SCHOTT

Accredited Testing Laboratories SCHOTT

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

The testing laboratory hereby publishes the list of all testing methods in the flexible scope of accreditation of the CAB with reference to
Working area FB 3.4 Medicine, pharmacy, non-active medical devices,
Partial certificate annex D-PL-14645-01-04

Coding:	01_LIST_00003 (Excerpt)
Version:	18.0
Issue date:	2026-08-18

Newly introduced procedures according to category A, B or C as well as changes are marked in **green**.

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

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

[Flex 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.

[Flex 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 complete certificate and the partial certificates issued by DAkkS for the above-mentioned conformity assessment body can be found at www.dakks.de, Accredited Bodies, D-PL-14645-01-00.
The testing procedures listed there are exemplary.

Certificate holder of the partial certificate annex:

SCHOTT AG
Hattenbergstraße 10, 55122 Mainz

The test procedures are identified by the symbols of the locations listed below, where they are performed:

MZ-HS = Mainz, Hattenbergstr. MZ-OS = Mainz, Otto-Schott-Str. DY-YA = Duryea, York Ave

Tests are carried out in the following working areas:

Medicines and active ingredients
Testing of pharmaceutical primary packaging materials

Locations:

SCHOTT AG
Otto-Schott-Straße 2, 55127 Mainz

SCHOTT AG
400 York Ave, Duryea/PA 18642 USA

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 for performing the conformity assessment activities listed in this annex. The testing laboratory fulfills any additional legal and normative requirements, including those in relevant sectoral programs, provided that these are expressly confirmed below.

The requirements for the management system are written in the relevant language and are fully compliant with the principles of DIN EN ISO 9001.

Medicines and active ingredients

Testing of primary pharmaceutical packaging materials

Test type: Determination of leakage [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
DIN EN ISO 7886-1 2020-11 Annex D	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 7886-1 2017-05 Annex D	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
DIN ISO 11040-4 2025-04 Annex H Annex G2	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
ISO 11040-4 2024-06 Annex H Annex G2	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
DIN ISO 11040-6 2021-05 Annex H Annex G2	Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 11040-6 2019-01 Annex H Annex G2	Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS

DIN EN ISO 11608-3 2022-09 Section 5.1	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 11608-3 2022-04 Section 5.1	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
DIN ISO 21881 2020-12 Annex F	Sterile packaged ready for filling glass cartridges (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
ISO 21881 2019-10 Annex F	Sterile packaged ready for filling glass cartridges (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
USP <1207.2> 2016-08 Table 1, row 2 and Section 2.2	Package integrity leak test technologies (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Determination of residual emptying capacity [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
DIN EN ISO 7886-1 2020-11 Annex C	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 7886-1 2017-05 Annex C	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00816 2025-09	Determination of the delivered dose of glass and plastic syringes (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Mechanical functional tests [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
DIN EN ISO 8871-5 2017-03 Annex A	Elastomeric parts for parentals and for devices for pharmaceutical use - Part 5: Functional requirements and testing (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 8871-5 2016-10 Annex A	Elastomeric parts for parentals and for devices for pharmaceutical use - Part 5: Functional requirements and testing (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
DIN ISO 11040-4 2025-04 Annex C1 Annex C2 Annex E Annex F Annex G1 Annex G3 Annex G6	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
ISO 11040-4 2024-06 Annex C1 Annex C2 Annex E Annex F Annex G1 Annex G3 Annex G6	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
DIN ISO 11040-6 2021-05 Annex C1 Annex C2 Annex E Annex G1 Annex G6	Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS

ISO 11040-6 2019-01 Annex C1 Annex C2 Annex E Annex G1 Annex G6	Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
DIN ISO 21881 2020-12 Annex D	Sterile packaged ready for filling glass cartridges (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
ISO 21881 2019-10 Annex D	Sterile packaged ready for filling glass cartridges (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
USP <1207.3> 2016-08 Chapter 5	Package seal quality test technologies (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00817 2025-09	Needle penetration test for the closure systems of cartridges (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Chromatography (GC-MS, LC-MS) [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
USP <621> 2026-06	Chromatography (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00498 2025-09	Determination of plastic additives in and out of pharmaceutical packaging materials using gas chromatography - mass spectometry (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00684 2025-09	Gas chromatography - mass spectrometry for the analyses of extractable substances out of pharmaceutical packaging material (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

01_SOP_00499 2025-09	Determination of leachable monomers from cured adhesives using liquid chromatography - mass spectrometry (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00685 2025-09	Liquid chromatography - mass spectrometry for the analyses of extractable substances out of pharmaceutical packaging material (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Extraction and leaching processes [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
Ph. Eur. 2023-04 Chapter 3.2.9 Sample preparation of Solution S	Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Titrimetry [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
JP 18th edition 2021-06	Japanese Pharmacopoeia - 7. Test for Containers and Packing Materials - 7.01. Test for Glass Containers for Injections (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Ph. Eur. 2019-01 Chapter 3.2.1	Glass containers for pharmaceutical use - Test A: Hydrolytic resistance of the inner surfaces of glass containers (Surface Test) - Test B: Hydrolytic resistance of glass grains (Glass Grains Test) - Test C: To determine wether the containers have been surface treated (Etching Test) (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <660> 2023-10	USP <660>, Containers-Glass - Hydrolytic Resistance - Glass Grains Test - Surface Glass Test- Surface Etching Test (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Atomic absorption spectrometry (FAAS, HG-AAS) [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
Ph. Eur. 2019-01 Chapter 3.2.1	Glass containers for pharmaceutical use - Arsenic (HGAAS) - Annex - Test for surface hydrolytic resistance-determination by flame atomic absorption spectrometry (FAAS) (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
Ph. Eur. 2023-04 Chapter 3.2.9 2023-04	Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders - Extractable zinc (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Optical emission spectrometry with Inductively Coupled Plasma (ICP-OES)/ Mass Spectrometry with Inductively Coupled Plasma [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
USP <730> 2018-05	Plasma spectrochemistry (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <233> 2026-05	Chemical Test and Assays: Elemental Impurities - Procedures (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00028 2025-08	Trace element analysis of aqueous extracts from glass, glass ceramics and pharmaceutical packaging with ICP-MS or ICP-OES (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
Ph. Eur. 2019-01 Chapter 3.2.1	Glass containers for pharmaceutical use - Test A: Hydrolytic resistance of the inner surfaces of glass containers (Surface Test) - Test B: Hydrolytic resistance of glass grains (Glass Grains Test) - Test C: To determine whether the containers have been surface treated (Etching Test) - Annex - Test for surface hydrolytic resistance-determination by flame atomic absorption spectrometry (FAAS) (Modifikation: Bestimmung von weiteren Kationen mit ICP-OES oder ICP-MS) (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 3749 2022-03	Glass syringes – Determination of extractable tungsten (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

USP <660> 2023-10	USP <660>, Containers-Glass - Hydrolytic Resistance - Glass Grains Test - Surface Glass Test- Surface Etching Test (Modification: Detection of cations with ICP-OES or ICP-MS) (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Optical emission spectrometry with Inductively Coupled Plasma (ICP-OES) [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
USP <730> 2018-05	Plasma spectrochemistry (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA

Test type: UV-VIS spectrophotometry [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
DIN EN ISO 8871-1 2004-11 Annex C	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 1: Extractables in aqueous autoclavates (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 8871-1 2003-10 Annex C	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 1: Extractables in aqueous autoclavates (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
JP 18th edition 2021-06	Japanese Pharmacopoeia Physical Methods Spectroscopic Methods 2.24 Ultraviolet-visible Spectrophotometry (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Ph. Eur. 2019-01 Chapter 3.2.1	Glass containers for pharmaceutical use - Spectral Transmission for Colored Glass Containers (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <660> 2023-10	USP <660>, Container Glass - Functionality - Spectral Transmission for Colored Glass Containers (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: Microscopy [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
DIN EN ISO 8871-3 2019-08 Section 3	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released-particle count (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 8871-3 2003-08 Section 3	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released-particle count (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 8871-3 AMD 1 2018-01	Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3: Determination of released-particle count; Amendment 1 (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
DIN EN ISO 8871-5 2017-03 Annex B	Elastomeric Parts for Parenteral Preparations and Devices for Pharmaceutical Use - Part 5: Functional Requirements and Testing (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS

ISO 8871-5 2016-10 Annex B	Elastomeric parts for parentals and for devices for pharmaceutical use - Part 5: Functional requirements and testing (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
DIN EN ISO 11608-3 2022-09 Section 4.2.3 and Section 5.2	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 11608-3 2022-04 Section 4.2.3 and Section 5.2	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
Ph. Eur. 2023-04 Chapter 3.2.9	Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders - Appearance of solution S - Ammonium, Reference to Ph. Eur. 2.4.1 Method A - Volatile sulfides (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00041 2025-09	Determination of delamination risk in primary packaging containers for storage of pharmaceutical products by Stereo-microscopy (Qualitative Analysis) (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA
USP <1181> 2014-12	Scanning Electron Microscopy (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA
01_SOP_00508 2025-09	Separation of particles from solution by filtration and suitable particle analyses (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA

DIN ISO 11040-4 2025-04 Annex D2	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
ISO 11040-4 2024-06 Annex D2	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass	MZ-OS
DIN ISO 11040-6 2021-05 Annex D2	Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
ISO 11040-6 2019-01 Annex D2	Prefilled syringes - Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of plastic	MZ-OS
DIN EN ISO 11608-3 2022-09 Annex A Table A1, row 3	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
ISO 11608-3 2022-04 Annex A Table A1, row 3	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
USP <788> 2026-08	Particulate Matter in Injections (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
Ph. Eur. 2021-01 Chapter 2.9.19	European Pharmacopoeia - 2.9.19 Particulate contamination: Sub-visible particles (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

DIN EN 843-6 2009-12	Advanced technical ceramics - Mechanical properties of monolithic ceramics at room temperature - Part 6: Guidance for fractographic investigation (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA
ASTM C 1256 2025-00a	Standard Practice for Interpreting Glass Fracture Surface Features (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA
01_SOP_00496 2025-09	Fractography/Fracture analysis on brittle materials (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA
01_SOP_00501 2025-09	Sample characterization of glasses, glass ceramics, ceramics, metals, plastics, composite and solid materials by light microscopy (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA

Test type: Raman Spectroscopy [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
JIS K 0137 2010-05	General rules for Raman spectrometry (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS
01_SOP_00508 2025-09	Separation of particles from solution by filtration and suitable particle analyses (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS

Test type: pH-measurement [Flex B]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
DIN 19268 2021-10	pH-measurement - pH-measurement of aqueous solutions with pH measuring chains with pH glass electrodes and evaluation of measurement uncertainty (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	DY-YA

Test type: Particle contamination - visible particles [Flex C]

Norm / Issue date / In-house procedure / Version	Title of the standard or in-house procedure (if necessary deviations / modifications of standard procedures)	Test item	Location
Ph. Eur. 2020-01 Chapter 2.9.20	European Pharmcopoeia 2.9.20 Particulate contamination: Visible Particles (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA
USP <790> 2016-05	Visible particulates in injections (No conformity assessment of medical devices)	Pharmaceutical primary packaging materials made of glass and plastic	MZ-OS DY-YA