



17025 Calibration Certificate and 8655 Test Report

for Pipettes, Dispensers, and
other Volumetric Apparatus

Overview, Definitions and Notes

Simplifying Progress

SARTORIUS

Precise and Reliable Results

Requirements regarding the accuracy and reliability of laboratory data are constantly increasing. According to leading regulations and quality assurance standards (e.g. ISO 9000 series of standards, GMP), measuring and test equipment needs to be checked and calibrated regularly. This is the only way to always ensure precise, reliable, and traceable results.

Sartorius Service is accredited in many countries in accordance with ISO | IEC 17025 and issues calibration certificates for pipettes and dispensers, as well as test reports for piston-operated volumetric apparatus in

accordance with ISO 8655. This means that Sartorius calibration follows the internationally recognized state of the art. The accredited calibration certificate also guarantees complete traceability of measuring equipment to national standards and ensures you can trust your measurement and test results.

This document is intended to explain the individual parts of the Sartorius DAkkS calibration certificate and the ISO 8655 test report and to highlight significant differences between the two documents, as well as to explain important terms.

Definitions and Frequently Asked Questions

What does calibration mean?

Calibration is the comparison of a measured value with a known or correct value. Gravimetric calibration of volumetric apparatus normally involves dispensing ten liquids with three different volumes onto a calibrated balance.

The values documented during calibration and the evaluation of these values is the calibration result.

How often do devices need to be calibrated?

In order to continually verify the quality of test equipment results, it is essential to determine appropriate calibration intervals. Calibration intervals should be based on the criticality of the application and can be defined based on risk analyses.

According to DIN EN ISO 8655, volumetric apparatus should be calibrated at least once a year.

Why do I need proof of traceability?

A measuring device is considered traceable if it is related to a national or international standard by an uninterrupted chain of comparative measurements. Proof of traceability therefore ensures international comparability and reliability of measurement results.

What does uncertainty of measurement mean?

The uncertainty of measurement is a statement about the quality of a measured value. It indicates the value range within which the true measured value lies. The smaller the uncertainty of measurement, the more precisely the true value can be narrowed down. The accredited calibration certificates issued by Sartorius present the uncertainty of measurement in a way that is easy to understand and provide reliability when interpreting measurement results.

Comparison of the 17025 Calibration Certificate and the 8655 Test Report

	DIN EN ISO IEC 17025 Calibration Certificate	DIN EN ISO 8655 Test Report
Is the document proof of calibration?	Yes	Yes
Is the document issued for every calibration?	No, it is an optional service	Yes
Calibration is performed according to which quality management standard?	<ul style="list-style-type: none"> ISO 9001 ISO IEC 17025 	<ul style="list-style-type: none"> ISO 9001
Results are evaluated according to which standard?	<ul style="list-style-type: none"> DIN EN ISO 8655 DKD-R 8-1 and DKD-R 8-2 	<ul style="list-style-type: none"> DIN EN ISO 8655
Sartorius offers calibration for which volumetric apparatus?	<ul style="list-style-type: none"> Pipettes Dispensers 	<ul style="list-style-type: none"> Pipettes Dispensers Piston burettes Dilutors
Is it an accredited calibration?	Yes	No
Does the calibration act as proof of traceability?	Yes	No
Is the uncertainty of measurement indicated?	Yes	No
Is there verification of compliance with DIN EN ISO 8655 tolerance value specifications?	No	Yes
Is there verification of compliance with manufacturer or customer-specific tolerance value specifications?	No	Yes, if requested by the customer
Can calibration be performed at the customer's site?	Yes, provided the necessary ambient conditions can be maintained	Yes, provided the necessary ambient conditions can be maintained
What test liquid is used for calibration?	Grade 3 water in accordance with ISO 3696	Grade 3 water in accordance with ISO 3696
For how long are samples calibration objects allowed to acclimatize in the test laboratory?	At least 2 hours	At least 2 hours
What temperatures and temperature fluctuations are permitted during calibration?	20°C to 25°C ≤ 0.5°C	15°C to 30°C ± 0.5°C
What differences in temperature are permitted between the air and water temperature during calibration?	< 0.5 K	No specifications
What level of relative humidity needs to be maintained in the laboratory?	Between 50% and 60%	> 50%
Is all test equipment used in the test laboratory regularly calibrated and is its traceability guaranteed?	Yes	Yes

The Accredited 17025 Calibration Certificate

Accreditation of a laboratory according to ISO/IEC 17025 is proof of the quality of the calibration by an independent accreditation body. Calibration certificates from accredited laboratories are internationally recognized as proof of traceability. The accredited calibration certificate contains all information about the calibration object, the measurement results, and their uncertainty.

Notes:

- It is the user's responsibility to allow a reasonable period of time for a repeat calibration.
- Calibration certificates may only be further distributed in full and unaltered. Extracts or amendments require the permission of the issuing calibration laboratory.

Kalibrierschein
Calibration certificate

erstellt durch das Kalibrierlaboratorium/
issued by the calibration laboratory

Sartorius Lab Instruments GmbH & Co. KG

akkreditiert nach DIN EN ISO/IEC 17025:2018
accredited according to the German Version of ISO/IEC 17025:2017

1

Mitglied im / Member of
Deutschen Kalibrierdienst

Kalibrierzeichen
Calibration mark

V104461
D-K-
19398-01-00
2020-10

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3	Gegenstand <i>Object</i> Hersteller <i>Manufacturer</i> Typ <i>Type</i> Fabrikat / Serien-Nr. <i>Serial number</i> Auftraggeber <i>Customer</i> Auftragsnummer <i>Order No.</i> Anzahl der Seiten des Kalibrierscheines <i>Number of pages of the certificate</i> Datum der Kalibrierung <i>Date of calibration</i>	Volumenmessgerät elektronische Einkanal Sartorius Picus Nxt 10 - 300 µl 14025930 Sartorius Lab Instruments GmbH & Co. KG Groner Siekanger 1 37081 Göttingen 2 16.10.2020	<p>Dieser Kalibrierschein dokumentiert die Rückführung auf nationale Normale zur Darstellung der Einheiten in Übereinstimmung mit dem internationalen Einheitensystem (SI). Die DAkkS ist Unterzeichnerin der multilateralen Übereinkommen der European co-operation for Accreditation (EA) und der International Laboratory Accreditation Cooperation (ILAC) zur gegenseitigen Anerkennung der Kalibrierscheine. Für die Einhaltung einer angemessenen Frist zur Wiederholung der Kalibrierung ist der Benutzer verantwortlich.</p> <p><i>This calibration certificate documents the traceability to national standards, which realize the units of measurement according to the International System of Units (SI). The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates. The user is obliged to have the object recalibrated at appropriate intervals.</i></p>									
4		<table> <tr> <th>Datum</th> <th>Leiter des Kalibrierlaboratoriums</th> <th>Bearbeiter</th> </tr> <tr> <th>Date</th> <th>Head of the calibration laboratory</th> <th>Person in charge</th> </tr> <tr> <td>16.10.2020</td> <td>Dipl.-Ing. (FH) Karin Hagedorn</td> <td>Max Mustermann</td> </tr> </table>	Datum	Leiter des Kalibrierlaboratoriums	Bearbeiter	Date	Head of the calibration laboratory	Person in charge	16.10.2020	Dipl.-Ing. (FH) Karin Hagedorn	Max Mustermann	
Datum	Leiter des Kalibrierlaboratoriums	Bearbeiter										
Date	Head of the calibration laboratory	Person in charge										
16.10.2020	Dipl.-Ing. (FH) Karin Hagedorn	Max Mustermann										

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Description of the Different Entries:

1 The Accreditation and ILAC-MRA¹ Symbol

- Sartorius is accredited for the performance of calibrations on piston pipettes and dispensers in various countries by national accreditation bodies (e.g. DAkkS, UKAS, Cofrac, etc.). This accreditation applies to both calibrations performed in the Sartorius calibration laboratory and calibrations performed at customer sites.
- The ILAC-MRA guarantees recognition of the calibration certificate in all ILAC member states.

2 The Calibration Mark

- Top section: certificate number
- Middle section: registration number of the calibration laboratory
- Bottom section: year and month of the calibration

3 Basic Calibration Data

- Basic data about the calibration object and the customer is recorded in this section.
- If the calibration certificate needs to be used as proof of traceability, this data needs to correspond to the data in test equipment management.

4 Date and Signatures

- The issue date of the calibration certificate (may differ from the calibration date) and the signatures of the person in charge and the person authorized to release the calibration certificate (usually the laboratory management).

¹ ILAC: International Laboratory Accreditation Cooperation;
MRA: Mutual Recognition Arrangement

Page 2 of 2 pages to the calibration certificate

V104462
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 19398-01-00
 2020-10

5 Location of calibration:
 Sartorius Lab Instruments GmbH & Co. KG, Groner Siekanger 1, 37081 Göttingen

6 Calibration object
 Manufacturer: Sartorius Type of pipette: Picos NxT Used tip: Sartorius Tip 350 µl
 Volume range: 10 - 300 µl Device ID No: 33908
 Serial No: 14025930 End customer No:
 Customer: Sartorius Lab Instruments GmbH & Co. KG

7 Calibration procedure: DIN EN ISO 8655
 Version: S-02-20170726-1117

8 Measurement results

Test volume	30 µl		150 µl		300 µl	
	mg	µl	mg	µl	mg	µl
1	29.88	29.87	148.67	148.16	298.54	299.52
2	29.82	29.82	148.60	148.10	298.46	299.45
3	29.79	29.88	148.59	148.19	298.55	299.54
4	29.86	29.86	148.80	148.30	298.67	299.56
5	29.81	29.81	148.77	148.26	298.41	299.39
6	29.73	29.82	148.76	148.24	298.54	299.53
7	29.72	29.82	148.73	148.22	298.42	299.41
8	29.76	29.86	148.87	148.37	298.64	299.62
9	29.82	29.82	148.70	148.19	298.50	299.48
10	29.78	29.88	148.76	148.25	298.37	299.38

Comments
 Caption: (...) deleted values

9 Evaluation according to DIN EN ISO 8655 and DKD-R 8-1

	29.80	29.90	148.74	148.23	298.51	299.50
Average Value (es)		-0.10		-0.78		-0.51
(CV)		0.05		0.08		0.09
Spec. (es)		± 3.99		± 4.00		± 3.98
Spec. (CV)		± 1.50		± 1.50		± 1.50
(U)		0.21		0.32		0.42

Caption: (es) systematic measurement error, (CV) random measurement error, (U) expanded measurement uncertainty

10 Environmental conditions

Calibrated by	Max Mustermann
Date of Calibration	16.10.2020
Print date	16.10.2020
Data transfer from scale	automatic
Balance-Type	Sartorius MSA6.6S
Balance serial number	766789
Last calibration	17.12.2019
With corresponding weights E2 Serial No.	GW0564
Climate module serial number	#00372
Water temperature	(22.0 ± 0.5) °C
Density of water	(mg/µl) 0.99777
Air pressure	(hPa) (995 ± 4)
Air humidity	(%) (64 ± 2)
Factor-Z	(µl/mg) 1.00330

11 Comments

Measurement conditions:
 Prior the test the calibration object is kept for more than 2 hours in the air conditioned calibration lab to reach equilibrium. Used test liquid is conforming grade 3 as specified in ISO 8655. The stated volume is determined from 10 measurements. The conversion from mass to volume is performed with correction factor "Z" according to ISO 8655-6.

Measurement uncertainty:
 Stated is the expanded measurement uncertainty determined according to DAAS-DKD-3 and calculated by standard measurement uncertainty multiplied by coverage factor k = 2. This value of measurement is inside the assigned value interval with 95 % probability.

Sartorius Lab Instruments GmbH & Co. KG, D-K 19398-01-00
 Otto-Brenner-Straße 20, 37107 Göttingen

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The first page of the calibration certificate contains information that are important and essential for the monitoring of test equipment and its accuracy. The completeness of the documents and the accuracy of the entries should always be checked once the calibration certificate has been received.

The second page of the calibration certificate includes the measurement results and the result of the calibration. This information is important for working with your test equipment.

5 Location of Calibration

- The address of the permanent Sartorius calibration laboratory or the address of the customer in the case of a calibration at customer site (on-site calibration). Before an on-site calibration Sartorius checks the location to ensure that the required ambient conditions are met.

6 Calibration Object

- Basic data about the pipette or dispenser (manufacturer, type, serial number, device ID and end customer number).
- The tips (pipette tips) used during calibration. **Please note that the calibration is only valid for the tips listed here.**
- Changing the tip type may cause the measurement results to change so drastically that recalibration is required.
- The volume range of the pipette or dispenser is also specified here. **Please note that the calibration certificate can only be used as proof of traceability for the volume range listed here.**

7 Calibration Procedure

- Calibration is carried out in accordance with the standard "ISO 8655 - Calibration of Piston-operated Volumetric Apparatus". This standard represents the internationally recognized state of the art in the calibration of pipettes and dispensers.

8 Measurement Results

- During calibration, 10 measured values are usually recorded for each test volume. Measured values at three different volumes are generally recorded for volumetric apparatus with variable volumes.

9 Evaluation

- The evaluation of the measurement results is carried out in accordance with DIN EN ISO 8655 and the "DKD-R 8-1" or "DKD-R 8-2" guideline. The mean value is specified as well as the expanded measurement uncertainty. The systematic and random error according to ISO 8655 is also included.
- Verification of compliance with customer or manufacturer tolerances is not performed as part of the DAkS calibration certificate, nor is verification of the tolerances specified in DIN EN ISO 8655. An evaluation like this is only performed in the DIN EN ISO 8655 test report.

10 Environmental Conditions

- This is where the basic conditions under which the calibration took place are outlined. The balance used during calibration, the calibration data of the balance, and the temperature, humidity, and air pressure values are listed here. These values are taken into account when evaluating the calibration.

11 Comments

- The calibration certificate ends with a comment box and general remarks about the measurement conditions and uncertainty of measurement.

The DIN EN ISO 8655 Test Report

As with the 17025 calibration certificate, the ISO 8655 test report for piston-operated volumetric apparatus includes information about the calibration object and the measurement results. However, it does not act as proof of traceability for the test equipment. If pipettes and dispensers are used as measuring and test equipment in a quality management system, traceability demonstrated by the accredited calibration certificate is an essential requirement.

<small>Sartorius Lab Instruments GmbH & Co. KG Otto-Brenner-Straße 20 37073 Göttingen</small>		SARTORIUS	
1 Sartorius Lab Instruments GmbH & Co. KG Groner Siekanger 1 37081 Göttingen		Servicezentrum	
2 Test report number V104462		3 test procedure-no.: 2937	
Client		Sartorius Lab Instruments GmbH & Co. KG Groner Siekanger 1 37081 Göttingen	
4 Calibration object		Sartorius SAR-Picus NxT-10 - 300 µl	
Serial No.		14025930	
Used pipette tip		Sartorius Tip 350 µl	
5 Testing method		Gravimetric test methods for determining the error of measurement according to DIN EN ISO 8655	
Basis of the adjustment		Ex (20°C +/- 0,5°C)	
6 Balance type		Sartorius MSA6.6S	
Balance serial number		756789	
Last calibration		17.12.2019 With corresponding weights E2: GW19564 Data transfer from scale: automatic	
Test liquid		Water according to DIN EN ISO 3696	
7 Inspection result		passed	
		Created by Max Mustermann	
8 Test date: 16.10.2020		Information: The details of the air humidity in the laboratory are only for information. All balances have evaporation traps. This guarantees a relative humidity from > 90% .	
9 Next proposed calibration date: 16.04.2021		Print date: 16.10.2020 Version: A-01-20150914-1117	
<small>This calibration certificate may not be reproduced other than in full except with the permission of the issuing laboratory. Calibration certificates without signature are not valid.</small>			
Page 1 from 2			

Description of the Different Entries:

1 Calibration Laboratory

- Information about the calibration laboratory.

2 Test Report Number

- The test report number is a sequential number.

3 Test Instruction

- The test instruction number refers to the test instruction used by the calibration laboratory.

4 Test Object

- This is where basic data about the pipette or dispenser is listed, such as the manufacturer, serial number, and the pipette tips used, to ensure that the test can be unequivocally assigned to the test object. **Please note that the test is only valid for the type of pipette tips listed here.**

5 Test Procedure

- DIN EN ISO 8655 is indicated here as the test procedure.

- Basis of adjustment: "Ex" means that the test liquid is dispensed from the test object into the weighing vessel. The specification of 20°C indicates that all correction factor calculations are based on 20°C.

6 Testing Device

- This is where information is provided about the test equipment used for the test and its calibration.

7 Test Results

- Indicates whether the pipette or dispenser has moved within the tolerance limits during the test. A test can be performed against manufacturer, customer, or DIN EN ISO 8655 tolerances (see page 2).

8 Date and Signature

- The test date (may differ from the print date) of the test report and the signature of the tester.

Page 2 of 2 pages to the calibration certificate

10 Location of calibration:
Sartorius Lab Instruments GmbH & Co. KG, 37081, Göttingen

11 Calibration object

Manufacturer	Sartorius	Type of pipette	Picos NxT
Volume range	10 - 300 µl	Device-ID Nr.	33908
Serial No.	14025930	End customer No.	
Customer	Sartorius Lab Instruments GmbH & Co. KG		

Test according to: DIN EN ISO 8655

12 Measurement results

Test volume	30 µl	30 µl	150 µl	150 µl	300 µl	300 µl
	mg	µl	mg	µl	mg	µl
1	29.88	29.87	148.67	148.16	298.54	299.52
2	29.82	29.82	148.60	148.10	298.46	299.45
3	29.79	29.88	148.59	148.19	298.56	299.54
4	29.86	29.86	148.80	148.30	298.57	299.56
5	29.81	29.81	148.77	148.26	298.41	299.39
6	29.73	29.82	148.76	148.24	298.54	299.53
7	29.72	29.82	148.73	148.22	298.42	299.41
8	29.76	29.86	148.87	148.37	298.64	299.62
9	29.82	29.82	148.70	148.19	298.50	299.48
10	29.78	29.88	148.76	148.25	298.37	299.36

Comments

Caption: (...) deleted values

13 Evaluation according to: DIN EN ISO 8655

Evaluation

Average Value	29.80	29.90	148.74	148.23	298.51	299.50
(es) [µl]	-0.10	-0.78				-0.51
(CV) [µl]	0.05	0.08				0.08
Spec. (es) [µl]	± 3.99	± 4.00				± 3.98
Spec. (CV) [µl]	± 1.50	± 1.50				± 1.50
Evaluation	OK	OK				OK

Caption: (es) systematic measurement error, (CV) random measurement error, (U) expanded measurement uncertainty

14 Measuring conditions

Calibrated by	Max Mustermann
Date of Calibration	16.10.2020
Print date	16.10.2020
Data transfer from scale	automatic
Balance-Type	Sartorius MSA6.6S
Balance serial number	766789
Last calibration	17.12.2019
With corresponding weights E2 Serial No.	GW0564
Climate module serial number	#00372
Water temperature	[°C] 22.00
Density of water	[mg/µl] 0.99777
Air pressure	[hPa] 996.00
Air humidity	[%] 54.00
Factor-Z	[µl/mg] 1.00330

15 Comments

Information:
The details of the air humidity in the laboratory are only for information. All balances have evaporation traps. This guarantees a relative air humidity of > 90%.

Sartorius Lab Instruments GmbH & Co. KG, Servicezentrum DAK 19398-01-00
Greiner-Straße 1, 37081 Göttingen

The first page of the test report includes information about the customer, the test equipment, and the test equipment used for the calibration.

The second page of the test report includes the measurement results and the result of the test.

9 Next Calibration

- The valid test interval for the customer is queried during the calibration.
- DIN EN ISO 8655 requires volumetric apparatus to be tested at least once a year.
- However, the test interval should be shortened in consideration of the following factors: frequency of use, number of users of the device, accuracy requirements, aggressiveness of the liquids to be dispensed, laboratory regulations.
- The date of validity is also noted on the test object. Pipettes and dispensers should not be used if their recalibration date has been exceeded.

10 Calibration Location

- Sartorius performs calibrations at its calibration laboratory and at customer sites (on-site calibration). Before an on-site calibration Sartorius checks the location to ensure that the required ambient conditions are met.

11 Test Object

- The information about the test object from page 1 is repeated here.

12 Measurement Results

- Ten measured values for three different volumes are usually recorded during the calibration.
- An as-found calibration can also be performed if requested. A smaller number of measured values may be recorded for this. The measured values for each test are issued on a separate test report.

13 Evaluation of the Measurement Results

- This is where the tolerances against which the measurement results are checked are specified. Testing is carried out against the values specified in DIN EN ISO 8655 as standard and unless otherwise requested by the customer. However, testing can also be performed against the tolerances specified by the manufacturer or against tolerance values specified by the customer. **If customer tolerances are narrower than the tolerance values specified by the manufacturer, these may not be met.**

14 Measurement Conditions

- This is where the basic conditions under which the calibration took place are outlined. The balance used during calibration, the calibration data of the balance, and the temperature, humidity, and air pressure values are listed here. These values are taken into account during the calibration evaluation.

15 Comments

- The test report ends with a comment box and general information.

Germany

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