method for Physical Integrity Testing of Single-Use Systems. Confirmation of integrity for components and assemblies at a given temperature. This includes pressure testing under operating conditions and at elevated pressures.	<a href="#">ASTM E3244-20</a>	Final Article	<a href="#">ASTM E3244-20</a>	<a href="#">ASTM E3244-20</a>	<a href="#">ASTM E3244-20</a>
		<a href="#">ASTM E515-22</a>				<a href="#">ASTM E515-22</a>
		<a href="#">ASTM D4991-99</a>				<a href="#">ASTM D4991-99</a>
		<a href="#">ASTM E 3251-20</a>		<a href="#">ASTM E 3251-20</a>	<a href="#">ASTM E 3251-20</a>	
		<a href="#">ASTM E3336-22</a>		<a href="#">ASTM E3336-22</a>	<a href="#">ASTM E3336-22</a>	
	Junction Testing (barbed fittings)	Manufacturer Defined Method	Final Article			
Hydrostatic leak testing	Manufacturer Defined Method	Final Article	<a href="#">Manufacturer Defined Method</a>	<a href="#">Manufacturer Defined Method</a>	<a href="#">Manufacturer Defined Method</a>	
		<a href="#">ASMTM E1003-13 (2022)</a>			<a href="#">ASMTM E1003-13 (2022)</a>	

# A. Physical Tests

A. PHYSICAL TESTS				COMPONENT CATEGORY APPLICABLE TO THIS TEST							
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies	
Chamber Integrity/Seal Integrity-Peel	Used to measure manufactured product and seal barrier performance of a variety of package types and forms, as well as seal and/or closure types.	ASTM E3244-20	Container			ASTM E3244-20					
	Performed to ensure that functional strength requirements are met.	ASTM F89 F89M Rite Manufacturer Defined Method, Risk Assessment	Container			ASTM E3244-20 ASTM F89 F89M Rite Manufacturer Defined Method Risk Assessment					
	Microbial ingress test of single-use systems	ASTM E 3251-20	Container			ASTM E 3251-20					
	Physical integrity of single-use systems	ASTM E3336-22	Container			ASTM E3336-22					
	Used to measure manufactured product and seal barrier performance of a variety of package types and forms, as well as seal and/or closure types.	Manufacturer Defined Method	Packaging							Manufacturer Defined Method	
Compression Set Test	Compression set measures the residual deformation after compressive loading under specified conditions.	ASTM D295 ISO 815	Cured raw material test plaque					ASTM D295 ISO 815			
Durometer (Hardness)	A measurement of the hardness of a material.	ASTM D2240 ISO 868	Cured raw material test plaque					ASTM D2240 ISO 868			
Elongation	A measure of a material ductility. Elastic modulus or modulus of elasticity is a measure of a material's tendency to deform when a force is applied. (Modulus at 100%, 200%)	ASTM D812 ISO 37	Cured raw material test plaque OR Final Article					ASTM D812 ISO 37			
Integrity (Leak) Test	Hydrostatic Pressure Test (Shell/Seat Test)	ASTM E 3251-20 ASTM E3244-20	Final Article		ASTM E 3251-20						
	Standard Test Method for Physical Integrity Testing of Single-Use Systems. Confirmation of integrity for components and assemblies at a given temperature. This includes pressure testing under operating conditions and at elevated pressures.	ASTM E512-22	Final Article	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20	ASTM E3244-20
		ASTM D4951-20									
		ASTM E 3251-20		ASTM E 3251-20	ASTM E 3251-20	ASTM E 3251-20	ASTM E 3251-20	ASTM E 3251-20	ASTM E 3251-20	ASTM E 3251-20	ASTM E 3251-20
	Junction Testing (Barbed fittings)	ASTM E3336-22	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method
	Single-use assembly junction connections should be qualified by the supplier to ensure they meet performance criteria as stated in their specification. The supplier shall have an established testing program to substantiate performance of the mechanical connection. The testing should reference at least one of the following: (a) Pressure Testing (b) Leak Testing (c) Tracer Gas Testing	Manufacturer Defined Method		Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method
Hydrostatic leak testing	ASTM F1003-13 (2022)	Final Article	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	
O <sub>2</sub> and CO <sub>2</sub> Permeability	Determines the steady-state rate of transmission of O <sub>2</sub> or CO <sub>2</sub> gases through material.	ASTM D3986 - (ISO10648) ASTM F1927-20 ASTM F2435	Film			ASTM D3986 ISO10648 ASTM F1927-20 ASTM F2435					
Pressure Burst Test	Characterization of device with regard to operating pressure and behavior under elevated pressure conditions at a given temperature, typically including determination of burst pressure under static pressure.	ISO 1869-2017	Final Article	ISO 1869-2017							
		ASTM D1599-18		ASTM D1599-18	ASTM D1599-18	ASTM D1599-18	ASTM D1599-18	ASTM D1599-18	ASTM D1599-18		
		Manufacturer Defined Method		Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method		
		ISO 1402-2021		ISO 1402	ISO 1402	ISO 1402	ISO 1402	ISO 1402	ISO 1402		
		EN 12286-1		EN 12286-1	EN 12286-1	EN 12286-1	EN 12286-1	EN 12286-1	EN 12286-1		
ISO 7241-2	ISO 7241-2	ISO 7241-2	ISO 7241-2	ISO 7241-2	ISO 7241-2	ISO 7241-2	ISO 7241-2	ISO 7241-2	ISO 7241-2		
Puncture Resistance	Puncture resistance testing predicts the durability of the film while in use. Films with high puncture resistance correspond with materials that can absorb the energy of an impact by both resistance to deformation and increased elongation. Puncture resistance, measured in energy units, evaluates the film strength and tenability properties. Puncture resistance is similar to tensile toughness.	ASTM D7192-20  PTMS1 101C Method 2065.1	Film			ASTM D7192-20  PTMS1 101C Method 2065.1					
Shelf Life	Demonstrates functional performance at end of manufacturer-specified shelf life (typically does not test to failure).	Manufacturer Defined Method	Container			Manufacturer Defined Method					
Specific Gravity	Density relative to water.	ASTM D292 ISO 1187	Cured raw material test plaque OR Final Article					ASTM D292 ISO 1187			
Tear Resistance	Tear strength measures the resistance to propagation of a rip or tear once the rip has been initiated.	ASTM D624-00 ASTM D1438-19 ISO 38	Film/Cured raw material test plaque or Final Article			ASTM D624-16		ASTM D624-00 ASTM D1438-19 ISO 38			
Tensile Strength	Determines resistance of loading on a jointed union/connection/fitting.	ASTM D602-18 Manufacturer Defined Method ISO 37	Final Article		Manufacturer Defined Method	ASTM D602-18		ASTM D602-18 ISO 37		Manufacturer Defined Method	
	Film thickness and material composition to be defined.	ASTM D1177	Film			ASTM D1177					
	List of potential visual observations regarded as defects vs cosmetic imperfections. Observations should consider secondary packaging material that may contribute to visual observations, as well as the installation state of the bio container at the time such inspections would typically be performed.	Manufacturer Defined Method	Container			Manufacturer Defined Method					
	(WVTR) The rate at which water vapor will permeate through solid material over a specified time period.	ASTM F1140-20	Film			ASTM F1140-20		ASTM F1140-20			

\* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations



# B. Functional Tests

- Updates
- Additions
  - General Functionality
  - Weldability
  - Pump Life

B. FUNCTIONAL TESTS				
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography
Accelerated or Real Time Aging (Shelf Life)	Accelerated and/or real time studies to determine the effects, if any, due to the passage of time and environmental effects on the properties of product, and on the sterile integrity of packages and the physical properties of their component packaging materials.	Manufacturer Defined Method	Final Article	Manufacturer Defined Method
		<a href="#">ASTM F1980-21</a>		<a href="#">ASTM F1980-21</a>
Accuracy/Calibration	Verification that the sensor meets the published accuracy specification, or if applicable, is properly calibrated	Manufacturer Defined Method	Final Article	
Adsorbent Capacity	Static (equilibrium) and/or dynamic binding capacity of the adsorbent, determined for contacting an adsorbing substance and the adsorbent (typically gel or membrane) under specific buffer conditions.	Manufacturer Defined Method	Raw Material and/or Final Article	Manufacturer Defined Method
Bacterial Retention Test (Sterilizing Grade Filters)	Bacterial challenge and effluent sterility test based on standard methodology.	<a href="#">ASTM F838-05</a>	Final Article	

# B. Functional Tests

## General Functionality

- The Manufacturer/user shall establish that the Single-Use components, SUS assemblies, and SUS systems are designed for integrity and functionality, appropriately. These considerations should be maintained during installation and ensured throughout the use of the item based on scientific product and process understanding for both SUS manufacturing and end user requirement. Qualification of design, manufacturing, testing and distribution should be conducted by the suppliers of Single-Use components and assemblies with a planned and structured verification approach being applied throughout the system life cycle to deliver reliability of performance.
- Critical aspects of the SUS are typically functions, features, abilities, performance, and characteristics necessary for the manufacturing process and use, that ensure consistent product quality and patient safety.

# B. Functional Tests

TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	COMPONENT CATEGORY APPLICABLE TO THIS TEST						
				1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Accelerated or Real Time Aging (Shelf Life)	Accelerated and/or real time studies to determine the effects, if any, due to the passage of time and environmental effects on the properties of product, and on the sterile integrity of packages and the physical properties of this component packaging materials.	Manufacturer Defined Method ASTM F1380-21	Final Article ASTM F1380-21	Manufacturer Defined Method ASTM F1380-21	Manufacturer Defined Method ASTM F1380-21	Manufacturer Defined Method ASTM F1380-21	Manufacturer Defined Method ASTM F1380-21	Manufacturer Defined Method ASTM F1380-21	Manufacturer Defined Method ASTM F1380-21	Manufacturer Defined Method ASTM F1380-21
Accuracy/Calibration	Verification that the sensor meets the published accuracy specification, or if applicable, is properly calibrated.	Manufacturer Defined Method	Final Article				Manufacturer Defined Method			
Adsorbent Capacity	Static equilibrium adsorbent capacity determined by the adsorbent, determined for contacting an adsorbing substance and the adsorbent (typically gel or material) under specific buffer conditions.	Manufacturer Defined Method	Raw Material and/or Final Article	Manufacturer Defined Method						
Bacterial Retention Test (Sterilizing Grade Filters)	Bacterial challenge and effluent clarity test based on standard methodology.	ASTM F480-06	Final Article						ASTM F480-06	
Break at Cold Temperature Test	Determines cold crack temperature of plastic film.	ISO 8770	Film				ISO 8770			
Cell Growth	Cell Culture Growth Assessment of Single-Use Material	ASTM F2311 Manufacturer Defined Method	Containers/Film Containers/Film				ASTM F2311 Manufacturer Defined Method			
Chromatographic Efficiency Test (HETP test)	Characterization of separation efficiency, typically performed on chromatography columns.	Manufacturer Defined Method	Final Article	Manufacturer Defined Method						
Dart Drop	Test method covers the determination of the energy as part of mechanical properties that causes plastic film to fail under specified conditions of impact of a free falling dart.	ASTM D4200-06	Film				ASTM D4200-06			
Filter Integrity Test	Confirms the membrane integrity (no defects, holes etc.) at given conditions of pressure/temperature.	Manufacturer Defined Method	Final Article	Manufacturer Defined Method					Manufacturer Defined Method	
Gelbo	Determines the flow resistance of materials by the formation of pellets.	ASTM F200-00	Film				ASTM F200-00			
General Functionality Fit for Intended Use	The Manufacturer/User shall establish that the Single-Use components, SIS assemblies, and SIS systems are designed for integrity and functionality, respectively. These considerations should be maintained during installation and ensured throughout the use of the item based on scientific product and process understanding for both SIS manufacturing and end user requirements. Qualification of design, manufacturing, testing and distribution should be conducted by the supplier of Single-Use components and assemblies with a planned and structured verification approach being applied throughout the system life cycle to deliver reliability of performance. Critical aspects of the SIS are typically function, features, abilities, performance, and characteristics necessary for the manufacturing process and use, that ensure consistent product quality and patient safety.	Manufacturer Defined Method ASTM 3001	Final Article	Manufacturer Defined Method ASTM 3001	Manufacturer Defined Method ASTM 3001	Manufacturer Defined Method ASTM 3001	Manufacturer Defined Method ASTM 3001	Manufacturer Defined Method ASTM 3001	Manufacturer Defined Method ASTM 3001	Manufacturer Defined Method ASTM 3001
	Min./Max Temperature	ASME BPE SD 2.4.1.2		ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2
Glass Transition Temperature	Determines the glass transition temperature (Tg) of materials. The Tg is the temperature where the polymer goes from a hard, rigid state to a rubber like, flexible state.	ASTM D1624-11 ASTM D1624-11a	Film				ASTM D1624-11 ASTM D1624-11a			
Haze and Transmittance	Evaluation of specific light transmitting and side-angle light scattering properties of material.	ASTM D4903-11	Film				ASTM D4903-11			
Kink Resistance Bend Radius	The terms bend radius and kink resistance are used interchangeably to describe the change in the ability of a fluid to flow through the tubing when the tubing is bent.	Manufacturer Defined Method (supplier-specific)	Final Article						Manufacturer Defined Method (supplier-specific)	
Low Temperature Brittleness	Determines the temperature at which plastics and elastomers exhibit brittle failure.	ASTM D1201-14 ASTM D2041	Film				ASTM D1201-14 ASTM D2041			
Microbial Ingress Soil Test	Identification of external bacteria's ability to breach a seal and ingress into a sterile bag path.	Manufacturer Defined Method ASTM D4160-04	Final Article	Manufacturer Defined Method ASTM D4160-04						
Package Testing Transportation Shipping Integrity	Qualify that product packaging will protect the product during shipping. Standard practice for performance testing of shipping containers and systems by provide a uniform basis of evaluating, in a laboratory, the ability of shipping units to withstand the distribution environment.	ASTM D4160-04 ASTM D4160-04a ASTM D4160-04b ASTM D4160-04c ASTM D4160-04d ASTM D4160-04e ASTM D4160-04f ASTM D4160-04g ASTM D4160-04h ASTM D4160-04i ASTM D4160-04j ASTM D4160-04k ASTM D4160-04l ASTM D4160-04m ASTM D4160-04n ASTM D4160-04o ASTM D4160-04p ASTM D4160-04q ASTM D4160-04r ASTM D4160-04s ASTM D4160-04t ASTM D4160-04u ASTM D4160-04v ASTM D4160-04w ASTM D4160-04x ASTM D4160-04y ASTM D4160-04z	Final Article	ASTM D4160-04 ASTM D4160-04a ASTM D4160-04b ASTM D4160-04c ASTM D4160-04d ASTM D4160-04e ASTM D4160-04f ASTM D4160-04g ASTM D4160-04h ASTM D4160-04i ASTM D4160-04j ASTM D4160-04k ASTM D4160-04l ASTM D4160-04m ASTM D4160-04n ASTM D4160-04o ASTM D4160-04p ASTM D4160-04q ASTM D4160-04r ASTM D4160-04s ASTM D4160-04t ASTM D4160-04u ASTM D4160-04v ASTM D4160-04w ASTM D4160-04x ASTM D4160-04y ASTM D4160-04z						
Particulate Matter	Evaluates and quantifies the presence of particulates (visible and/or sub-visible) in or on a sample.  Practice for Detection of Particulate Matter from the Surfaces of Single-Use Components and Assemblies Designed for Use in Biopharmaceutical Manufacturing	USP <788> USP <788>-1 USP <788>-2 USP <788>-3 USP <788>-4 USP <788>-5 USP <788>-6 USP <788>-7 USP <788>-8 USP <788>-9 USP <788>-10 USP <788>-11 USP <788>-12 USP <788>-13 USP <788>-14 USP <788>-15 USP <788>-16 USP <788>-17 USP <788>-18 USP <788>-19 USP <788>-20 USP <788>-21 USP <788>-22 USP <788>-23 USP <788>-24 USP <788>-25 USP <788>-26 USP <788>-27 USP <788>-28 USP <788>-29 USP <788>-30 USP <788>-31 USP <788>-32 USP <788>-33 USP <788>-34 USP <788>-35 USP <788>-36 USP <788>-37 USP <788>-38 USP <788>-39 USP <788>-40 USP <788>-41 USP <788>-42 USP <788>-43 USP <788>-44 USP <788>-45 USP <788>-46 USP <788>-47 USP <788>-48 USP <788>-49 USP <788>-50 USP <788>-51 USP <788>-52 USP <788>-53 USP <788>-54 USP <788>-55 USP <788>-56 USP <788>-57 USP <788>-58 USP <788>-59 USP <788>-60 USP <788>-61 USP <788>-62 USP <788>-63 USP <788>-64 USP <788>-65 USP <788>-66 USP <788>-67 USP <788>-68 USP <788>-69 USP <788>-70 USP <788>-71 USP <788>-72 USP <788>-73 USP <788>-74 USP <788>-75 USP <788>-76 USP <788>-77 USP <788>-78 USP <788>-79 USP <788>-80 USP <788>-81 USP <788>-82 USP <788>-83 USP <788>-84 USP <788>-85 USP <788>-86 USP <788>-87 USP <788>-88 USP <788>-89 USP <788>-90 USP <788>-91 USP <788>-92 USP <788>-93 USP <788>-94 USP <788>-95 USP <788>-96 USP <788>-97 USP <788>-98 USP <788>-99 USP <788>-100 USP <788>-101 USP <788>-102 USP <788>-103 USP <788>-104 USP <788>-105 USP <788>-106 USP <788>-107 USP <788>-108 USP <788>-109 USP <788>-110 USP <788>-111 USP <788>-112 USP <788>-113 USP <788>-114 USP <788>-115 USP <788>-116 USP <788>-117 USP <788>-118 USP <788>-119 USP <788>-120 USP <788>-121 USP <788>-122 USP <788>-123 USP <788>-124 USP <788>-125 USP <788>-126 USP <788>-127 USP <788>-128 USP <788>-129 USP <788>-130 USP <788>-131 USP <788>-132 USP <788>-133 USP <788>-134 USP <788>-135 USP <788>-136 USP <788>-137 USP <788>-138 USP 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# C. Biological

- Updates
- Risk Assessment
  - ISO 10993-1
  - USP<1031>

C. BIOLOGICAL TESTS					
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connector Valves Retainers
Bacterial Endotoxin	Quantify bacterial endotoxins in/on a test article	<a href="#">USP &lt;85&gt;</a>	Final Article	<a href="#">USP &lt;85&gt;</a>	<a href="#">USP &lt;85&gt;</a>
		<a href="#">EP 2.6.14</a>			
		<a href="#">USP &lt;161&gt;</a>		<a href="#">USP &lt;161&gt;</a>	<a href="#">USP &lt;161&gt;</a>
		<a href="#">AAMI ST72</a>		<a href="#">AAMI ST72</a>	<a href="#">AAMI ST72</a>
Bioburden	Effluent bioburden quantification of colony forming units per effluent volume (CFU/ml); identification and quantification based on standard methodology.	Manufacturer Defined Method based on USP methodology	Raw (adsorbent) material/Final Article	Manufacturer Defined Method based on USP methodology	Manufacturer Defined Method based on USP methodology
Biocompatibility Risk Assessment	Evaluates the interaction of SUT with blood or the biological reactivity of animals to polymeric material.	<a href="#">ISO 10993-1</a>	Raw Material/ Final Article	<a href="#">ISO 10993-1</a>	<a href="#">ISO 10993-1</a>
		<a href="#">USP &lt;1031&gt;</a>		<a href="#">USP &lt;1031&gt;</a>	<a href="#">USP &lt;1031&gt;</a>
Biological Reactivity In Vitro	Evaluates the response of mammalian cell cultures to extracts of polymeric materials.	<a href="#">ISO 10993-5</a>	Raw Material/ Final Article	<a href="#">ISO 10993-5</a>	<a href="#">ISO 10993-5</a>
		<a href="#">USP &lt;87&gt;</a>		<a href="#">USP &lt;87&gt;</a>	<a href="#">USP &lt;87&gt;</a>
Biological Reactivity In Vivo	Evaluates the interaction of medical devices with blood or the biological reactivity of animals to polymeric material:	Subsections	Raw Material/ Final Article		
	Intracutaneous	<a href="#">USP &lt;88&gt;</a>		<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>
	Acute Systemic Toxicity	<a href="#">ISO 10993-10</a>		<a href="#">ISO 10993-10</a>	<a href="#">ISO 10993-10</a>
		<a href="#">USP &lt;88&gt;</a>		<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>
	Muscle Implantation	<a href="#">ISO 10993-11</a>		<a href="#">ISO 10993-11</a>	<a href="#">ISO 10993-11</a>
<a href="#">USP &lt;88&gt;</a>		<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>		
Hemolysis	Test that measures the breakdown of red blood cells by chemical or physical means.	<a href="#">ISO 10993-4</a>	Final Article/Film		
		<a href="#">ASTM F756</a>			

\* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section



# C. Biological


C. BIOLOGICAL TESTS				COMPONENT CATEGORY APPLICABLE TO THIS TEST						
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Bacterial Endotoxin	Quantify bacterial endotoxins in/on a test article	<a href="#">USP &lt;85&gt;</a>	Final Article	<a href="#">USP &lt;85&gt;</a>	<a href="#">USP &lt;85&gt;</a>	<a href="#">USP &lt;85&gt;</a>	<a href="#">USP &lt;85&gt;</a>	<a href="#">USP &lt;85&gt;</a>	<a href="#">USP &lt;85&gt;</a>	<a href="#">USP &lt;85&gt;</a>
		<a href="#">EP 2.6.14</a>							<a href="#">EP 2.6.14</a>	
		<a href="#">USP &lt;161&gt;</a>		<a href="#">USP &lt;161&gt;</a>	<a href="#">USP &lt;161&gt;</a>	<a href="#">USP &lt;161&gt;</a>	<a href="#">USP &lt;161&gt;</a>	<a href="#">USP &lt;161&gt;</a>	<a href="#">USP &lt;161&gt;</a>	<a href="#">USP &lt;161&gt;</a>
		<a href="#">AAMI ST72</a>		<a href="#">AAMI ST72</a>	<a href="#">AAMI ST72</a>	<a href="#">AAMI ST72</a>	<a href="#">AAMI ST72</a>	<a href="#">AAMI ST72</a>	<a href="#">AAMI ST72</a>	<a href="#">AAMI ST72</a>
Bioburden	Effluent bioburden quantification of colony forming units per effluent volume (CFU/ml); identification and quantification based on standard methodology.	Manufacturer Defined Method based on USP methodology	Raw (adsorbent) material/Final Article	Manufacturer Defined Method based on USP methodology	Manufacturer Defined Method based on USP methodology					Manufacturer Defined Method based on USP methodology
Biocompatibility Risk Assessment	Evaluates the interaction of SUT with blood or the biological reactivity of animals to polymeric material.	<a href="#">ISO 10993-1</a>	Raw Material/ Final Article	<a href="#">ISO 10993-1</a>	<a href="#">ISO 10993-1</a>	<a href="#">ISO 10993-1</a>	<a href="#">ISO 10993-1</a>	<a href="#">ISO 10993-1</a>	<a href="#">ISO 10993-1</a>	
		<a href="#">USP &lt;1031&gt;</a>		<a href="#">USP &lt;1031&gt;</a>	<a href="#">USP &lt;1031&gt;</a>	<a href="#">USP &lt;1031&gt;</a>	<a href="#">USP &lt;1031&gt;</a>	<a href="#">USP &lt;1031&gt;</a>	<a href="#">USP &lt;1031&gt;</a>	
Biological Reactivity In Vitro	Evaluates the response of mammalian cell cultures to extracts of polymeric materials.	<a href="#">ISO 10993-5</a>	Raw Material/ Final Article	<a href="#">ISO 10993-5</a>	<a href="#">ISO 10993-5</a>	<a href="#">ISO 10993-5</a>	<a href="#">ISO 10993-5</a>	<a href="#">ISO 10993-5</a>	<a href="#">ISO 10993-5</a>	
		<a href="#">USP &lt;87&gt;</a>		<a href="#">USP &lt;87&gt;</a>	<a href="#">USP &lt;87&gt;</a>	<a href="#">USP &lt;87&gt;</a>	<a href="#">USP &lt;87&gt;</a>	<a href="#">USP &lt;87&gt;</a>	<a href="#">USP &lt;87&gt;</a>	
Biological Reactivity In Vivo	Evaluates the interaction of medical devices with blood or the biological reactivity of animals to polymeric material:	Subsections	Raw Material/ Final Article							
	Intracutaneous	<a href="#">USP &lt;88&gt;</a>		<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	
		<a href="#">ISO 10993-10</a>		<a href="#">ISO 10993-10</a>	<a href="#">ISO 10993-10</a>	<a href="#">ISO 10993-10</a>	<a href="#">ISO 10993-10</a>	<a href="#">ISO 10993-10</a>	<a href="#">ISO 10993-10</a>	
	Acute Systemic Toxicity	<a href="#">USP &lt;88&gt;</a>		<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	
		<a href="#">ISO 10993-11</a>	<a href="#">ISO 10993-11</a>	<a href="#">ISO 10993-11</a>	<a href="#">ISO 10993-11</a>	<a href="#">ISO 10993-11</a>	<a href="#">ISO 10993-11</a>	<a href="#">ISO 10993-11</a>		
	Muscle Implantation	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	<a href="#">USP &lt;88&gt;</a>	
		<a href="#">ISO 10993-6</a>	<a href="#">ISO 10993-6</a>	<a href="#">ISO 10993-6</a>	<a href="#">ISO 10993-6</a>	<a href="#">ISO 10993-6</a>	<a href="#">ISO 10993-6</a>	<a href="#">ISO 10993-6</a>	<a href="#">ISO 10993-6</a>	
Hemolysis	Test that measures the breakdown of red blood cells by chemical or physical means.	<a href="#">ISO 10993-4</a>	Final Article/Film			<a href="#">ISO 10993-4</a>	<a href="#">ISO 10993-4</a>	<a href="#">ISO 10993-4</a>		
		<a href="#">ASTM F756</a>		<a href="#">ASTM F756</a>						

# D. Chemical Tests

- Updates
- Risk Assessment
- Chemical Process Compatibility

D. CHEMICAL TESTS				1	2
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	Chromatography	Connectors Valves Retainers
Chemical Process Compatibility	Qualification of wetted parts to show compatibility (resistance) with chemical reagents used as process liquids.	<a href="#">Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.</a>	Raw Material and/or Final Article		<a href="#">Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.</a>
Chemical Risk Assessment Process Compatibility	Materials should be robust and compatible with product and process fluids and should not be excessively prone to damage, which compromise structural integrity either by the shedding of any materials as solid particles which impact product quality and/or process performance.  Process Compatibility (a) The physicochemical properties, mechanical strength, optical properties, and anticipated operating temperature of the Materials of construction shall be capable of withstanding the processing conditions such as temperature, pressure, and chemical corrosiveness, thus ensuring the purity and integrity of the product. (b) Materials shall be compatible with the stated bio processing conditions, cleaning/sterilizing solutions, and SIP conditions, etc.	Manufacturer Defined Method	Raw Material and/or Final Article	Manufacturer Defined Method	Manufacturer Defined Method
		<a href="#">ASTM D543-14</a>		<a href="#">ASTM D543-14</a>	<a href="#">ASTM D543-14</a>
		ASME BPE SD 2.4.1.2			ASME BPE SD 2.4.1.2
Conductivity Test	Qualification of flush effluent for hydrophilic filters.	<a href="#">USP &lt;645&gt;</a>	Final Article		
Elastomeric Closures for Injections	A battery of tests designed to determine pertinent physicochemical extraction characteristics of elastomeric closures. (Does not apply for silicones)	<a href="#">USP &lt;381&gt;</a>	Final Article		<a href="#">USP &lt;381&gt;</a>
EP/Physicochemical	A battery of tests specific to Silicone	<a href="#">EP 3.1.9</a>	Raw Material or Final Article - Post Sterilization		<a href="#">EP 3.1.9</a>
	A battery of tests specific to Thermoplastic Elastomers	<a href="#">EP 3.2.9</a>		<a href="#">EP 3.2.9</a>	
Extractables	Quantitative and qualitative characterizations of extractables in model solvents. Semivolatiles, nonvolatile impurities, and identification of unknowns. Included should be regulatory compounds of interest (e.g., Bisphenol A (BPA), Per- and Polyfluoroalkyl substances (PFAS), nitrosamines (or N-Nitrosamines)	<a href="#">USP &lt;665&gt;</a>	Final Article	<a href="#">USP &lt;665&gt;</a>	<a href="#">USP &lt;665&gt;</a>
		<a href="#">BPOG Extractables Protocol</a>		<a href="#">BPOG Extractables Protocol</a>	<a href="#">BPOG Extractables Protocol</a>
Oxidizable Substances	Qualification of flush effluent for hydrophobic filters.	<a href="#">USP &lt;1231&gt;</a>	Final Article		
pH Shift Test	Qualification of flush effluent for hydrophilic filters.	<a href="#">USP &lt;791&gt;</a>	Final Article		
Total Organic Carbon (TOC)	Qualification of flush effluent for hydrophilic filters.	<a href="#">USP &lt;643&gt;</a>	Final Article		

# D. Chemical Tests

D. CHEMICAL TESTS				COMPONENT CATEGORY APPLICABLE TO THIS TEST						
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Chemical Process Compatibility	Qualification of wetted parts to show compatibility (resistance) with chemical reagents used as process liquids.	<a href="#">Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.</a>	Raw Material and/or Final Article		<a href="#">Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.</a>	<a href="#">Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.</a>	<a href="#">Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.</a>	<a href="#">Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.</a>	<a href="#">Manufacturer defined method typically aligned with ASTM D543-14 and/or risk assessment.</a>	*
Chemical Risk Assessment Process Compatibility	Materials should be robust and compatible with product and process fluids and should not be excessively prone to damage, which compromise structural integrity either by the shedding of any materials as solid particles which impact product quality and/or process performance.  Process Compatibility (a) The physicochemical properties, mechanical strength, optical properties, and anticipated operating temperature of the Materials of construction shall be capable of withstanding the processing conditions such as temperature, pressure, and chemical corrosiveness, thus ensuring the purity and integrity of the product. (b) Materials shall be compatible with the stated bio processing conditions, cleaning/sterilizing solutions, and SIP conditions, etc.	Manufacturer Defined Method	Raw Material and/or Final Article	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	
		<a href="#">ASTM D543-14</a>		<a href="#">ASTM D543-14</a>	<a href="#">ASTM D543-14</a>	<a href="#">ASTM D543-14</a>	<a href="#">ASTM D543-14</a>	<a href="#">ASTM D543-14</a>		
		ASME BPE SD 2.4.1.2		ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2	ASME BPE SD 2.4.1.2		
Conductivity Test	Qualification of flush effluent for hydrophilic filters.	<a href="#">USP &lt;645&gt;</a>	Final Article						<a href="#">USP &lt;645&gt;</a>	*
Elastomeric Closures for Injections	A battery of tests designed to determine pertinent physicochemical extraction characteristics of elastomeric closures. (Does not apply for silicones)	<a href="#">USP &lt;381&gt;</a>	Final Article		<a href="#">USP &lt;381&gt;</a>			<a href="#">USP &lt;381&gt;</a>		*
EP/Physicochemical	A battery of tests specific to Silicone	<a href="#">EP 3.1.9</a>	Raw Material or Final Article - Post Sterilization		<a href="#">EP 3.1.9</a>			<a href="#">EP 3.1.9</a>		*
	A battery of tests specific to Thermoplastic Elastomers	<a href="#">EP 3.2.9</a>		<a href="#">EP 3.2.9</a>	<a href="#">EP 3.2.9</a>					
Extractables	Quantitative and qualitative characterizations of extractables in model solvents. Semivolatiles, nonvolatile impurities, and identification of unknowns. Included should be regulatory compounds of interest (e.g., Bisphenol A (BPA, Per- and Polyfluoroalkyl substances (PFAS), nitrosamines (or N-Nitrosamines)	<a href="#">USP &lt;665&gt;</a>	Final Article	<a href="#">USP &lt;665&gt;</a>	<a href="#">USP &lt;665&gt;</a>	<a href="#">USP &lt;665&gt;</a>	<a href="#">USP &lt;665&gt;</a>	<a href="#">USP &lt;665&gt;</a>	<a href="#">USP &lt;665&gt;</a>	*
		<a href="#">BPOG Extractables Protocol</a>		<a href="#">BPOG Extractables Protocol</a>	<a href="#">BPOG Extractables Protocol</a>	<a href="#">BPOG Extractables Protocol</a>	<a href="#">BPOG Extractables Protocol</a>	<a href="#">BPOG Extractables Protocol</a>		
Oxidizable Substances	Qualification of flush effluent for hydrophobic filters.	<a href="#">USP &lt;1231&gt;</a>	Final Article						<a href="#">USP &lt;1231&gt;</a>	*
pH Shift Test	Qualification of flush effluent for hydrophilic filters.	<a href="#">USP &lt;791&gt;</a>	Final Article						<a href="#">USP &lt;791&gt;</a>	*
Total Organic Carbon (TOC)	 Bio-Process Systems Alliance Qualification of flush effluent for hydrophilic filters. Advancing Single-Use Worldwide	<a href="#">USP &lt;643&gt;</a>	Final Article						International <a href="#">USP &lt;643&gt;</a> Use Summit	*

\* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations

# E. Regulatory

- Updates
- Additions
  - EMC
  - PFAS
- Food Contact Deletion

E. REGULATORY				
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography
Electromagnetic Compatibly (EMC)	EMC requirements for immunity and emissions for sensors with active electronics	<a href="#">EN/IEC 61326-1</a>	Final Article	
PFAS and BPA Combined Chemical Statement	Combined Chemical statements inclusion of components which use of restricted chemicals. EG bisphenol A and PFAS.	Manufacturer Define Risk Assessment	Final Article	Manufacturer Define Risk Assessment
REACH Statement	European Community Regulation on chemicals and their safe use.	<a href="#">EC/1907/2006</a>	Raw Material	<a href="#">EC/1907/2006</a>
RoHS 3 Statement	Restriction of Hazardous Substances in Electric and Electronic Equipment.	<a href="#">2002/95/EC</a>	Raw Material	<a href="#">2002/95/EC</a>
TSE BSE/Animal Origin Free Statements	Statement of inclusion of components and processes which contain animal-derived materials, minimizing the risk of transmitting spongiform encephalopathy agents via medicinal products.	<a href="#">EMA 410/01</a>	Raw Material / Final Article	<a href="#">EMA 410/01</a>
		<a href="#">EC 1774</a>		<a href="#">EC 1774</a>
* Individual components within the Single-Use Assembly are subject to test recommendations within specific category				

# E. Regulatory

E. REGULATORY				COMPONENT CATEGORY APPLICABLE TO THIS TEST						
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies
Electromagnetic Compatibly (EMC)	EMC requirements for immunity and emissions for sensors with active electronics	<a href="#">EN/IEC 61326-1</a>	Final Article				<a href="#">EN/IEC 61326-1</a>			*
PFAS and BPA Combined Chemical Statement	Combined Chemical statements inclusion of components which use of restricted chemicals. EG bisphenol A and PFAS.	Manufacturer Define Risk Assessment	Final Article	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	Manufacturer Define Risk Assessment	*
RECh Statement	European Community Regulation on chemicals and their safe use.	<a href="#">EC/1907/2006</a>	Raw Material	<a href="#">EC/1907/2006</a>	<a href="#">EC/1907/2006</a>	<a href="#">EC/1907/2006</a>	<a href="#">EC/1907/2006</a>	<a href="#">EC/1907/2006</a>	<a href="#">EC/1907/2006</a>	<a href="#">EC/1907/2006</a>
RoHS 3 Statement	Restriction of Hazardous Substances in Electric and Electronic Equipment.	<a href="#">2002/95/EC</a>	Raw Material	<a href="#">2002/95/EC</a>	<a href="#">2002/95/EC</a>	<a href="#">2002/95/EC</a>	<a href="#">2002/95/EC</a>	<a href="#">2002/95/EC</a>	<a href="#">2002/95/EC</a>	<a href="#">2002/95/EC</a>
TSE BSE/Animal Origin Free Statements	Statement of inclusion of components and processes which contain animal-derived materials, minimizing the risk of transmitting spongiform encephalopathy agents via medicinal products.	<a href="#">EMA 410/01</a>	Raw Material / Final Article	<a href="#">EMA 410/01</a>	<a href="#">EMA 410/01</a>	<a href="#">EMA 410/01</a>	<a href="#">EMA 410/01</a>	<a href="#">EMA410/01</a>	<a href="#">EMA410/01</a>	<a href="#">EMA410/01</a>
		<a href="#">EC 1774</a>		<a href="#">EC 1774</a>	<a href="#">EC 1774</a>	<a href="#">EC 1774</a>	<a href="#">EC 1774</a>	<a href="#">EC 1774</a>	<a href="#">EC 1774</a>	<a href="#">EC 1774</a>
* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations										

# F. Sterilization/Sanitization

- Updates

F. STERILIZATION / SANITATION				COMPONENT CATEGORY APPLICATION			
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors
Irradiation Validation	Qualify the sterilization of healthcare products by ionizing irradiation: Gamma irradiation, X-ray or E-Beam.	<a href="#">ANSI AAMI ISO 11137</a>	Final Article		<a href="#">ANSI/AAMI/ISO 11137</a>	<a href="#">ANSI/AAMI/ISO 11137</a>	<a href="#">ANSI AAMI ISO 11137</a>
		<a href="#">AAMI TIR 35</a>			<a href="#">AAMI TIR 35</a>	<a href="#">AAMI TIR 35</a>	
		<a href="#">ISO TS 13004</a>			<a href="#">ISO/TS 13004</a>	<a href="#">ISO TS 13004</a>	
		<a href="#">AAMI Technical Information Report 33</a>			<a href="#">AAMI Technical Information Report 33</a>		
Moist Heat Sterilization	Sterilization of healthcare products.	<a href="#">ANSI AAMI ISO 17665</a>	Final Article		<a href="#">ANSI/AAMI/ISO 17665</a>	<a href="#">ANSI/AAMI/ISO 17665</a>	<a href="#">ANSI/AAMI/ISO 17665</a>
Sanitization Test (Bacterial Challenge Test)	Evaluation of anti-microbial effectiveness and endotoxin removal with recommended cleaning protocols; i.e. clean in place (CIP).	Manufacturer Defined Method based on USP methodology	Final Article	Manufacturer Defined Method based on USP methodology			
Sterilization Process Compatibility	Confirmation of manufacturer's specified performance claims after sterilization process. Perform or repeat Functional and Physical Testing after worst case sterilization process.	<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	Final Article		<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>
	Guidance on sterilization process material compatibility	Manufacturer Defined Method			Manufacturer Defined Method	Manufacturer Defined Method	
		<a href="#">AAMI TIR 17</a>			<a href="#">AAMI TIR 17</a>	<a href="#">AAMI TIR 17</a>	<a href="#">AAMI TIR 17</a>
* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations							

# F. Sterilization/Sanitization

F. STERILIZATION / SANITATION				COMPONENT CATEGORY APPLICABLE TO THIS TEST							
TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	1 Chromatography	2 Connectors Valves Retainers	3 Containers Film	4 Sensors	5 Tubing	6 Filters	7 Single-Use Assemblies	
Irradiation Validation	Qualify the sterilization of healthcare products by ionizing irradiation: Gamma irradiation, X-ray or E-Beam.	<a href="#">ANSI AAMI ISO 11137</a>	Final Article			<a href="#">ANSI/AAMI/ISO 11137</a>	<a href="#">ANSI AAMI ISO 11137</a>	<a href="#">ANSI/AAMI/ISO 11137</a>	<a href="#">ANSI/AAMI/ISO 11137</a>	<a href="#">ANSI/AAMI/ISO 11137</a>	<a href="#">ANSI/AAMI/ISO 11137</a>
		<a href="#">AAMI TIR 35</a>				<a href="#">AAMI TIR 35</a>	<a href="#">AAMI TIR 35</a>	<a href="#">AAMI TIR 35</a>	<a href="#">AAMI TIR 35</a>	<a href="#">AAMI TIR 35</a>	
		<a href="#">ISO TS 13004</a>				<a href="#">ISO/TS 13004</a>	<a href="#">ISO TS 13004</a>	<a href="#">ISO/TS 13004</a>	<a href="#">ISO/TS 13004</a>	<a href="#">ISO/TS 13004</a>	
		<a href="#">AAMI Technical Information Report 33</a>				<a href="#">AAMI Technical Information Report 33</a>					
Moist Heat Sterilization	Sterilization of healthcare products.	<a href="#">ANSI AAMI ISO 17665</a>	Final Article		<a href="#">ANSI/AAMI/ISO 17665</a>	<a href="#">ANSI/AAMI/ISO 17665</a>	<a href="#">ANSI/AAMI/ISO 17665</a>	<a href="#">ANSI/AAMI/ISO 17665</a>	<a href="#">ANSI/AAMI/ISO 17665</a>	<a href="#">ANSI/AAMI/ISO 17665</a>	<a href="#">ANSI/AAMI/ISO 17665</a>
Sanitization Test (Bacterial Challenge Test)	Evaluation of anti-microbial effectiveness and endotoxin removal with recommended cleaning protocols; i.e. clean in place (CIP).	Manufacturer Defined Method based on USP methodology	Final Article	Manufacturer Defined Method based on USP methodology					Manufacturer Defined Method based on USP methodology	*	
Sterilization Process Compatibility	Confirmation of manufacturer's specified performance claims after sterilization process. Perform or repeat Functional and Physical Testing after worst case sterilization process.	<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	Final Article		<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	<a href="#">BPSA X-Ray Sterilization of Single-Use Bioprocess Equipment</a>	*
		Manufacturer Defined Method			Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method	Manufacturer Defined Method			
	Guidance on sterilization process material compatibility	<a href="#">AAMI TIR 17</a>			<a href="#">AAMI TIR 17</a>	<a href="#">AAMI TIR 17</a>	<a href="#">AAMI TIR 17</a>	<a href="#">AAMI TIR 17</a>			
* Individual components within the Single-Use Assembly are subject to test recommendations within specific categories, see section 1-6 for subassembly recommendations											

# Component Categories

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1. Chromatography
2. Connectors, Valves and Retainers
3. Containers and Film
4. Sensors
5. Tubing
6. Filters
7. **Single-Use Assemblies**



# 7. Single-Use Assemblies

- Representative of the full assembly as the test article.
- for the components within which are spelled out in the tables 1-6.
- Suitable for a Single-Use Assembly as the “test article”,
- It does not preclude the need for component-specific qualification testing and verification on the full assemblies; therefore, the reader should consult tabs 1 to 6 (i.e., filters, containers, sensors, as applicable) as well to follow the test expectations listed for those qualify components within the assemblies.
- The level of lot release testing required is to be determined by the end user based on the product and process requirements where the single use assembly is utilized.

# 7. Single-Use Assemblies

**Table 7: SINGLE USE ASSEMBLIES**

The tests listed in Table 7 are representative of the full assembly as the test article. It does not preclude the recommendation or "requirement" to apply tests listed for the components within which are spelled out in the tables 1-6. The tests listed in this tab under columns F to I are suitable for a Single-Use Assembly as the "test article", unless further specified. It does not preclude the need for component-specific qualification testing and verification on the full assemblies; therefore, the reader should consult tabs 1 to 6 (i.e., filters, containers, sensors, as applicable) as well to follow the test expectations listed for those qualify components within the assemblies. The level of lot release testing required is to be determined by the end user based on the product and process requirements where the single use assembly is utilized.

TEST TYPE	GENERAL DESCRIPTION	TEST REFERENCES	TEST ARTICLE	TEST APPLICATION				
				Material Qualification	Product (Article) Qualification	Batch/Lot	Material Change	Article Change
<b>A. PHYSICAL</b>								
Chamber Integrity/ Seal Integrity-Peel (Bags only)	Used to measure manufactured product and seal barrier performance of a variety of package types and forms, as well as seal and/or closure types.	Manufacturer Defined Method	Packaging		●	○	●	○
Integrity (Leak) Test	Standard Test Method for Physical Integrity Testing of Single-Use Systems. Confirmation of integrity for components and assemblies at a given temperature. This includes pressure testing under operating conditions and at elevated pressures.	<a href="#">ASTM E3244-20</a> <a href="#">ASTM E 3251-20</a> <a href="#">ASTM E3336-22</a>	Final Article		●	○	○	○
	Junction Testing (barbed fittings)  Single-use assembly junction connections should be qualified by the supplier to ensure they meet performance criteria as stated in their specification.  The supplier shall have an established testing program to substantiate performance of the mechanical connection. The testing should reference at least one of the following: (a) Pressure Testing (b) Leak Testing (c) Tracer Gas Testing	Manufacturer Defined Method			●			
Tensile Strength	Determines resistance of loading on a jointed union/connection/fitting.	Manufacturer Defined Method			●	○	○	○
<b>B. FUNCTIONAL</b>								
Accelerated or Real Time Aging (Shelf Life)	Accelerated and/or real time studies to determine the effects, if any, due to the passage of time and environmental effects on the properties of product, and on the sterile integrity of packages and the physical properties of their component packaging materials.	Manufacturer Defined Method  <a href="#">ASTM F1980-21</a>	Final Article		●		○	○
General Functionality Fit for Intended Use	The manufacturer/user shall establish that the single-use components, SUS assemblies, and SUS systems are designed for integrity and functionality, appropriately. These considerations should be maintained during installation and ensured throughout the use of the item based on scientific product and process understanding for both SUS manufacturing and use equipment. Qualification of design, manufacturing, testing and distribution should be	Manufacturer Defined Method  <a href="#">ASTM 3051</a>	Final Article		●	●	●	●
	Min./Max. Temperature	ASME BPE SD 2.4.1.2						
Package Testing/ Transportation Shipping Integrity	Qualify that product packaging will protect the product during shipping. Standard practice for performance testing of shipping containers and systems to provide a uniform basis of evaluating, in a laboratory, the ability of shipping units to withstand the distribution environment.	<a href="#">ASTM D4169-14</a>	Final Article		●		○	
		<a href="#">ASTM D4728-06</a>						
		<a href="#">DIN ISO 2872</a>						
		<a href="#">ISTA 2A</a>						
		<a href="#">ISTA 3A</a>						
<a href="#">ISTA 3B</a>								
<a href="#">ISTA 3E</a>								
		<a href="#">BPSA Recommendations for</a>						

# 2023 Completion

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- 7/10-7/12 BPSA Summit-7/11 presentation
- 7/14-SAB review complete
- 7/14-QTM meeting if needed at summit.
- 7/14 SAB comments to QTM if any.
- 7/20-QTM meeting to address SAB comments if needed.
- 7/21-Final to BPSA Board
- 7/28-BPSA Board approval

# Future QTM Updates

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- Items did not make the cut
- Standard Updates
- Industry guidance

# Topics

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- Endotoxin/Pyrogen Free
- Accelerated Aging-Humidity
- Animal Testing
- Physical Joining
- Others?





Bio-Process Systems Alliance  
*Advancing Single-Use Worldwide*



BPSA International  
Single-Use Summit



# **COLLABORATION, TECHNOLOGY & INNOVATION: SHAPING THE FUTURE OF SINGLE-USE**

**JULY 10-JULY 12, FOUR SEASON HOTEL, WASHINGTON, DC**