

Accreditation



The Deutsche Akkreditierungsstelle attests with this **Partial Accreditation Certificate** that the

PAConsult GmbH
Birkenau 3, 22087 Hamburg

meets the requirements according to DIN EN ISO/IEC 17025:2018 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the testing laboratory, including those in relevant sectoral schemes, provided they are explicitly confirmed in the annex to this certificate.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and confirm generally with the principles of DIN EN ISO 9001.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This partial accreditation certificate only applies in connection with the notice of 10.10.2023 with accreditation number D-PL-11130-01.

It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 22 pages.

Registration number of the partial accreditation certificate: **D-PL-11130-01-01**

It is a part of the accreditation certificate: D-PL-11130-01-00.

Berlin, 10.10.2023

Ralf Egner
Head of Department

Translation issued:
17.12.2024


Dipl.-Biol. Andrea Gabler
Head of Technical Unit

The certificate together with the annex reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf

Deutsche Akkreditierungsstelle GmbH

Office Berlin
Spittelmarkt 10
10117 Berlin

Office Frankfurt am Main
Europa-Allee 52
60327 Frankfurt am Main

Office Braunschweig
Bundesallee 100
38116 Braunschweig

The Deutsche Akkreditierungsstelle GmbH (DAkKS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkKS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

DAkKS is a signatory to the multilateral agreements for mutual recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Co-operation (ILAC).

The up-to-date state of membership can be retrieved from the following websites:

EA: www.european-accreditation.org

ILAC: www.ilac.org

IAF: www.iaf.nu

Deutsche Akkreditierungsstelle

Annex to the Partial Accreditation Certificate D-PL-11130-01-01 according to DIN EN ISO/IEC 17025:2018¹

Valid from: 10.10.2023

Date of issue: 13.01.2025

This annex is a part of the accreditation certificate D-PL-11130-01-00.

Holder of partial accreditation certificate:

PAConsult GmbH
Birkenau 3, 22087 Hamburg

with the locations

PAConsult GmbH
Kolpingstraße 14, 88416 Ochsenhausen

PAConsult GmbH
Humboldtstraße 33, 22083 Hamburg

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the general with the principles of DIN EN ISO 9001.

physical and visual testing of medical devices and sterile barrier and packaging systems

outside of recognition in accordance with § 18 of the German Medical Devices Implementation Act.

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <https://www.dakks.de>.

Abbreviations used: see last page

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This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Annex to the Partial Accreditation Certificate D-PL-11130-01-01

for the location Ochsenhausen

Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing	Sterile barrier systems and packaging systems	Test for proof of compliance	DIN EN ISO 11607-1 ASTM F2097
		- Transport simulation	ASTM D4169 ASTM D7386 ISTA Series 1-3
		- Conditioning of Packaging Systems	ASTM D4332 ASTM F2825
		- Climatic pre-conditioning	ASTM D4332 ASTM F2825 DIN EN ISO 2233 ISTA Series 1-3
		- Compressive resistance	ASTM D642
		- Compression test	ASTM D4169
		- Stacking test	ASTM D7386 DIN 55440-1 DIN EN ISO 2234 DIN EN ISO 4180 DIN EN ISO 12048 ISTA Series 1-3
		- Shaking test	ASTM D4169
		- Oscillation test	ASTM D4728
		- Vibration test	ASTM D7386 DIN EN 60068-2-64 ISTA Series 1-3
		- Low-frequency vibration test with fixed amplitude	ASTM D999 ASTM D4169 DIN EN ISO 2247 ISTA Series 1-3
		- Loose-Load-Vibration	ASTM D999

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Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing	Sterile barrier systems and packaging systems	Test for proof of compliance - Manual Handling - Impact (Concentrated Impact) - Speed - Atmospheric pressure test - Accelerated Aging - Peel-Test / Sealing force - Determination of the peel characteristics - Method for determining fine holes in plastic composite films - Strength of sealing seams / sealing force measurement - Determination of the peel characteristics (peel behavior and Sealing seam width)	DIN EN ISO 11607-1 ASTM F2097 ASTM D4169 ASTM D5276 ASTM D6055 ASTM D6179 ASTM D7386 DIN EN 22248 DIN EN 22876 DIN EN 28768 DIN EN ISO 4180 ISTA Series 1-3 ASTM D 6344 ASTM D4169 ASTM D880 DIN EN ISO2244 ASTM D6653/D6653M ASTM F1980 ASTM F88/F88M DIN EN 868-5 (Appendix C) DIN EN 868-5 (Appendix D) DIN EN 868-5 (Appendix E)

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Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing	Sterile barrier systems and packaging systems	<ul style="list-style-type: none"> - Seal strength / sealing force measurement and visual inspection of the adhesive layer - Tensile strength of plastic films - Tensile properties of plastics - Measurement of thickness - Dye-Test (porous/ nonporous) - Creep-Test / Burst-Test - Leakage-Test in vacuum chamber - Bubble-Test - Bubble-Emission Test in vacuum chamber - Air permeability Gurley Method 	<p>DIN EN 868-7 (Appendix D)</p> <p>ASTM D 882</p> <p>DIN EN ISO 527-1 DIN EN ISO 527-3</p> <p>ASTM D6988</p> <p>ASTM F1929-method A and B ASTM F 3039-method A</p> <p>ASTM F1140/ F1140M</p> <p>ASTM D4991</p> <p>ASTM F2096</p> <p>ASTM D3078</p> <p>ISO 5636-5</p>
Physical testing and visual inspection	Sterile barrier systems and packaging systems	<p>Test for proof of compliance</p> <ul style="list-style-type: none"> - Visual inspection seal seam - Visual inspection of labels, coatings after pre-treatment with adhesive tape 	<p>DIN EN ISO 11607-1</p> <p>ASTM F1886/ F1886M</p> <p>ASTM F2252/ F2252M</p>

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Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing and visual inspect	Syringes, cannulas and medical devices	Test for proof of compliance	DIN 13097-4 applicable: DIN EN ISO 7864
		<ul style="list-style-type: none"> - Packaging - Tube dimension - Grinding types - Ovality - Straightness - Grinding properties - Sharpness - Punch freedom - Penetration - Piercing and cutting - properties - Number of fragments 	
		Test for proof of compliance	DIN EN ISO 9626
		<ul style="list-style-type: none"> - Surface finish - Cleanliness - Limit values for acidity and alkalinity - Corrosion resistance 	

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Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing and visual inspection	Syringes, cannulas and medical devices	Test for proof of compliance <ul style="list-style-type: none"> - Size designation - Dimensions - Corrosion resistance - Labeling of individual-, collective-, storage- and transport-packaging - Absence of impurities - Cannula tube - Connection of cannula base and cannula tube - Patency of the lumen - Acidity or alkalinity 	DIN EN 7864
		Test for proof of compliance <ul style="list-style-type: none"> - Labeling of individual-, collective-, storage- and transport-packaging - Visual inspection for particles and foreign material - Scale division - Cylinder (dimensions and grip plates) - Piston/piston rod (piston rod design, position of the piston in the cylinder incl. piston movement, reference line) - Residual volume 	DIN EN ISO 7886-1

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Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing and visual inspect.	Syringes, cannulas and medical devices	Test for proof of compliance - Impermeability for air and liquids between piston and cylinder - Acidic or alkaline components Residual volume - Volume	DIN EN ISO 7886-1
	Catheters	Test for proof of compliance - Labeling on the product and/or the primary packaging/secondary packaging - Instructions for use - Surface - Corrosion resistance - Maximum tensile force - Tightness - Flow rate - Nominal size (outside diameter and usable nominal length)	DIN EN ISO 10555-1
	Infusion devices	Test for proof of compliance - Length marking - Labeling the lumens - Maximum tensile force	DIN EN ISO 10555-3

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Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing and visual inspection	Infusion devices for gravity infusions	Test for proof of compliance <ul style="list-style-type: none"> - Marking Single pack/multipack - Packaging - Tightness - Tensile strength - Piercing part - Aeration section (volume flow) - Tube - Drip chamber and drip tube - Flow regulator - Injection part - Protective caps 	DIN EN ISO 8536-4
	Plastic bags (conventional) for blood and blood components	Test for proof of compliance <ul style="list-style-type: none"> - Labeling plastic bags/outer packaging - Packaging - Requirements for the label - Air volume - Emptying under pressure - Pilot samples - Coloring 	DIN EN ISO 3826-1

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Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing and visual inspection	Ophthalmic implants	Test for proof of compliance - Testing the filling rate - Extraction and transfer tube or tubes - Blood collection cannula - Insertion nozzle - Hängers - Water vapor permeability - Tightness	DIN EN ISO 3826-1
	Ophthalmic implants - Intraocular lenses (IOL)	Storage stability - Accelerated ageing - Real time aging	DIN EN ISO 11979-6
		Strength of the sealed and glued seams	ASTM F1929
		Climate	DIN EN ISO 2233

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for the location Hamburg

Testing field	Test item Device (category)	Type of testing Test	Regulation Test method	
Physical testing	Sterile barrier and packaging systems	Test for proof of compliance	DIN EN ISO 11607-1 ASTM F2097	
		- Transportsimulation	ASTM D4169 ASTM D7386 ISTA Series 1-3	
		- Climatic Stressing of Packaging Systems	ASTM D4332 ASTM F2825	
		- Climatic conditioning	ASTM D4332 ASTM F2825 DIN EN ISO 2233 ISTA Series 1-3	
		- Compressive resistance	ASTM D642	
		- Compression test	ASTM D4169	
		- Stacking test	ASTM D7386 DIN 55440-1 DIN EN ISO 2234 DIN EN ISO 4180 DIN EN ISO 12048 ISTA Series 1-3	

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Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing	Sterile barrier systems and packaging systems	Test for proof of compliance	DIN EN ISO 11607-1 ASTM F2097
		- Shaking test	ASTM D4169
		- Oscillation test	ASTM D4728
		- Vibration test	ASTM D7386 DIN EN 60068-2-64 ISTA Series 1-3
		- Low-frequency vibration test with fixed amplitude	ASTM D999 ASTM D4169 DIN EN ISO 2247 ISTA Series 1-3
		- Loose-Load-Vibration	ASTM D4169 ASTM D5276 ASTM D6055 ASTM D6179 ASTM D7386 DIN EN 22248 DIN EN 22876 DIN EN 28768 DIN EN ISO 4180 ISTA Series 1-3
		- Impact (Concentrated Impact)	ASTM D6344
		- Speed	ASTM D4169 ASTM D880 DIN EN ISO 2244
		- Atmospheric pressure test	ASTM D6653/D6653M
		- Accelerated Aging	ASTM F1980
		- Visual inspection seal seam	ASTM F1886/ F 1886M

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Testing field	Test item Device (category)	Type of testing Test	Regulation Test method
Physical testing	Sterile barrier and packaging systems	Test for proof of compliance - Visual inspection of labels or coatings after pre-treatment with adhesive tape - Peel Test / Sealing Force Measurement - Determination of the peel characteristics - Strength of sealing seams / sealing force measurement - Determination of peel characteristics (peeling behavior and sealing seam width) - Sealing strength / sealing force measurement and visual inspection of the adhesive layer - Tensile strength on plastic films - Tensile properties of plastics - Dye-Test (porous/ nonporous) - Creep-Test / Burst-Test - Leakage-Test in vacuum camber - Bubble-Test - Air permeability - Gurley	DIN EN ISO 11607-1 ASTM F2097 ASTM F2252/ F2252M ASTM F88/F 88M DIN EN 868-5 (Appendix D) DIN EN 868-5 (Appendix E) DIN EN 868-7 (Appendix D) ASTM D882 DIN EN ISO 527-1 DIN EN ISO 527-3 ASTM F1929 method A and B ASTM F3039 method A ASTM F11140/ F1140M ASTM D4991 ASTM F2096 ISO 5636-5

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Regulations:

Location Ochsenhausen

DIN EN ISO 527-1 2019-12	Plastics - Determination of tensile properties - Part 1: General principles (ISO 527-1:2019)
DIN EN ISO 527-3 2019-02	Plastics - Determination of tensile properties - Part 3: Test conditions for films and sheets (ISO 527-3:2018)
DIN EN 868-5 2019-03	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
DIN EN 868-7 2017-05	Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods
DIN EN ISO 2233 2001-11	Packaging - Complete, filled transport packages and unit loads - Conditioning for testing (ISO 2233:2000)
DIN EN ISO 2234 2002-12	Packaging - Complete, filled transport packages and unit loads - Stacking tests using a static load (ISO 2234:2000)
DIN EN ISO 2244 2002-12	Packaging - Complete, filled transport packages and unit loads - Horizontal impact tests (ISO 2244:2000)
DIN EN ISO 2247 2002-12	Packaging - Complete, filled transport packages and unit loads - Vibration tests at fixed low frequency (ISO 2247:2000)
DIN EN ISO 3826-1 2020-01	Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO 3826-1:2019)
DIN EN ISO 4180 2020-03	Packaging - Complete, filled transport packages - General rules for the compilation of performance test schedules (ISO 4180:2019)
ISO 5636-5 2013-11	Paper and board - Determination of air permeance (medium range) - Part 5: Gurley method
DIN EN ISO 7864 2016-12	Sterile hypodermic needles for single use - Requirements and test methods (ISO 7864:2016)

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DIN EN ISO 7886-1 2020-11	terile hypodermic syringes for single use - Part 1: Syringes for manual use (ISO 7886-1:2017, Corrected version 2019-08)
DIN EN ISO 8536-4 2020-05	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)
DIN EN ISO 9626 2016-12	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods (ISO 9626:2016)
DIN EN ISO 10555-1 2018-04	Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO 10555-1:2013 + Amd 1:2017)
DIN EN ISO 10555-3 2013-11	Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters (ISO 10555-3:2013)
DIN EN ISO 11607-1 2020-05	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
DIN EN 11979-4 2013-01	Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information (ISO 11979-4:2008 + Amd.1:2012)
DIN EN 11979-6 2015-02	Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability testing (ISO 11979-6:2014)
DIN EN ISO 12048 2001-04	Packaging - Complete, filled transport packages - Compression and stacking tests using a compression tester (ISO 12048:1994)
DIN 13097 2019-06	Hypodermic needles - Part 4: Point geometry, requirements and testing
DIN EN ISO 16671 2018-03	Ophthalmic implants - Irrigating solutions for ophthalmic surgery (ISO 16671:2015 + Amd 1:2017)
DIN EN 22248 1993-02	Packaging; complete, filled transport packages; vertical impact test by dropping (ISO 2248:1985)
DIN EN 22876 1993-02	Packaging; complete, filled transport packages; rolling test (ISO 2876:1985)

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DIN EN 28768 1993-02	Packaging; complete, filled transport packages; toppling test (ISO 8768:1986)
DIN 55440-1 2019-10	Packaging test - Determination of compression resistance - Part 1: Test with constant conveyance speed
DIN EN 60068-2-64 2020-09	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008 + A1:2019)
ASTM D642 2020	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads
ASTM D880 1992 (reapproved 2015)	Standard Test Method for Impact Testing for Shipping Containers and Systems
ASTM D882 2018	Standard Test Method for Tensile Properties of Thin Plastic Sheeting
ASTM D999 2008 (reapproved 2015)	Standard Test Methods for Vibrations Testing of Shipping Containers
ASTM D3078 2002 (reapproved 2013)	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
ASTM D4169 2016	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4332 2014	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM D4728 2017	Standard Test Method for Random Vibration Testing of Shipping Containers
ASTM D4991 2007 (reapproved 2015)	Standard Test Method for Leakage Testing of Empty Rigid Containers by Vacuum Method
ASTM D5276 2019	Standard Test Method for Drop Test of Loaded Containers by Free Fall

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ASTM D6055 1996 (reapproved 2019)	Standard Test Methods for Mechanical Handling of Unitized Loads and Large Shipping Cases and Crates
ASTM D6179 2020	Standard Test Methods for Rough Handling of Unitized Loads and Large Shipping Cases and Crates
ASTM D6344 2004 (reapproved 2017)	Standard Test Methods for Concentrated Impacts to Transport Packages
ASTM D6653/D6653M 2013 (reapproved 2021)	Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method
ASTM D6988 2021	Standard Guide for Determination of Thickness of Plastic Film Test Specimens
ASTM D7386 2016	Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems
ASTM F88/F88M 2021	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F 1140/F 1140M 2013	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
ASTM F1886/F1886M 2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929 2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980 2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F2096 2011 (reapproved 2019)	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F2097 2020	Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products
ASTM F2252/F2252 M 2013	Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials using Tape

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ASTM F2825 2018	Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery
ASTM F3039 2015	Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration
ISTA Procedure 1A : 2014	Non-Simulation Integrity Tests: Integrity Testing for Packaged-Products weighing 150 lb (68 kg) or Less
ISTA Procedure 1B : 2014	Non-Simulation Integrity Tests: Integrity Testing Packaged-Products weighing Over 150 lb (68 kg)
ISTA Procedure 1C : 2014	Non-Simulation Integrity Tests: Extended Integrity Testing for Individual Packaged-Products weighing 150 lb (68 kg) or Less
ISTA Procedure 1D : 2014	Non-Simulation Integrity Tests: Extended Integrity Testing for Individual Packaged-Products weighing Over 150 lb (68 kg)
ISTA Procedure 1E : 2014	Non-Simulation Integrity Tests: Integrity Testing for Unitized Loads
ISTA Procedure 1G : 2014	Non-Simulation Integrity Tests: Packaged-Products weighing 150 lb (68 kg) or Less utilizing Random Vibration
ISTA Procedure 1H : 2014	Non-Simulation Integrity Tests: Integrity Testing for Packaged-Products weighing Over 150 lb (68 kg) utilizing Random Vibration
ISTA Procedure 2A : 2011	Partial Simulation Tests: Packaged-Products weighing 150 lb (68 kg) or Less
ISTA Procedure 2B : 2011	Partial Simulation Tests: Packaged-Products weighing over 150 lb (68 kg)
ISTA Procedure 2C : 2011	Partial Simulation Tests: Furniture Packages
ISTA Procedure 3A : 2018	General Simulation Tests: Parcel Delivery System Shipments 150 lb (70kg) or Less
ISTA Procedure 3B : 2017	General Simulation Tests: Less-Than-Truckload (LTL) Shipment
ISTA Procedure 3E : 2016	General Simulation Tests: Similar Packaged-Products in Unitized Loads for Truckload Shipment
ISTA Procedure 3F : 2017	General Simulation Tests: Distribution Center to Retail Outlet Shipment 100 lb (45 kg)

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ISTA Procedure 3H : 2011	General Simulation Tests: Mechanically Handled Bulk Transport Containers
ISTA Procedure 3K : 2011	General Simulation Tests: Fast Moving Consumer Goods for the European Retail Supply Chain

Regulations:

Location Hamburg

DIN EN ISO 527-1 2019-12	Plastics - Determination of tensile properties - Part 1: General principles (ISO 527-1:2019)
DIN EN ISO 527-3 2019-02	Plastics - Determination of tensile properties - Part 3: Test conditions for films and sheets (ISO 527-3:2018)
DIN EN 868-5 2019-03	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
DIN EN 868-7 2017-05	Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods
DIN EN ISO 2233 2001-11	Packaging - Complete, filled transport packages and unit loads - Conditioning for testing (ISO 2233:2000)
DIN EN ISO 2234 2002-12	Packaging - Complete, filled transport packages and unit loads - Stacking tests using a static load (ISO 2234:2000)
DIN EN ISO 2244 2002-12	Packaging - Complete, filled transport packages and unit loads - Horizontal impact tests (ISO 2244:2000)
DIN EN ISO 2247 2002-12	Packaging - Complete, filled transport packages and unit loads - Vibration tests at fixed low frequency (ISO 2247:2000)
DIN EN ISO 4180 2020-03	Packaging - Complete, filled transport packages - General rules for the compilation of performance test schedules (ISO 4180:2019)
ISO 5636-5 2013-11	Paper and board - Determination of air permeance (medium range) - Part 5: Gurley method

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DIN EN ISO 11607-1 2020-05	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
DIN EN ISO 12048 2001-04	Packaging - Complete, filled transport packages - Compression and stacking tests using a compression tester (ISO 12048:1994)
DIN EN 22248 1993-02	Packaging; complete, filled transport packages; vertical impact test by dropping (ISO 2248:1985)
DIN EN 22876 1993-02	Packaging; complete, filled transport packages; rolling test (ISO 2876:1985)
DIN EN 28768 1993-02	Packaging; complete, filled transport packages; toppling test (ISO 8768:1986)
DIN 55440-1 2019-10	Packaging test - Determination of compression resistance - Part 1: Test with constant conveyance speed
DIN EN 60068-2-64 2020-09	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008 + A1:2019)
ASTM D642 2015	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads
ASTM D880 1992 (reapproved 2015)	Standard Test Method for Impact Testing for Shipping Containers and Systems
ASTM D882 2018	Standard Test Method for Tensile Properties of Thin Plastic Sheet
ASTM D999 2008 (reapproved 2015)	Standard Test Methods for Vibrations Testing of Shipping Containers
ASTM D4169 2016	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4332 2014	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM D4728 2017	Standard Test Method for Random Vibration Testing of Shipping Containers

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ASTM D4991 2007 (reapproved 2015)	Standard Test Method for Leakage Testing of Empty Rigid Containers by Vacuum Method
ASTM D5276 2019	Standard Test Method for Drop Test of Loaded Containers by Free Fall
ASTM D6055 1996 (reapproved 2019)	Standard Test Methods for Mechanical Handling of Unitized Loads and Large Shipping Cases and Crates
ASTM D6179 2020	Standard Test Methods for Rough Handling of Unitized Loads and Large Shipping Cases and Crates
ASTM D6344 2004 (reapproved 2017)	Standard Test Methods for Concentrated Impacts to Transport Packages
ASTM D6653/D6653M 2013	Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method
ASTM D7386 2016	Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems
ASTM F88/F88M 2015	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F 1140/F 1140M 2013	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
ASTM F1886/F1886M 2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929 2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980 2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F2096 2011 (reapproved 2019)	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F2097 2016	Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

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ASTM F2252/F2252 M 2013	Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials using Tape
ASTM F2825 2018	Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery
ASTM F3039 2015	Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration
ISTA Procedure 1A : 2014	Non-Simulation Integrity Tests: Integrity Testing for Packaged-Products weighing 150 lb (68 kg) or Less
ISTA Procedure 1B : 2014	Non-Simulation Integrity Tests: Integrity Testing Packaged-Products weighing Over 150 lb (68 kg)
ISTA Procedure 1C : 2014	Non-Simulation Integrity Tests: Extended Integrity Testing for Individual Packaged-Products weighing 150 lb (68 kg) or Less
ISTA Procedure 1D : 2014	Non-Simulation Integrity Tests: Extended Integrity Testing for Individual Packaged-Products weighing Over 150 lb (68 kg)
ISTA Procedure 1E : 2014	Non-Simulation Integrity Tests: Integrity Testing for Unitized Loads
ISTA Procedure 1G : 2014	Non-Simulation Integrity Tests: Packaged-Products weighing 150 lb (68 kg) or Less utilizing Random Vibration
ISTA Procedure 1H : 2014	Non-Simulation Integrity Tests: Integrity Testing for Packaged-Products weighing Over 150 lb (68 kg) utilizing Random Vibration
ISTA Procedure 2A : 2011	Partial Simulation Tests: Packaged-Products weighing 150 lb (68 kg) or Less
ISTA Procedure 2B : 2011	Partial Simulation Tests: Packaged-Products weighing over 150 lb (68 kg)
ISTA Procedure 2C : 2011	Partial Simulation Tests: Furniture Packages
ISTA Procedure 3A : 2018	General Simulation Tests: Parcel Delivery System Shipments 150 lb (70kg) or Less
ISTA Procedure 3B : 2017	General Simulation Tests: Less-Than-Truckload (LTL) Shipment
ISTA Procedure 3E : 2016	General Simulation Tests: Similar Packaged-Products in Unitized Loads for Truckload Shipment

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ISTA Procedure 3F : 2017	General Simulation Tests: Distribution Center to Retail Outlet Shipment 100 lb (45 kg)
ISTA Procedure 3H : 2011	General Simulation Tests: Mechanically Handled Bulk Transport Containers
ISTA Procedure 3K : 2011	General Simulation Tests: Fast Moving Consumer Goods for the European Retail Supply Chain

Abbreviations used:

ASTM	American Society for Testing and Materials
DIN	German institute for standardization
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
ISTA	International Safe Transit Association

¹ General requirements for the competence of testing and calibration laboratories