

ISO/IEC 17025:2017

מעבדות כיול

תעודת הסמכה מס' 0437

אס. אי. שרותי פארמה בע"מ

כתובת אתר ייחוס: הזורע 1 ; ד.נ העמקים 3658100 קיבוץ הזורע

עד יום: 03.11.2026

בתוקף מיום:24.07.2024

הארגון נבדק ונבחן על ידי הרשות הלאומית להסמכת מעבדות (להלן הרשות) ונמצא ראוי להסמכה בהתאם לנספח פירוט היקף ההסמכה המצורף לתעודה זו, המהווה חלק בלתי נפרד ממנה ומספרו זהה למספר התעודה.

הסמכה מצביעה על כשירות מקצועית ותפעול מערכת ניהול איכות בעלת הכרה בינלאומית.

הארגון המוסמך על ידי הרשות, עומד בתקנים/ בדרישות המפורטים מעלה. דרישות התקנים הם לכשירות מקצועית ולמערכות ניהול, שהינן הכרחיות למתן תוצאות אמינות. הסמכה זו ניתנה בהתאם לכללי ISO/IEC 17011:2017 לפיהם פועלת הרשות ובמסגרתם מקיימת פיקוח שוטף על הארגון לצורך בחינת תפקודו המתמשך בהתאם לדרישות ההסמכה.

ההסמכה תקפה כל עוד הארגון עונה לאמות המידה שנקבעו על ידי הרשות.

.(EA) European Accreditation Cooperation מול ארגון (MLA) מול הסכם הכרה רב צדדי

תעודה זו אינה מהווה אישור לפי סעיף 12 לחוק התקנים.

04/11/2018 :תאריך הסמכה ראשון

אתי פלר מנכ"ל הרשות הלאומית להסמכת מעבדות

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Calibration Laboratory

ISO/IEC 17025:2017

Accreditation Certificate No. 0437 SE Pharma Services Ltd.

Main site address: Kibbutz Hazorea, 3658100, Israel

Valid from:24.07.2024 Until: 03.11.2026

The organization was assessed by the Israel Laboratory Accreditation Authority (ISRAC) and found to be worthy of accreditation to the detailed schedule attached.

The schedule is an integral part of this certificate and is numbered with the above certificate number.

Accreditation demonstrates technical competence and operation of an internationally recognized quality management system.

The organization accredited by ISRAC complies with the standards/requirements mentioned above, meets the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically competent results. This accreditation is granted in accordance with the requirements of ISO/IEC 17011:2017, and entails periodic surveillance and reassessment by ISRAC to ensure that the organization continues to comply with the accreditation requirements.

The accreditation is valid provided that the organization continues to meet the criteria as laid down by ISRAC. ISRAC is an EA-MLA (European Accreditation Cooperation Multi-Lateral Agreement) signatory.

This certificate does not constitute an approval in accordance with article 12 of the standard law.

Date of first accreditation: 04.11.2018

Etty Feller
General Manager
Israel Laboratory Accreditation Authority

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Name and Address:

Organization name SE Pharma Services LTD.

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Lab Address Kibbutz Hazorea, 3658100, Israel

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Site: P or T or M, P-Permanent, T-Temporary, M-Mobile

A permanent (P) or temporary (T) place, or a stationary or mobile (M) facility, at or from which the organization performs activities forming part of its scope of accreditation, starting from sampling to final issuance of a report or certificate and / or quality system activities. A temporary (T) site is a site established under the responsibility of an accredited permanent site. All activities performed at a temporary site are the responsibility of the permanent site. An outdoors work is also considered to be a temporary site. Temporary site will be a site that involves work for special project and the activity will be defined in time (up to 2 years).

Type of Scopes: A- Fixed, C- Flexible scope in analytical tests: Type of matrix, analytes, experimental systems and/or analytical characteristics may be subject to changes, in accordance with the laboratory's approved and documented procedures. For details, please refer to the list of Accredited Tests, available from the laboratory upon request.

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Item	Scope Type	Site	Measurand Ins	strument, Gauge	Range [Including margins] (Does not include margins)	Uncertainty of Measurement ¹	Reference Documents	Remarks
Calibra	tion - P	Physica	l quantities - Temperatu	re	<u> </u>		מפרטורה	כיול - גדלים פיזיקליים - ט
1	A	P;T	Temperature, Temperature indicators,	טמפרטורה, מדי, בקרי, רשמי ומדמי	[-200 °C to 0 °C]	0.15 °C	EURAMET/cg-11/v.02 Manufacturer/customer	Calibration by means of electrical measurement or
2	A	P;T	controllers, recorders and	טמפרטורה עבור מדי התנגדות	(0 °C to 250 °C]	0.4 °C	specifications	simulation
3	A	P;T	simulators for Resistance sensors		(250 °C to 850 °C]	0.6 °C	SOP-CAL-07	
4	A	P;T	Temperature,	טמפרטורה,	[-200 °C to 0 °C]	0.7 °C	EURAMET/cg-11/v.02	Calibration by means of
5	A	P;T	Temperature indicators, controllers, recorders and simulators for Base metal thermocouple	מדי, בקרי, רשמי ומדמי טמפרטורה עבור צמדים תרמיים ,מתכות בסיסיות סוג K	(0 °C to 1372 °C]	0.6 °C	Manufacturer/customer specifications SOP-CAL-07	electrical measurement or simulation including cold junction compensation
			Туре К					
6	A	P;T	Temperature, Temperature indicators, controllers, recorders and simulators for Base metal thermocouple Type J	טמפרטורה, מדי, בקרי, רשמי ומדמי טמפרטורה עבור צמדים תרמיים ,מתכות בסיסיות מסוג J	[-200 °C to 1200 °C]	0.6 °C	EURAMET/cg-11/v.02 Manufacturer/customer specifications SOP-CAL-07	Calibration by means of electrical measurement or simulation including cold junction compensation
7	A	P;T	Temperature, Temperature indicators, controllers, recorders and simulators for Base metal thermocouple Type T	טמפרטורה, מדי, בקרי, רשמי ומדמי טמפרטורה עבור צמדים תרמיים ,מתכות בסיסיות סוג T	[-200 °C to 400 °C]	0.6 ℃	EURAMET/cg-11/v.02 Manufacturer/customer specifications SOP-CAL-07	Calibration by means of electrical measurement or simulation including cold junction compensation
8	A	P;T	Temperature,	טמפרטורה,	[-35 °C to 165 °C]	0.1 °C	ITS-90	Calibration bath
9	A	P;T	Digital and mechanical thermometers with sensor.	מדי טמפרטורה דיגיטליים ומכניים עם רגש.	(165 °C to 300 °C]	0.25 °C	ASTM E2877 126 נוהל משרד הבריאות מסי Manufacturer instructions SOP-CAL-02	PRT, TC

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Item	Scope Type	Site	Measurand Instrument, Gauge		Range [Including margins] (Does not include margins)	Uncertainty of Measurement ¹	Reference Documents	Remarks					
Calibra	ibration - Physical quantities - Temperature												
10	A	Т	Temperature, Temperature indicators, controllers and recorders in controlled temperature transport vehicles and refrigeration rooms.	טמפרטורה, מדי, בקרי ורשמי טמפרטורה ברכב להובלה בטמפרטורה מבוקרת וחדרי קירור.	-30 °C to 30 °C	0.5 °C	ח"י 1291 Manufacturer/customer specifications SOP-CAL-14	RRT, TC, Data logger					
11 12 13	A A A	P P P	Temperature, Temperature meters, data loggers, sensors	טמפרטורה, מדי טמפרטורה, אוגרי נתונים לטמפרטורה, רגשי טמפרטורה	[-40 °C to 0 °C] (0 °C to 50 °C] (50 °C to 150 °C]	0.3 °C 0.2 °C 0.4 °C	ITS-90 Manufacturer/customer specifications SOP-CAL-04	Temperature controlled chamber PRT, TC					
14	A	P;T	Temperature, Temperature, calibration of temperature instruments in ambient air	טמפרטורה, טמפרטורה, כיול מדי טמפרטורה באוויר סביבתי	[10 °C to 50 °C]	0.5 °C	Manufacturer/customer specifications Customer requirements SOP-CAL-03	PRT, TC, Reference temperature and humidity probe. Single point calibration in ambient conditions					
15	A	P;T	Temperature, Freezing chambers Including uniformity	טמפרטורה, תאי הקפאה, מקפיאים. כולל בדיקת אחידות.	[-80 °C to -20 °C]	0.8 °C	DKD-R-5-7 Manufacturer/customer specifications SOP-CAL-05	PRT, TC, Data logger					
16	A	P;T	Temperature, Freezers, Incubators,	טמפרטורה, מקפיאים, אינקובטורים, תאי	[-20 °C to 60 °C]	0.5 °C	DKD-R-5-7 DIN 12880	PRT, TC, Data logger					
17	A	P;T	Temperature chambers, Ovens, Autoclaves.	טמפרטורה, תנורים, אוטוקלבים כולל בדיקת אחידות	(60 °C to 150 °C]	0.8 °C	ISO17665 Manufacturer/customer						
18	A	P;T	Including uniformity		(150 °C to 260 °C]	1.0 °C	specifications SOP-CAL-05						
19 20	A A	P;T P;T	Temperature, Temperature controlled bath Including uniformity	טמפרטורה, אמבט מבוקר טמפרטורה כולל בדיקת אחידות.	[-196 °C to 150 °C] (150 °C to 260 °C]	0.1 °C 0.25 °C	Manufacturer/customer specifications SOP-CAL-05	PRT, TC, Data logger					

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Item	Scope Type	Site	Measurand Instr	rument, Gauge	Range [Including margins] (Does not include margins)	Uncertainty of Measurement ¹	Reference Documents	Remarks
Calibra	ition - P	Physica	l quantities - Temperature	е			מפרטורה	כיול - גדלים פיזיקליים - ט
21	A	P;T	Temperature, Temperature indicators,	טמפרטורה, מדי, בקרי ורשמי טמפרטורה	[-80 °C to -20 °C)	0.35 °C	Manufacturer/customer specifications	RRT, TC, Data logger comparison calibration in
22	A	P;T	controllers and recorders in controlled temperature	בתאים מבוקרי טמפרטורה , אינקובטורים ותנורים.	[-20 °C to 150 °C]	0.3 °C	Customer requirements 126 נוהל משרד הבריאות מסי	customer chamber conditions
23	A	P;T	chambers, incubators & ovens.		(150 °C to 400 °C]	0.4 °C	SOP-CAL-16	
24	A	P;T	Temperature, Temperature Sensor at LN	טמפרטורה, רגש טמפרטורה בחנקן נוזלי	-196 °C	0.1 °C	Manufacturer/customer specifications Customer requirements SOP-CAL-15	RRT, TC, Data logger

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Item	Scope Type	Site	Measurand Instrument, Gauge		Range [Including margins] (Does not include margins)	Uncertainty of Measurement ¹	Reference Documents	Remarks
Calibra	tion - P	Physica	l quantities - Humidity				חות	כיול - גדלים פיזיקליים – ל
25	A	P	Relative Humidity, Hygrometers, Data loggers and humidity sensors	לחות יחסית, מדי לחות, אוגרי נתונים ללחות, רגשי לחות	(15 °C to 50 °C) [15 %rh to 90 %rh]	1.6 %rh	NPL-ISBN 0-904457-24-9 Manufacturer/customer specifications SOP-CAL-04	Temperature and Humidity controlled chamber Reference temperature and humidity probe.
26	A	P;T	Relative Humidity, Calibration of humidity instruments in ambient air	לחות יחסית, כיול מדי לחות באוויר סביבתי	(10 °C to 50 °C) [10 %rh to 90 %rh]	2.0 %rh	Manufacturer/customer specifications Customer requirements SOP-CAL-03	Reference temperature and humidity probe. Single point calibration in ambient conditions
27	A	P;T	Relative Humidity, Humidity controlled chambers	לחות יחסית, תאים מבוקרים לחות	(10 °C to 50 °C) [10 %rh to 90 %rh]	2.0 %rh	NPL-ISBN 0-904457-24-9 Manufacturer/customer specifications SOP-CAL-05	Reference temperature and humidity probe. Humidity data logger.
28	A	P;T	Relative Humidity, Hygrometers, Data loggers and humidity sensors at controlled chambers	לחות יחסית, מדי לחות, אוגרי נתונים ללחות, רגשי לחות בתאים מבוקרים	(5 °C to 50 °C) [5 %rh to 95 %rh]	1.6 %rh	Manufacturer/customer specifications Customer requirements SOP-CAL-16	Reference temperature and humidity probe. comparison calibration in customer chamber conditions

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Item	Scope Type	Site	Measurand Inst	trument, Gauge	Range [Including margins] (Does not include margins)	Uncertainty of Measurement ¹	Reference Documents	Remarks
Calibra	tion - P	Physica	l quantities - Pressure				γn	כיול - גדלים פיזיקליים - ל
29 30 31 32 33 34	A A A A A	P;T P;T P;T P;T P;T	Pressure, Pneumatic pressure, Hydraulic pressure, Pressure gauges and transducers	לחץ, לחץ יחסי פנאומטי לחץ הידראולי מדי לחץ ומתמרי לחץ	[-95 kPa to -2.5 kPa) [-2.5 kPa to -2.0 kPa) [-2.0 kPa to 2.0 kPa) [2.0 kPa to 2.5 kPa] (2.5 kPa to 2000 kPa] (2 MPa to 40 MPa]	0.3 kPa 8.0 Pa 0.4 Pa 8.0 Pa 0.3 kPa 45 kPa	EURAMET/cg-17 OIML-R101 DKD R-6-1 Manufacturer/customer specifications SOP-CAL-06	Pressure calibrator. Calibration can be given in other units as required.
35 36	A	P;T	Pressure, Absolute pressure Pressure gauges and transducers	לחץ, לחץ אבסולוטי מדי לחץ ומתמרי לחץ	[3.5 kPa to 350 kPa] (350 kPa to 1500 kPa]	0.6 kPa 1.5 kPa	EURAMET/cg-17/v.03 OIML-R101 DKD R-6-1 Manufacturer/customer specifications SOP-CAL-06	

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Item	Scope Type	Site	Measurand Instrument, Gauge		Range [Including margins] (Does not include margins)	Uncertainty of Measurement ¹	Reference Documents	Remarks
Calibration - Physical quantities - Mass					3 /			כיול - גדלים פיזיקליים –מסה
37	A	P;T	Mass, Nom automatic weighting machines	מסה, מאזניים לא אוטומטיים	Up to 200 kg	$2 \times \sqrt{\left(\frac{res}{\sqrt{12}}\right)^2 + \left(\frac{mpe}{1.7}\right)^2}$		res- resolution of the balance. mpe- maximum permissible error of the weights according to OIML-R-111. Available standard weights are: OIML class E2 from 1 mg to 200 g, OIML class F1 from 1 mg to 5 kg, OIML class M1 10 kg (20 pieces).

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Item	Scope Type	Site	Measurand Instrument, Gauge		Range [Including margins] (Does not include margins)	CMC Expressed as an Expanded Uncertainty (95%)	Reference Documents	Remarks
Calibra	tion - P	Physica	l quantities – Torque					כיול - גדלים פיזיקליים –מומנט
38	A	P	Torque, Torque Wrenches and	מומנט,	[0.04 Nm to 0.1 Nm]	0.0022 Nm	ISO 6789	Torque measuring system
39	A	P	Drivers	ידיות ומברגי מומנט	(0.1 Nm to 0.2 Nm]	0.003 Nm	Manufacturer/customer specifications	Torque transducers
40	A	P			(0.2 Nm to 0.4 Nm]	0.0065 Nm	SOP-CAL-17	
41	A	P			(0.4 Nm to 0.8 Nm]	0.008 Nm		
42	A	P			(0.8 Nm to 1.2 Nm]	0.012 Nm		
43	A	P			1.2 Nm to 2 Nm]	0.02 Nm		
44	A	P			(2 Nm to 5 Nm]	0.045 Nm		
45	A	P			(5 Nm to 10 Nm]	0.1 Nm		
46	A	P			(10 Nm to 25 Nm]	0.2 Nm		
47	A	P			(25 Nm to 50 Nm]	0.37 Nm		
48	A	P			(50 Nm to 100 Nm]	0.9 Nm		
49	A	P			(100 Nm to 200 Nm]	1.5 Nm		
50	A	P			(200 Nm to 400 Nm]	3.7 Nm		
51	A	P	Torque, Electric screwdrivers	מומנט, מברגות חשמליות	[0.1 Nm to 1 Nm)	0.05 Nm	Manufacturer/customer specifications	Torque measuring system Torque transducers
52	A	P			(1 to 10 Nm]	0.2 Nm	SOP-CAL-18	

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Item	Scope Type	Site	Measurand Instrument, Gauge		Range [Including margins] (Does not include margins)	CMC Expressed as an Expanded Uncertainty (95%)	Reference Documents	Remarks				
Calibro	alibration - Physical quantities - Length											
53	A	P, T	Length, Vernier Caliper	אורך, זחון ורניר	Up to 200 mm]	0.015 mm	ISO 13385-1 DIN 862	Gauge blocks, caliper checker				
54	A	P, T	Digital Caliper	זחון אלקטרוני זחון חוגן	(200 mm to 600 mm]	0.03 mm	Manufacturer/customer specifications					
			Dial Caliper				SOP-CAL-19					
55	A	P, T	Length,	אורך,	Up to 25 mm]	0.0012 mm	ISO 3611	Gauge blocks				
56	A	P, T	Micrometer	מיקרומטר	ter מיקרומטר	(25 mm to 125mm]	0.0017 mm	DIN 863 Manufacturer/customer				
57	A	P, T			(125 mm to 225 mm]	0.0024 mm	specifications SOP-CAL-20					
58	A	P	Length, Length Rod	אורך, מוטות אורך	[25 mm to 100 mm]	0.0032 mm	ASME B89.1.13 Manufacturer/customer	Gauge blocks, Dial indicator				
59	A	P	Length Rod		(100 mm to 200 mm]	0.0048 mm	specifications SOP-CAL-21					
60	A	P; T	Length, Height Gauge	אורך, מד גובה	Up to 600 mm]	0.0055 mm	Based on JIS B 7517 Manufacturer/customer specifications SOP-CAL-22	Caliper checker				

¹⁾ The uncertainty covered by the CMC expressed as the standard measurement uncertainty multiplied by the coverage factor *k* such that the coverage probability corresponds to approximately 95 %.