**Accredited Testing Laboratories SCHOTT**

**Complete list of all accredited testing methods in the flexible scope according to D-PL-14645-01-00**

The testing laboratory hereby publishes the list of all testing methods in the flexible scope of accreditation with reference to   
**Working area FB 2.3 Material Testing and Materials Technology (destructive testing),   
Partial certificate annex D-PL-14645-01-02**

|  |  |
| --- | --- |
| **Coding:** | 01\_LIST\_00003 |
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Updates/changes are marked in **green**. Newly introduced procedures according to category B or C are marked with "NEW in flexible scope".

Within the marked test scopes, the testing laboratory is permitted to do the following without having to inform and obtain prior approval from DAkkS:

A) The extension of the scope of accreditation by standardized or equivalent test methods with different issue dates within a defined testing scope.

B) Includes category A as well as the extension of the scope of accreditation by standardized or equivalent test methods within a defined test scope. Category B includes - where applicable - new specifications for test objects, provided that these can be determined using the procedure within the test scope.

C) Includes categories A and B as well as the extension of the scope of accreditation by modified as well as further and newly developed test methods (e.g. in-house procedures) within a defined test area.

The original DAkkS accreditation certificate and the partial certificate annexes can be found under [www.dakks.de](http://www.dakks.de), Accredited Bodies, D-PL-14645-01-00. The testing procedures listed there are exemplary.

Tests are carried out in the following working areas:

**Testing of the chemical resistance of glasses, glass-ceramics, pharmaceutical packaging materials, decorations on glasses or glass-ceramics and other materials;**

**Determination of the physical properties (thermal, thermodynamic, elastic, electrical, optical and surface properties) of glasses, glass-ceramics, ceramics and composite materials, as well as the calculation of the parameters derived from these measured variables;**

**Qualitative and quantitative analysis of element depth profiles in glasses, glass-ceramics, ceramics and thin films;**

**High-resolution imaging of glasses, glass-ceramics, powders, metals, surfaces, layers and fracture surfaces;**

**Examination of glasses, glass articles and mold tools, e.g. as part of defect and damage analysis;**

**Determination of geometric parameters (e.g. pore sizes, particle sizes, layer thicknesses, roughness);**

**Determination of solid defects in glasses and glass-ceramics in/on surfaces, e.g. for glass defect diagnosis;**

**Corrosion, leaching and hydration tests;**

**Strength tests and fracture analysis (fractography) on glasses, glass-ceramics, plastics and composite materials (material and product properties);**

**Determination of the volume content of gaseous substances in inclusions of oxidic materials such as glasses and glass-ceramics;**

Locations:  
**Otto-Schott-Straße 2, 55127 Mainz  
Hattenbergstraße 10, 55122 Mainz  
400 York Ave, Duryea/PA 18642 USA**

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**Laboratory location Otto-Schott-Straße 2, 55127 Mainz**

# 1 Determination of the chemical resistance of glasses, glass ceramics, decorations on glasses or glass ceramics and other materials

## 1.1 Determination of resistance to liquid media

### 1.1.1 Mass loss and/or time needed for defined removal in µm by differential weighing and visual inspectionC)

|  |  |  |
| --- | --- | --- |
| ISO 8424  2023-07 | Raw optical glass - Resistance to attack by aqueous acidic solutions - Test method and classification |  |

|  |  |  |
| --- | --- | --- |
| ISO 9689  1990-12 | Raw optical glass -  Testing of the resistance to attack by aqueous alkaline phosphate-containing solutions at 50°C -  Testing and classification |  |

|  |  |  |
| --- | --- | --- |
| ISO 10629  1996-07 | Raw optical glass -  Resistance to attack by aqueous alkaline solutions at 50°C -  Test method and classification |  |

|  |  |  |
| --- | --- | --- |
| ISO 695  1991-05 | Glass; resistance to attack by a boiling aqueous solution of mixed alkali; method of test and classification |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 695  1994-02 | Glass: Resistance to attack by a boiling aqueous solution of mixed alkali - Method of test and classification |  |

|  |  |  |
| --- | --- | --- |
| DIN 12116  2001-03 | Testing of glass - Resistance to attack by a boiling aqueous solution of hydrochloric acid - Method of test and classification |  |

|  |  |  |
| --- | --- | --- |
| JOGIS  2007-03 | Japanese Optical Glass Industrial Standards -  Measuring Method for Chemical Durability of Optical Glass  (Powder Method) |  |

|  |  |  |
| --- | --- | --- |
| YBB00342004-2015  2015-00 | Test for Resistance to Attack of Glass by Boiling Hydrochloric Acid |  |

|  |  |  |
| --- | --- | --- |
| YBB00352004-2015  2015-00 | Test for Resistance to Attack of Glass by Boiling Aqueous Solution of Mixed Alkali |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00472  2018-02 | Determination of the chemical resistance of glasses, glass ceramics and other materials after chemical stresses by differential weighing and visual inspection |  |

### 1.1.2 Staining, Color and Gloss changes, Abrasion Resistance

#### 1.1.2.1 Visual InspectionC)

|  |  |  |
| --- | --- | --- |
| USP <211>  2023-06 | Arsenic <211> Method I |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00476  2018-02 | Determination of staining, color and gloss changes, abrasion resistence of glasses, glass ceramics and other materials after chemical stresses by visual inspection |  |

# 2 Thermal Characterization of glasses, glass ceramics, ceramics, sinter glasses, composites with glass or glass ceramic as well as raw materials of glass industry

## 2.1 Testing of thermal expansion (static, dynamic) of glasses, glass ceramics and plastics by inductive and optical methods for a temperature range of -180°C to 1300°CC)

|  |  |  |
| --- | --- | --- |
| DIN 51045-1  2005-08 | Determination of the thermal expansion of solids -  Part 1: Basic rules |  |

|  |  |  |
| --- | --- | --- |
| ISO 7991  1987-12 | Glass - Determination of coefficient of mean linear thermal expansion |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 7991  1998-02 | Glass - Determination of coefficient of mean linear thermal expansion |  |

|  |  |  |
| --- | --- | --- |
| YBB00202003-2015  2015-00 | Test for Coefficient of Mean Linear Thermal Expansion |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00470  2021-05 | Determination of the static and dynamic thermal expansion behaviour of solids by dilatometry and thermomechanical analysis |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00469  2024-01 | Determination of the compaction of glasses and glass ceramics by length comparison measurement |  |

## 2.2 Determination of viscosity of glasses for a viscosity range of 100-5 x 1013 dPa sC)

|  |  |  |
| --- | --- | --- |
| ISO 7884-1  1987-12 | Glass; Viscosity and viscometric fixed points; Part 1 : Principles for determining viscosity and viscometric fixed points |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 7884-1  1998-02 | Glass - Viscosity and viscometric fixed points  Part 1: Principles for determining viscosity and viscometric fixed points |  |

|  |  |  |
| --- | --- | --- |
| ISO 7884-2  1987-12 | Glass; Viscosity and viscometric fixed points; Part 2 : Determination of viscosity by rotation viscometers |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 7884-2  1998-02 | Glass - Viscosity and viscometric fixed points  Part 2: Determination of viscosity by rotation viscometers |  |

|  |  |  |
| --- | --- | --- |
| ISO 7884-3  1987-12 | Glass; Viscosity and viscometric fixed points; Part 3 : Determination of viscosity by fibre elongation viscometer |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 7884-3  1998-02 | Glass - Viscosity and viscometric fixed points  Part 3: Determination of viscosity by fibre elongation viscometer |  |

|  |  |  |
| --- | --- | --- |
| ISO 7884-4  1987-12 | Glass; Viscosity and viscometric fixed points; Part 4 : Determination of viscosity by beam bending |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 7884-4  1998-02 | Glass - Viscosity and viscometric fixed points  Part 4: Determination of viscosity by beam bending |  |

|  |  |  |
| --- | --- | --- |
| ISO 7884-7  1987-12 | Glass; Viscosity and viscometric fixed points; Part 7 : Determination of annealing point and strain point by beam bending |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 7884-7  1998-02 | Glass - Viscosity and viscometric fixed points - Part 7: Determination of annealing point and strain point by beam bending |  |

|  |  |  |
| --- | --- | --- |
| ISO 7884-8  1987-12 | Glass; Viscosity and viscometric fixed points; Part 8 : Determination of (dilatometric) transformation temperature |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 7884-8  1998-02 | Glass - Viscosity and viscometric fixed points -  Part 8: Determination of (dilatometric) transformation temperature |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00471  2023-12 | Determination of the viscosity properties of glasses by beam bending, fibre elongation and rotation viscosimeters as well as dilatometric transformation temperature |  |

## 2.3 Determination of the rheological parameters of solids, slurries and highly viscous liquidsC)

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00671  2022-02 | Determination of the rheological parameters of solids using rheometric measurement techniques in rotational and oscillation mode |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00715  2022-02 | Determination of the rheological parameters of slurries and liquids using rheometric measurement techniques in rotational and oscillation mode |  |

## 2.4 Determination of the density of glasses, glass ceramics, ceramics and other materialsB)

|  |  |  |
| --- | --- | --- |
| ISO 2781  2018-06 | Rubber, vulcanized or thermoplastic – Determination of density |  |

|  |  |  |
| --- | --- | --- |
| ASTM C 693  1993-00 | Standard Test Method for Density of Glass by Buoyancy (Modification: Use of a surfactant additive as well as smaller sample mass) |  |

## 2.5 Thermal analysis (differential thermal analysis (DTA), differential scanning calorimetry (DSC) and calorimetry (specific heat)) on glasses, glass ceramics, ceramics and raw materials (powders)C)

|  |  |  |
| --- | --- | --- |
| DIN 51006  2024-02 | Thermal analysis (TA) - Thermogravimetry (TG) - Principles |  |

|  |  |  |
| --- | --- | --- |
| DIN 51007  2019-04 | Thermal analysis - Differential thermal analysis (DTA) and differential scanning calorimetry (DSC) - General Principles |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00156  2022-08 | Determination of the true and average specific heat capacity of solids by calorimetric methods |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00581  2023-12 | Thermal analysis of solids by differential thermal analysis (DTA), differential scanning calorimetry (DSC) and thermogravimetric analysis (TGA) as well as simultaneous DTA-TGA |  |

## 2.6 Determination of the thermal diffusity of solids by flash method and calculation of the thermal conductivityB)

|  |  |  |
| --- | --- | --- |
| ASTM E 1461  2013-00 | Standard Test Method for Thermal Diffusivity by the Flash Method |  |

|  |  |  |
| --- | --- | --- |
| ISO 18755  2022-12 | Fine ceramics (advanced ceramics, advanced technical ceramics) – Determination of thermal diffusivity of monolithic ceramics by flash method | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN EN ISO 18755  2024-01 | Fine ceramics (advanced ceramics, advanced technical ceramics) – Determination of thermal diffusivity of monolithic ceramics by flash method | NEW in flexible scope |

## 2.7 Determination of seal stress in glass by polarization microscopyA)

|  |  |  |
| --- | --- | --- |
| ISO 4790  1992-05 | Glass-to-glass sealings; determination of stresses |  |

## 2.8 Determination of crystallization properties of glasses by gradient furnace methodC)

|  |  |  |
| --- | --- | --- |
| ASTM C 829  1981-00 | Standard Practices for Measurement of Liquidus Temperature of Glass by the Gradient Furnace Method |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00486  2024-01 | Determination of the crystallization properties of glasses and glass ceramics by the gradient furnace method |  |

## 2.9 Determination of Young`s Modulus, Shear Modulus and Poisson`s constant of glass, glass ceramic and ceramic by resonance methodC)

|  |  |  |
| --- | --- | --- |
| ASTM C 1259  2021-00 | Standard Test Method for Dynamic Youngs Modulus, Shear Modulus, and Poissons Ratio for Advanced Ceramics by Impulse Excitation of Vibration |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00502  2024-01 | Determination of the dynamic Young`s modulus, shear modulus and Poisson`s coefficient of glasses, glass ceramics, ceramics and metals by impulse excitation of vibrations |  |

# 3 Electrical characterization of glasses, glass-ceramics, ceramics and other materials

## 3.1 Determination of the electrical contact resistance of glasses, glass-ceramics, ceramics and other materialsC)

|  |  |  |
| --- | --- | --- |
| DIN 52326  1986-05 | Testing of glass; determination of electrical resistivity |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00511  2024-01 | Determination of the specific electric volume resistance of glasses and glass ceramics by current and voltage measurements |  |

## 3.2 Determination of dielectric properties of glasses, glass ceramics, ceramics and other materials in the GHz rangeA)

|  |  |  |
| --- | --- | --- |
| IEC 61189-2-721  2015-04 | Test methods for electrical materials, printed boards and other interconnection structures and assemblies – Part 2-721: Test methods for materials for interconnection structures – Measurement of relative permittivity and loss tangent for copper clad laminate at microwave frequency using split post dielectric resonator (Modifikation: Die Probenvorkonditionierung und die Messung erfolgen bei (25 ± 5) °C und ungeregelter Luftfeuchte.) |  |

# 4 Optical characterization of glasses, glass ceramics, ceramics, sintered glasses, composites with glass or glass ceramics as well as raw materials of the glass industry

## 4.1 Determination of transmission, reflection, remission, scattered light/haze, solarization, spectral color measurement, refractive index and dispersion, fluorescence of glasses, glass ceramics, liquids by spectroscopyC)

|  |  |  |
| --- | --- | --- |
| ISO 15368  2021-03 | Optics and optical instruments - Measurement of reflectance of plane surfaces and transmittance of plane parallel elements |  |

|  |  |  |
| --- | --- | --- |
| Ph. Eur. 3.2.9  2023-04 | European Pharmacopoeia -  3.2.9 Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders -  Test: Absorbance, Reference to Ph. Eur. 2.2.25 -  Test A: Infrared absorption spectrometry, Reference to Ph. Eur. 2.2.24 |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00487  2023-12 | Determination of the spectral transmission, remission, reflection, scattering, color value and solarization of solids, especially glasses and glass ceramics, plastics and liquids by optical spectroscopy |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00488  2024-01 | Determination of the refractive index and dispersion of glasses, glass ceramics, plastics and solids by prism coupler method |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00490  2024-01 | Determination of the spectral fluorescence properties, decay time and quantum yield of glasses, glass ceramics, solids and liquids by fluorescence spectroscopy |  |

|  |  |  |
| --- | --- | --- |
| Anal. Chem. 2010, 82, p. 2129-2133  2010-00 | Recommendations for Fluorescence Instrument qualification: The new ASTM Standard Guide -  Paul de Rose, Ute Resch-Genger |  |

## 4.2 Ellipsometric characterization of coatings and uncoated materials B)

|  |  |  |
| --- | --- | --- |
| DIN EN ISO 23131  2023-01 |  | NEW in flexible scope |

## 4.3 Stress measurements and stress-optical coefficient C)

|  |  |  |
| --- | --- | --- |
| ISO 10345-2  1992-05 | Glass - Determination of stress-optical coefficient -  Part 2: Bending test |  |

|  |  |  |
| --- | --- | --- |
| ISO 11455  1995-03 | Raw optical glass - Determination of birefringence |  |

|  |  |  |
| --- | --- | --- |
| ASTM C 770  2016-00 | Standard Specification for Chemically Strengthened Flat Glass | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ASTM C 1422/ C1422 M 20a  2020-00 | Standard Specification for Chemically Strengthened Flat Glass |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00509  2024-01 | Determination of mechanical tensions, birefringence and the stress-optical coefficient of transparent solids by polarization-optical measurement methods |  |

# 5 Characterization of glasses, glass ceramics, ceramics, metals, plastics and composite materials in micro and surface area

## 5.1 by Scanning Electron Microscopy/Energy Dispersive X-ray spectroscopy (SEM/EDX)C)

|  |  |  |
| --- | --- | --- |
| ISO 22309  2011-10 | Microbeam analysis – Quantitative analysis using energy-dispersive spectrometry (EDS) for elements with an atomic number of 11 (Na) or above |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 22309  2015-11 | Microbeam analysis – Quantitative analysis using energy-dispersive spectrometry (EDS) for elements with an atomic number of 11 (Na) or above |  |

|  |  |  |
| --- | --- | --- |
| ASTM B 748  1990-00 | Standard Test Method for Measurement of Thickness of Metallic Coatings by Measurement of Cross Section with a Scanning Electron Microscope |  |

|  |  |  |
| --- | --- | --- |
| ASTM E 1078  2014-00 | Standard Guide for Specimen Preparation and Mounting in Surface Analysis |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00491  2023-12 | High-resolution morphological surface characterization on glasses, glass ceramics, ceramics, metals, solid and composite materials by SEM as well as qualitative and quantitative analysis of surface composition by EDX |  |

## 5.2 by topographic methods (WLI, AFM, Laser-Interferometry)C)

|  |  |  |
| --- | --- | --- |
| ASTM E 2382  2004-00 | Guide to Scanner and Tip Related Artifacts in Scanning Tunneling Microscopy and Atomic Force Microscopy |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00489  2022-05 | Topographic determination on glasses, glass ceramics, ceramics, metals, plastics and composite materials by white-light interference microscopy |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00537  2022-01 | High-resolution determination of the surface topography of glasses, glass ceramics, ceramics, metals, plastics and composite materials and solids by atomic force microscopy |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00752  2022-10 | Determination of wavefront deformation by Fizeau phase laser interferometry |  |

## 5.3 by Light MicroscopyC)

|  |  |  |
| --- | --- | --- |
| ISO 643  2019-12 | Steels - Micrographic determination of the apparent grain size |  |

|  |  |  |
| --- | --- | --- |
| DIN EN ISO 643  2020-06 | Steels - Micrographic determination of the apparent grain size |  |

|  |  |  |
| --- | --- | --- |
| ASTM E 112  2013-00 | Standard Test Methods for Determining Average Grain Size |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00501  2018-02 | Sample characterization of glasses, glass ceramics, ceramics, metals, plastics, composite and solid materials by light microscopy |  |

## 5.4 by Time-of-Flight-Secondary Ion Mass Spectrometry (ToF-SIMS)C)

|  |  |  |
| --- | --- | --- |
| ISO 13084  2018-11 | Surface chemical analysis - Secondary-ion mass spectrometry - Calibration of the mass scale for a time-of-flight secondary-ion mass spectrometer |  |

|  |  |  |
| --- | --- | --- |
| ISO 18116  2005-08 | Surface chemical analysis - Guidelines for preparation and mounting of specimens for analysis |  |

|  |  |  |
| --- | --- | --- |
| ASTM E 2695  2009-00 | Standard Guide for Interpretation of Mass Spectral Data Acquired with Time-of-Flight Secondary Ion Mass Spectroscopy (withdrawn standard) |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00493  2023-12 | Qualitative analysis of the surface composition of glasses, glass ceramics, ceramics, metals, plastics, composite materials and solids by ToF-SIMS |  |

## 5.5 by Vibrational SpectroscopyC)

|  |  |  |
| --- | --- | --- |
| JIS K 0137  2010-05 | General rules for Raman spectrometry |  |

|  |  |  |
| --- | --- | --- |
| USP <1854>  2015-05 | Mid-infrared spectroscopy - Theory and practice |  |

# 6 Strength tests on glases, glass ceramics, plastics and composites, Determination of material and product properties by pressure and tensile testsC)

|  |  |  |
| --- | --- | --- |
| ISO 14704  2016-04 | Fine ceramics (advanced ceramics, advanced technical ceramics) -  Test method for flexural strength of monolithic ceramics at room temperature |  |

|  |  |  |
| --- | --- | --- |
| ISO 7458  2004-03 | Glass containers - Internal pressure resistance - Test methods |  |

|  |  |  |
| --- | --- | --- |
| DIN EN ISO 7458  2004-05 | Glass containers - Internal pressure resistance - Test methods |  |

|  |  |  |
| --- | --- | --- |
| ISO 8113  2004-03 | Glass containers - Resistance to vertical load - Test method |  |

|  |  |  |
| --- | --- | --- |
| DIN EN ISO 8113  2004-05 | Glass containers - Resistance to vertical load - Test method |  |

|  |  |  |
| --- | --- | --- |
| DIN EN 843-1  2008-08 | Advanced technical ceramics -  Mechanical properties of monolithic ceramics at room temperature Part 1: Determination of flexural strength |  |

|  |  |  |
| --- | --- | --- |
| ISO 1288-3  2016-02 | Glass in building - Determination of the bending strength of glass - Part 3: Test with specimen supported at two points (four point bending) |  |

|  |  |  |
| --- | --- | --- |
| DIN EN 1288-3  2000-09 | Glass in building - Determination of the bending strength of glass -  Part 3: Test with specimen supported at two points (four point bending) |  |

|  |  |  |
| --- | --- | --- |
| ISO 1288-5  2016-02 | Glass in building - Determination of the bending strength of glass - Part 5: Coaxial double ring test on flat specimens with small test surface areas |  |

|  |  |  |
| --- | --- | --- |
| DIN EN 1288-5  2000-09 | Glass in building - Determination of the bending strength of glass -  Part 5: Coaxial double ring test on flat specimens with small test surface areas |  |

|  |  |  |
| --- | --- | --- |
| ISO 11040-4  2015-04 | Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling |  |

|  |  |  |
| --- | --- | --- |
| ISO 11040-4 AMD 1  2020-02 | Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling; Amendment 1 |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 11040-4  2017-07 | Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling |  |

|  |  |  |
| --- | --- | --- |
| ISO 11040-6  2019-01 | Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 11040-6  2021-05 | Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11040-8  2016-11 | Prefilled syringes - Part 8: Requirements and test methods for finished prefilled syringes | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 11040-8  2020-11 | Prefilled syringes - Part 8: Requirements and test methods for finished prefilled syringes | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 8871-5  2016-10 | Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released-particle count | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN EN ISO 8871-5  2017-03 | Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released-particle count | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00495  2018-02 | Determination of the strength of brittle materials, plastics and composite materials by tensile and pressure tests with universal testing machines |  |

# 7 Fracture analysis (fractography) on glasses, glass ceramics, ceramics and plastics by light microscopic methodsC)

|  |  |  |
| --- | --- | --- |
| DIN EN 843-6  2009-12 | Advanced technical ceramics - Mechanical properties of monolithic ceramics at room temperature -  Part 6: Guidance for fractographic investigation; |  |

|  |  |  |
| --- | --- | --- |
| ASTM C 1256  1993-00 | Standard Practice for Interpreting Glass Fracture Surface Features |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00496  2023-12 | Fractography / fracture analysis on brittle materials |  |

# 8 Determination of the volume fractions of gaseous substances in inclusions of glasses, glass ceramics, oxide materials and stones by mass spectrometry and Raman spectroscopyC)

|  |  |  |
| --- | --- | --- |
| JIS K 0137  2010-05 | General rules for Raman spectrometry |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00497  2018-02 | Determination of volume fractions of gaseous substances in inclusions of glasses, glass ceramics, oxide materials and stones by mass spectrometry |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00504  2021-08 | Determination of volume fractions of gaseous substances in inclusions of glasses, glass ceramics, oxide materials and stones by Raman spectroscopy |  |

## 4 Functional tests on pharmaceutical packaging ---Extension of accreditation requested, DAkkS, May 2024

## 4.1 Determination of container integrity and leakage

### 4.1.1 by leakage testB)

|  |  |  |
| --- | --- | --- |
| ISO 7886-1  2017-05 | Sterile hypodermic syringes for single use - Part 1: Syringes for manual use | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN EN ISO 7886-1  2020-11 | Sterile hypodermic syringes for single use - Part 1: Syringes for manual use | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11040-4  2015-04 | Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11040-4 AMD 1  2020-02 | Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling; Amendment 1 | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 11040-4  2017-07 | Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11040-6  2019-01 | Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 11040-6  2021-05 | Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11040-8  2016-11 | Prefilled syringes - Part 8: Requirements and test methods for finished prefilled syringes | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 11040-8  2020-11 | Prefilled syringes - Part 8: Requirements and test methods for finished prefilled syringes | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11608-3  2022-04 | Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN EN ISO 11608-3  2022-09 | Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| USP <1207.2>  2016-08 | Package integrity leak test technologies | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 21881  2019-10 | Sterile packaged ready for filling glass cartridges | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 21881  2020-12 | Sterile packaged ready for filling glass cartridges | NEW in flexible scope |

## 4.2 Determination of residual volume and delivered dose --Extension of accreditation requested, DAkkS, May 2024

### 4.2.1 by delivery procedureC)

|  |  |  |
| --- | --- | --- |
| ISO 7886-1  2017-05 | Sterile hypodermic syringes for single use - Part 1: Syringes for manual use | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN EN ISO 7886-1  2020-11 | Sterile hypodermic syringes for single use - Part 1: Syringes for manual use | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00816  2023-12 | Determination of the delivered dose of glass and plastic syringes | NEW in flexible scope |

## 4.3 Mechanical functional testsC) ---Extension of accreditation requested, DAkkS, May 2024

|  |  |  |
| --- | --- | --- |
| USP <1207.3>  2016-08 | Package seal quality test technologies | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11040-4  2015-04 | Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11040-4 AMD 1  2020-02 | Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling; Amendment 1 | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 11040-4  2017-07 | Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11040-6  2019-01 | Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 11040-6  2021-05 | Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 11040-8  2016-11 | Prefilled syringes - Part 8: Requirements and test methods for finished prefilled syringes | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 11040-8  2020-11 | Prefilled syringes - Part 8: Requirements and test methods for finished prefilled syringes | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| ISO 21881  2019-10 | Sterile packaged ready for filling glass cartridges | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| DIN ISO 21881  2020-12 | Sterile packaged ready for filling glass cartridges | NEW in flexible scope |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00817  2023-12 | Needle penetration test for the closure systems of cartridges | NEW in flexible scope |

**Laboratory location Hattenbergstraße 10, 55122 Mainz**

# 1 Testing of thermal expansion (static, dynamic) of glasses, glass ceramics, ceramics, sinter materials, plastics and composites by inductive and optical methods for a temperature range of -50°C to +100°C C)

|  |  |  |
| --- | --- | --- |
| DIN 51045-1  2005-08 | Determination of the thermal expansion of solids -  Part 1: Basic rules |  |

|  |  |  |
| --- | --- | --- |
| ISO 7991  1987-12 | Glass; Determination of coefficient of mean linear thermal expansion |  |

|  |  |  |
| --- | --- | --- |
| DIN ISO 7991  1998-02 | Glass; Determination of coefficient of mean linear thermal expansion |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00470  2021-05 | Determination of the static and dynamic thermal expansion behaviour of solids by dilatometry and thermomechanical analysis |  |

# 2 Determination of optical properties (transmission and derived parameters, refractive index and dispersion) preferably on glasses by optical spectroscopy and optical refractography C)

|  |  |  |
| --- | --- | --- |
| ISO 15368  2021-03 | Optics and optical instruments - Measurement of reflectance of plane surfaces and transmittance of plane parallel elements |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00487  2023-12 | Determination of the spectral transmission, remission, reflection, scattering, color value and solarization of solids, especially glasses and glass ceramics, plastics and liquids by optical spectroscopy |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00510  2024-04 | Determination of the refractive index and dispersion of glasses with standard and/or precision accuracy by optical refractography |  |

# 3 Determination of the density of glasses, glass ceramics, ceramics and other materials A)

|  |  |  |
| --- | --- | --- |
| ASTM C 693  1993-00 | Standard Test Method for Density of Glass by Buoyancy (Modification: Use of a surfactant additive) |  |

**Laboratory location 400 York Ave, Duryea/PA 18642 USA**

# 1 Characterization of glasses, glass ceramics, ceramics, metals, plastics and composite materials in micro and surface area as well as fracture analysis (fractography)

## 1.1 by Scanning Electron Microscopy/ Energy Dispersive X-ray spectroscopy (SEM/EDX) C)

|  |  |  |
| --- | --- | --- |
| ISO 22309  2011-10 | Microbeam analysis – Quantitative analysis using energy-dispersive spectrometry (EDS) for elements with an atomic number of 11 (Na) or above |  |

|  |  |  |
| --- | --- | --- |
| ASTM E 1078  2014-00 | Standard Guide for Specimen Preparation and Mounting in Surface Analysis |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00491  2023-12 | High-resolution morphological surface characterization on glasses, glass ceramics, ceramics, metals, solid and composite materials by SEM as well as qualitative and quantitative analysis of surface composition by EDX |  |

## 1.2 by Light Microscopy MethodsC)

|  |  |  |
| --- | --- | --- |
| DIN EN 843-6  2009-12 | Advanced technical ceramics - Mechanical properties of monolithic ceramics at room temperature - Part 6: Guidance for fractographic investigation |  |

|  |  |  |
| --- | --- | --- |
| ASTM C 1256  1993-00 | Standard Practice for Interpreting Glass Fracture Surface Features |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00496  2023-12 | Fractography / fracture analysis on brittle materials |  |

|  |  |  |
| --- | --- | --- |
| 01\_SOP\_00501  2018-02 | Sample characterization of glasses, glass ceramics, ceramics, metals, plastics, composite and solid materials by light microscopy |  |