



 <div>ASSOCIATES OF <b>CAPE COD</b> INTERNATIONAL <i>Specialists in Endotoxin and Glucan Detection</i></div>	<b>Document No.:</b> TSIN021-3	<b>Revision #</b> 5	<b>Page</b> 1 of 1
	<b>Title:</b> Certificate of Calibration for PK Flex with Pyros Express		

**CERTIFICATE OF CALIBRATION FOR PYROS KINETIX® FLEX WITH PYROS EXPRESS**

<b>1.0 CUSTOMER INFORMATION</b>	<b>2.0 SERVICE INFORMATION</b>
Organisation: Synektik Pharma Sp. z o.o. Address: ul. Artwińskiego 3, 25-734 Kielce, Poland <b>Calibration Location:</b> Customer Site	ICN Number: CAL023-25 Calibration Date: 28 JAN 2025 Serial Number: PKF64-9E-2663 Performed By: Konstantin Velmozhko <b>NIST Traceable Thermometer</b> Serial Number:32404549 Calibration Due Date: 02 MAY 2025
<b>3.0 TRANSMITTED AND MEASURED TEMPERATURE AS FOUND</b> (37.0°C ± 0.5°C)	<b>3.1 TRANSMITTED AND MEASURED TEMPERATURE AS LEFT</b> (37.0°C ± 0.2°C)
Ambient (°C):23.5 Min (°C):37.02    Max (°C):37.13    Transmitted (°C):37.0  Found in tolerance <input checked="" type="checkbox"/> Found in tolerance - Fine adjustments made <input type="checkbox"/> Found out of tolerance - Adjustments made <input type="checkbox"/> Unable to obtain data <input type="checkbox"/>	If no adjustments made, tick to N/A section 3.1 <input checked="" type="checkbox"/>  Ambient (°C): Min (°C):    Max (°C):    Transmitted (°C): Adjusted temperatures left in tolerance <input type="checkbox"/> Adjusted temperatures left out of tolerance <input type="checkbox"/>
<b>4.0 405nm A/D VALUES AS FOUND</b> (Tubes Present 800–5500, Tubes Absent 1100-1400)	<b>4.1 405nm A/D VALUES AS LEFT</b> (Tubes Present 800–5500, Tubes Absent 1100-1400)
Found in tolerance <input checked="" type="checkbox"/> Tubes Present out of tolerance <input type="checkbox"/> Tubes Absent out of tolerance <input type="checkbox"/> Not Applicable <input type="checkbox"/>	No adjustments required <input checked="" type="checkbox"/> 405nm A/D values adjusted with 660nm <input type="checkbox"/> Adjusted 405nm A/D values in tolerance <input type="checkbox"/> Adjusted 405nm A/D out of tolerance <input type="checkbox"/>
<b>5.0 660nm A/D VALUES AS FOUND</b> (Tubes Present 800–5500, Tubes Absent 1100-1400)	<b>5.1 660nm A/D VALUES AS LEFT</b> (Tubes Present 800–5500, Tubes Absent 1100-1400)
Found in tolerance <input checked="" type="checkbox"/> Tubes Present out of tolerance <input type="checkbox"/> Tubes Absent out of tolerance <input type="checkbox"/> Not Applicable <input type="checkbox"/>	No adjustments required <input checked="" type="checkbox"/> 660nm A/D values adjusted with 405nm <input type="checkbox"/> Adjusted 660nm A/D values in tolerance <input type="checkbox"/> Adjusted 660nm A/D out of tolerance <input type="checkbox"/>
<b>6.0 405nm BASELINE STABILITY</b> (±3mAbs)	<b>6.1 660nm BASELINE STABILITY</b> (±3mAbs)
<b>PASS</b> <input checked="" type="checkbox"/> <b>FAIL</b> <input type="checkbox"/> <b>N/A</b> <input type="checkbox"/>	<b>PASS</b> <input checked="" type="checkbox"/> <b>FAIL</b> <input type="checkbox"/> <b>N/A</b> <input type="checkbox"/>
<b>7.0 STANDARD CURVE</b> (CC: ≥0.980, Negative Controls: onset time > lowest standard)	<b>PASS</b> <input type="checkbox"/> <b>FAIL</b> <input type="checkbox"/> <b>N/A</b> <input checked="" type="checkbox"/>
<b>CALIBRATION OF PYROS KINETIX® FLEX:</b>	<b>PASS</b> <input checked="" type="checkbox"/> <b>FAIL</b> <input type="checkbox"/>
<b>COMMENTS:</b> or N/A <input checked="" type="checkbox"/>	
<b>PERFORMED BY:</b>	<b>QA / REVIEW BOARD APPROVAL:</b>
<div>Signed by:   Signer Name: Konstantin Velmozhko Signing Reason: I am the author of this document Signing Time: 05-Feb-2025   17:59 CET  E5BFD7324EFC4EB0B7B79F1429452944</div>	<div>Signed by:   Signer Name: Anke Ruland Signing Reason: I approve this document Signing Time: 10-Feb-2025   09:37 CET  287EDE5D741C4A83BAABC91F1CAC3098</div>

**DATA AND SUPPORTING DOCUMENTATION ATTACHED:** Transmitted Temperature data, A/D data, Baseline data, Standard Curve data, calibration certificate for digital thermometer.



Performed By: kvelmozhko

Reader Serial #: PKF64-9E-2663

Firmware Version: PKF64 V1.50 (170404)

Test Complete Date: 28.01.2025

Test Complete Time: 11:25

## Results

### Block 1

37°C

### Block 2

37°C

## SIGNATURES

PERFORMED BY:

Name: (kvelmozhko)

Signed by:

*Konstantin Velmozhko*



Signer Name: Konstantin Velmozhko  
Signing Reason: I am the author of this document  
Signing Time: 05-Feb-2025 | 17:59 CET

Signature:

E5BFD7324EFC4EB0B7B79F1429452944

Date: 05-Feb-2025 | 18:00 CET

REVIEWED BY:

Name: Anke Ruland

Signed by:

*Anke Ruland*



Signer Name: Anke Ruland  
Signing Reason: I have reviewed this document  
Signing Time: 10-Feb-2025 | 09:36 CET

Signature:

287EDE5D741C4A83BAABC91F1CAC3098

Date: 10-Feb-2025 | 09:37 CET



<b>Performed By:</b> kvelmzhko	<b>Reader Serial #:</b> PKF64-9E-2663	<b>Firmware Version:</b> PKF64 V1.50 (170404)
<b>Test Complete Date:</b> 28.01.2025	<b>Test Complete Time:</b> 11:34	

**As Found**

**405 nm - As Found**

Tubes Present				Tubes Absent			
2680	2421	2804	2385	1261	1273	1265	1271
2756	2487	2899	2730	1259	1271	1257	1256
2699	2456	2872	2547	1265	1256	1258	1262
2841	2501	2935	2617	1260	1256	1260	1253
2826	2639	2864	2677	1269	1265	1252	1257
2836	2583	2860	2269	1262	1256	1260	1259
2869	2540	2920	2639	1252	1268	1238	1251
2663	2619	2807	2518	1278	1267	1259	1253
2782	2537	2672	2504	1258	1264	1251	1269
2756	2799	2786	2299	1254	1289	1260	1256
2692	2678	2687	2738	1251	1263	1240	1258
2775	2516	2855	2339	1253	1261	1267	1285
2609	2595	2885	2609	1261	1253	1261	1265
2657	2492	2878	2619	1265	1258	1264	1261
2776	2531	2852	2414	1264	1265	1248	1260
2767	2518	2841	2495	1254	1267	1261	1277
<b>Minimum</b>	2269	<b>Maximum</b>	2935	<b>Minimum</b>	1238	<b>Maximum</b>	1289

**660 nm - As Found**

Tubes Present				Tubes Absent			
2446	2095	2162	2175	1261	1254	1263	1261
2477	2138	1977	2181	1270	1261	1263	1266
2524	2141	2093	2365	1262	1268	1266	1252
2399	2074	1947	2238	1264	1267	1247	1258
2446	2395	2152	2388	1252	1255	1259	1246
2374	2266	1995	2323	1260	1272	1266	1262
2221	2210	1970	2340	1255	1260	1250	1253
2338	2129	2047	2440	1260	1268	1256	1252
2255	2155	1856	2371	1271	1267	1249	1256
2093	2175	1874	2355	1261	1275	1252	1251
2459	2190	1892	2231	1262	1265	1261	1261
2157	2298	1836	2533	1271	1255	1253	1275
2337	2362	2036	2338	1262	1256	1272	1262
2192	2335	1927	2312	1257	1269	1251	1270
2339	2148	2029	2312	1265	1266	1262	1253
2263	2011	1863	2402	1257	1257	1263	1264
<b>Minimum</b>	1836	<b>Maximum</b>	2533	<b>Minimum</b>	1246	<b>Maximum</b>	1275



SIGNATURES

PERFORMED BY:

Name: (kvelmozhko)

Signature:

Signed by:  
*Konstantin Velmozhko*  
Signer Name: Konstantin Velmozhko  
Signing Reason: I am the author of this document  
Signing Time: 05-Feb-2025 | 18:00 CET  
E5BFD7324EFC4EB9B7B70F1429452944

Date: 05-Feb-2025 | 18:00 CET

REVIEWED BY:

Name: Anke Ruland

Signature:

Signed by:  
*Anke Ruland*  
Signer Name: Anke Ruland  
Signing Reason: I have reviewed this document  
Signing Time: 10-Feb-2025 | 09:36 CET  
287EDE5D741C4A83BAABC91F1CAC3098

Date: 10-Feb-2025 | 09:37 CET



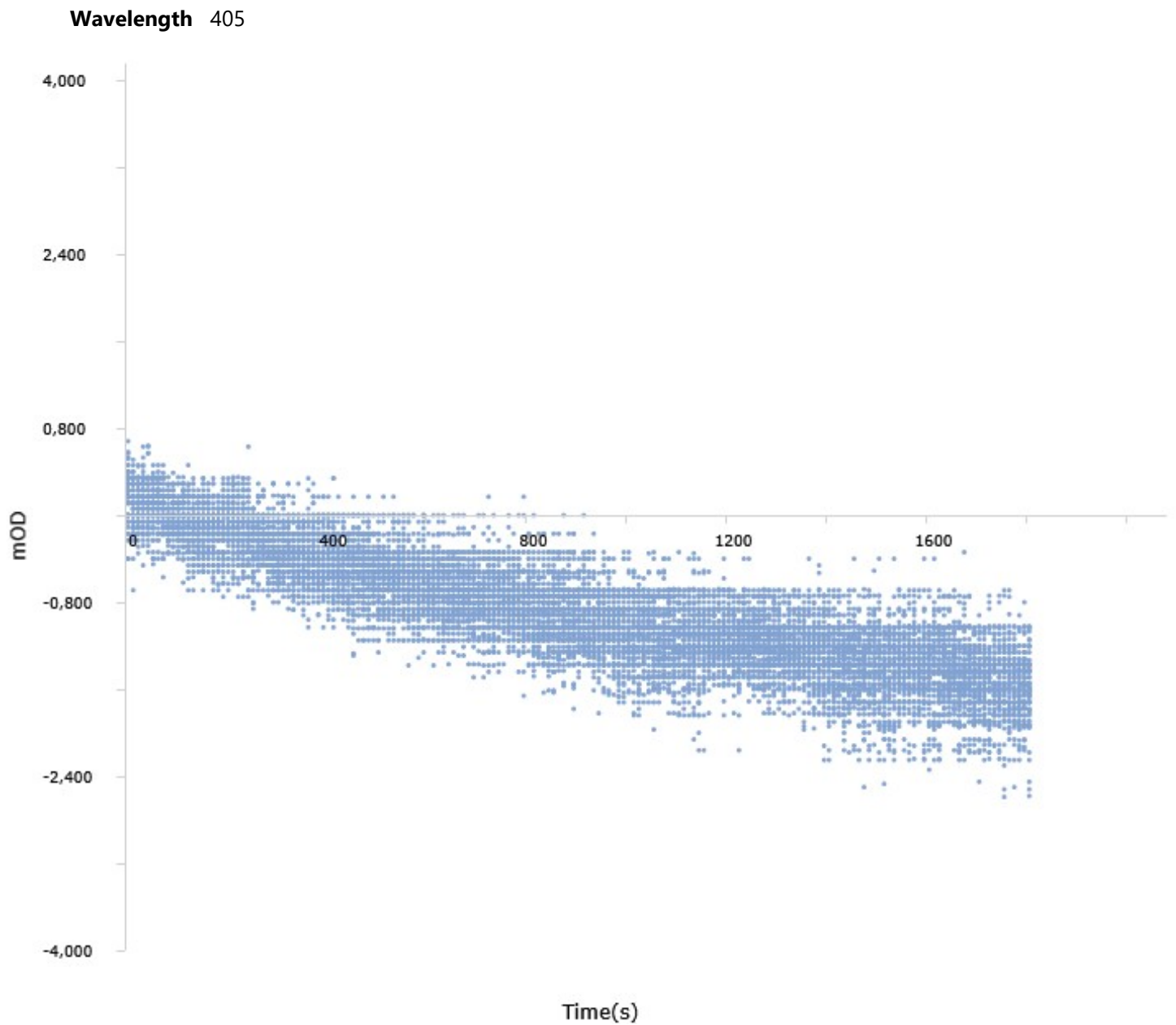
Performed By: kvelmozhko

Reader Serial #: PKF64-9E-2663

Firmware Version: PKF64 V1.50 (170404)

Test Complete Date: 28.01.2025

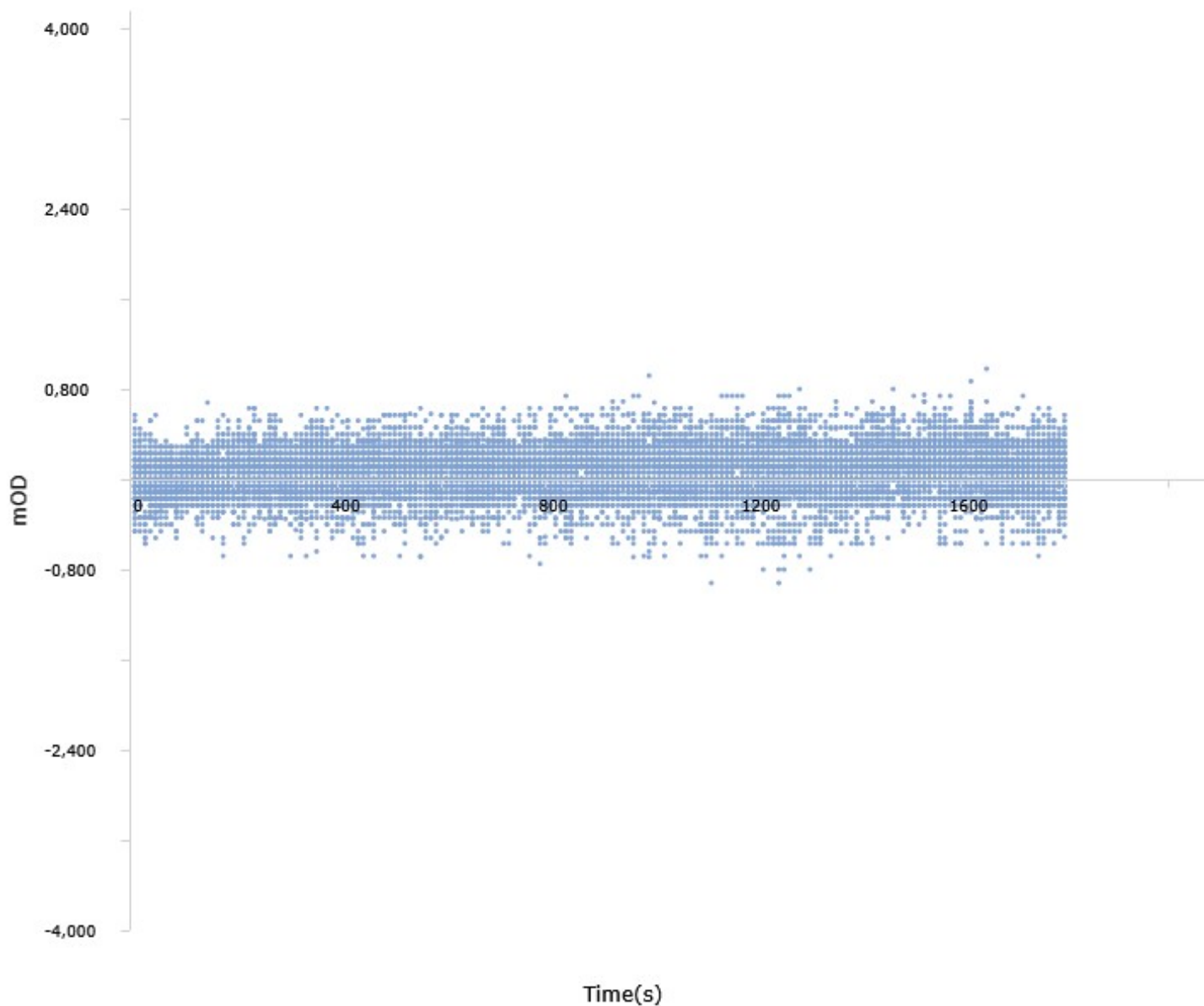
Test Complete Time: 12:05







**Wavelength** 660



**Results**

Min. mOD	-0,92
Max. mOD	0,98







SIGNATURES

PERFORMED BY:

Name: (kvelmozhko)

Signature:

Signed by:  
*Konstantin Velmozhko*  
Signer Name: Konstantin Velmozhko  
Signing Reason: I am the author of this document  
Signing Time: 05-Feb-2025 | 18:00 CET  
E5BED7324EFC4EB0B7B79E1429452944

Date: 05-Feb-2025 | 18:00 CET

REVIEWED BY:

Name: Anke Ruland

Signature:

Signed by:  
*Anke Ruland*  
Signer Name: Anke Ruland  
Signing Reason: I have reviewed this document  
Signing Time: 10-Feb-2025 | 09:37 CET  
287EDE5D741C4A83BAABC91F1CAC3668

Date: 10-Feb-2025 | 09:37 CET



# Zentrum für Messen und Kalibrieren & ANALYTIK GmbH

## Kalibrierschein / Calibration Certificate

erstellt durch das Kalibrierlaboratorium  
*issued by the calibration laboratory*

**ZMK & ANALYTIK GmbH**

akkreditiert nach DIN EN ISO/IEC 17025:2018  
*German translation of ISO/IEC 17025:2017*



Deutsche  
Akkreditierungsstelle  
D-K-15186-01-00

Mitglied im / Member of  
Deutschen Kalibrierdienst



Kalibrierzeichen  
*Calibration mark*

08-0719
D-K- 15186-01-00
2024-05

Gegenstand  
*Object*

**Widerstandsthermometer  
mit Anzeigegerät**

Hersteller  
*Manufacturer*

**Omega Engineering GmbH**

Typ  
*Type*

**Fühler: Pt100  
Gerät: GMH 3710**

Serien-/ Prüfmittel-Nr.  
*Serial number*

**Fühler-Ident.-Nr.: 10/03/17-1  
Gerät: 32404549**

Kunden- / Eigentümerdaten  
*Customer*

**Associates of Cape  
Cod Europe GmbH  
Opelstraße 14  
64546 Mörfelden-Walldorf**

Dieser Kalibrierschein dokumentiert die metrologische Rückführbarkeit auf nationale Normale zur Darstellung der Einheiten in Übereinstimmung mit dem Internationalen Einheitensystem (SI).

Die DAkkS ist Unterzeichner 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.

*This calibration certificate documents the metrological 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.*

Auftragsnummer  
*Order No.*

-

Anzahl der Seiten des Kalibrierscheines  
*Number of pages of the certificate*

3

Datum der Kalibrierung  
*Date of calibration*

**02.05.2024**

Dieser Kalibrierschein darf nur vollständig und unverändert weiterverbreitet werden. Auszüge oder Änderungen bedürfen der Genehmigung des ausstellenden Kalibrierlaboratoriums. Kalibrierscheine sind bei Nennung des für die Freigabe Verantwortlichen in Klarschrift auch ohne Unterschrift gültig.

*This calibration certificate may not be reproduced other than in full except with the permission of the issuing laboratory. Calibration certificates with the full name of the approval responsible person are valid without signature.*

Datum der Ausstellung  
*Date of issue*

Freigabe des Kalibrierscheines durch  
*Approval of the certificate of calibration by*

Dieser Kalibrierschein wurde erstellt durch  
*This calibration certificate was prepared by*

03.05.2024

Dr. Diana Jehnert

Niklas Vetter

**Kalibrierlaboratorium für mechanische, dimensionelle, elektrische, thermodynamische und analytische Messgrößen**

*Calibration laboratory for mechanical, dimensional, electrical, thermodynamical and analytical measuring quantities*

Ortsteil Wolfen, P-D ChemiePark Bitterfeld-Wolfen, Areal A, Filmstraße Nr.7, 06766 Bitterfeld-Wolfen

Tel.: +49 3494 / 6973-0 / E-Mail: info@zmk-wolfen.de / Homepage: www.zmk-wolfen.de

**Kalibriergegenstand**

Widerstandsthermometer

Hersteller: -  
Typ: Pt 100  
Ident.-Nr.: 10/03/17-1  
Kalibrierpunkte: (36/37/38) °C

Anzeigegerät

Hersteller: Omega Engineering GmbH  
Typ: GMH 3710  
Serien-Nr.: 32404549  
Auflösung: 0,01 °C

**Normale**

Normal-Platin-Widerstandsthermometer

Typ: Pt 25  
Ident.-Nr.: GD08/G308  
Kalibrierung: D-K-15186-01

DC-Temperaturmessbrücke

Typ: MKT 50  
Ident.-Nr.: GD08/G305  
Kalibrierung: D-K-15186-01

**Kalibrierverfahren**

Die Kalibrierung des Widerstandsthermometers mit Anzeigegerät erfolgte in Flüssigkeitsbädern mit Ausgleichsblock nach der Richtlinie DKD-R 5-1, Ausgabe 09/2018, durch direkten Vergleich von Normalthermometer und Kalibriergegenstand.

**Ort der Kalibrierung**

ZMK &amp; ANALYTIK GmbH, Bitterfeld-Wolfen

**Messbedingungen**

Die Eintauchtiefe betrug 50 mm.

Die Eigenerwärmung des Widerstandsthermometers wurde nicht bestimmt.  
Es wurde ein zusätzlicher Messunsicherheitsbeitrag in der Messunsicherheitsbilanz berücksichtigt.

**Hysterese**

Die Hysterese des Temperaturfühlers wurde nicht bestimmt und ist nicht Bestandteil der angegebenen Messunsicherheit.

In Abhängigkeit von den anwendungsspezifischen Genauigkeitsanforderungen ist für den Einfluss der Hysterese ein zusätzlicher Messunsicherheitsbeitrag von 0,2 % des Einsatzbereiches zu berücksichtigen.

**Umgebungsbedingungen**

Temperatur:  $(23 \pm 5)$  °C  
rel. Feuchte:  $(50 \pm 20)$  %

08-0719
D-K- 15186-01-00
2024-05

Messergebnisse

Temperatur Normal in °C	Anzeige Kalibriergegenstand in °C	Anzeige- korrektur in K	Messunsicherheit  in K
35,983	35,97	0,01	0,04
36,980	36,96	0,02	0,04
37,998	37,96	0,04	0,04
35,984	35,96	0,02	0,04

Die Temperaturmesswerte sind Mittelwerte aus Mehrfachmessungen.

Die Temperatur ergibt sich aus der Beziehung:  
Temperatur = Anzeige Kalibriergegenstand + Anzeigekorrektur

Die Messergebnisse gelten für den Zustand des oben aufgeführten Kalibriergegenstandes zum Zeitpunkt der Kalibrierung.

Messunsicherheit

Angegeben ist die erweiterte Messunsicherheit, die sich aus der Standardmessunsicherheit durch Multiplikation mit dem Erweiterungsfaktor  $k = 2$  ergibt. Sie wurde gemäß EA-4/02 M: 2022 ermittelt. Der Wert der Messgröße liegt mit einer Wahrscheinlichkeit von annähernd 95 % im zugeordneten Werteintervall.

Hinweis

Die Deutsche Akkreditierungsstelle GmbH ist Unterzeichner der multilateralen Übereinkommen der European co-operation for Accreditation (EA) und der International Laboratory Accreditation Cooperation (ILAC) zur gegenseitigen Anerkennung der Kalibrierscheine. Die weiteren Unterzeichner innerhalb und außerhalb Europas sind den Internetseiten von EA ([www.european-accreditation.org](http://www.european-accreditation.org)) und ILAC ([www.ilac.org](http://www.ilac.org)) zu entnehmen.

Ende des Kalibrierscheines




Certificate Of Completion

Envelope Id: B4CC1349-9D75-4B4F-B756-98D4A6AA27AD		Status: Completed
Subject: Complete with Docusign: CAL023-25 Cert PKF64-9E-2663, 5. 2024-05-02_Kalibrierschein GMH3710_SN ...		
Source Envelope:		
Document Pages: 13	Signatures: 8	Envelope Originator:
Certificate Pages: 5	Initials: 0	Anke Ruland
AutoNav: Enabled		124 Bernard E. Saint Jean Drive
Envelopeld Stamping: Enabled		East Falmouth, MA 02536
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna		aruland@accintl.com
		IP Address: 89.244.87.79


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Status: Original	Holder: Anke Ruland	Location: DocuSign
05-Feb-2025   09:44	aruland@accintl.com	

Signer Events

Signer Events	Signature	Timestamp
Konstantin Velmozhko kvelmozhko@accintl.com Sales Representative Security Level: Email, Account Authentication (Required)	  Signature Adoption: Pre-selected Style Signature ID: E5BFD732-4EFC-4EB0-B7B7-9F1429452944 Using IP Address: 95.90.239.177  With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I am the author of this document I am the author of this document I am the author of this document I am the author of this document	Sent: 05-Feb-2025   09:48 Viewed: 05-Feb-2025   17:58 Signed: 05-Feb-2025   18:00

Electronic Record and Signature Disclosure:  
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Anke Ruland aruland@accintl.com Security Level: Email, Account Authentication (Required)	  Signature Adoption: Pre-selected Style Signature ID: 287EDE5D-741C-4A83-BAAB-C91F1CAC3098 Using IP Address: 89.244.87.101  With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I have reviewed this document I have reviewed this document I have reviewed this document I approve this document	Sent: 05-Feb-2025   18:00 Viewed: 10-Feb-2025   09:35 Signed: 10-Feb-2025   09:37
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Electronic Record and Signature Disclosure:  
Accepted: 25-Jul-2024 | 10:21  
ID: 1288ca71-7741-4ae0-85f4-90cb4bedd557

In Person Signer Events

Editor Delivery Events

Signature

Status

Timestamp

Timestamp

Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Samantha Rhead srhead@acciuk.co.uk Security Level: Email, Account Authentication (Required) <b>Electronic Record and Signature Disclosure:</b> Accepted: 25-May-2022   11:24 ID: 74cf2578-1652-4cfc-acab-622079647196	<div>COPIED</div>	Sent: 10-Feb-2025   09:37 Viewed: 10-Feb-2025   16:27
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	05-Feb-2025   09:48
Certified Delivered	Security Checked	10-Feb-2025   09:35
Signing Complete	Security Checked	10-Feb-2025   09:37
Completed	Security Checked	10-Feb-2025   09:37
Payment Events	Status	Timestamps
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To contact us by email send messages to: [ejohnson@acciusa.com](mailto:ejohnson@acciusa.com)

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- ii. send us an e-mail to [ejohnson@acciusa.com](mailto:ejohnson@acciusa.com) and in the body of such request you must state your e-mail, full name, US Postal Address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

**Required hardware and software**

Operating Systems:	Windows® 2000, Windows® XP, Windows Vista®; Mac OS® X
Browsers:	Final release versions of Internet Explorer® 6.0 or above (Windows only); Mozilla Firefox 2.0 or above (Windows and Mac); Safari™ 3.0 or above (Mac only)
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Screen Resolution:	800 x 600 minimum

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