



ISO/IEC 17025:2017

מעבדות כיוול

תעודת הסמכה מס' 0437

## א.ס. אי. שרותי פארמה בע"מ

כתובת אתר ייחוס: פארק מתם, בניין 22, חיפה, 3190500

עד יום: 03.11.2024

בתוקף מיום: 27.07.2022

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

תעודה זו אינה מהווה אישור לפי סעיף 12 לחוק התקנים.

תאריך הסמכה ראשון: 04/11/2018

אתי פלר  
מנכ"ל

הרשות הלאומית להסמכת מעבדות



הרשות הלאומית להסמכת מעבדות  
Israel Laboratory Accreditation Authority

**Testing Laboratories**

**ISO/IEC 17025:2017**

**Accreditation Certificate No. 0437**  
**SE Pharma Services Ltd.**

**Main site address:** Matam Park, Building 22, Haifa ,319500

**Valid from:27.07.2022**

**Until: 03.11.2024**

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.*

**Etty Feller**  
**General Manager**  
**Israel Laboratory Accreditation Authority**

**Date of first accreditation: 04.11.2018**

Date of signature 05/12/2022

Page No. 2 of: 10



**Name and Address:**

<b>Organization name</b>	SE Pharma Services LTD.
<b>Mail Address</b>	P.O. Box 15038, zip 3190500, Haifa, Israel
<b>Lab Address</b>	Building 22 1 <sup>st</sup> floor, Matam park, Haifa, Israel
<b>Phone</b>	04-3731411
<b>Fax</b>	04-3731347
<b>E-mail (contact person)</b>	<a href="mailto:kerenw@gsap.co.il">kerenw@gsap.co.il</a>

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.



Item	Scope Type	Site	Measurand Instrument, Gauge	Range [Including margins] (Does not include margins)	Uncertainty of Measurement <sup>1</sup>	Reference Documents	Remarks	
<b>Calibration - Physical quantities - Temperature</b> <span style="float: right;"><b>כיוול - גדלים פיזיקליים - טמפרטורה</b></span>								
1	A	P;T	Temperature indicators, controllers, recorders and simulators for Resistance sensors	מדי, בקרי, רשמי ומדמי טמפרטורה עבור מדי התנגדות	[-200 °C to 0 °C]	0.15 °C	EURAMET/cg-11/v.02 Manufacturer/customer specifications SOP-CAL-07	Calibration by means of electrical measurement or simulation
2	A	P;T		(0 °C to 250 °C)	0.4 °C			
3	A	P;T		(250 °C to 850 °C)	0.6 °C			
4	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	[-200 °C to 0 °C]	0.7 °C	EURAMET/cg-11/v.02 Manufacturer/customer specifications SOP-CAL-07	Calibration by means of electrical measurement or simulation including cold junction compensation
5	A	P;T	Type K	(0 °C to 1372 °C)	0.6 °C			
6	A	P;T	Temperature indicators, controllers, recorders and simulators for Base metal thermocouple	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 indicators, controllers, recorders and simulators for Base metal thermocouple	מדי, בקרי, רשמי ומדמי טמפרטורה עבור צמדים תרמיים מתכות בסיסיות סוג T	[-200 °C to 400 °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
8	A	P;T	Digital and mechanical thermometers with sensor.	מדי טמפרטורה דיגיטליים ומכניים עם רגש.	[-35 °C to 165 °C]	0.1 °C	ITS-90 ASTM E2877 נוהל משרד הבריאות מס' 126 Manufacturer instructions SOP-CAL-02	Calibration bath PRT, TC
9	A	P;T			(165 °C to 300 °C)	0.25 °C		
10	A	T	Temperature indicators, controllers and recorders in controlled temperature transport vehicles and refrigeration rooms.	מדי, בקרי ורשמי טמפרטורה ברכב להובלה בטמפרטורה מבוקרת וחדרי קירור.	-30 °C to 30 °C	0.5 °C	1291 ת"י Manufacturer/customer specifications SOP-CAL-14	RRT, TC, Data logger



Item	Scope Type	Site	Measurand Instrument, Gauge	Range [Including margins] (Does not include margins)	Uncertainty of Measurement <sup>1</sup>	Reference Documents	Remarks
			<b>כיול - גדלים פיזיקליים - טמפרטורה</b>				
<b>Calibration - Physical quantities - Temperature</b>							
11	A	P	Temperature meters, data loggers, sensors מדי טמפרטורה, אוגרי נתונים לטמפרטורה, רגשי טמפרטורה	[-40 °C to 0 °C]	0.3 °C	ITS-90 Manufacturer/customer specifications SOP-CAL-04	Temperature controlled chamber PRT, TC
12	A	P		(0 °C to 50 °C)	0.2 °C		
13	A	P		(50 °C to 150 °C)	0.4 °C		
14	A	P;T	Temperature, calibration of temperature instruments in ambient air 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	Freezing chambers Including uniformity 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	Freezers, Incubators, Temperature chambers, Ovens, Autoclaves. Including uniformity מקפיאים, אינקובטורים, תאי טמפרטורה, תנורים, אוטוקלבים כולל בדיקת אחידות	[-20 °C to 60 °C]	0.5 °C	DKD-R-5-7 DIN 12880 ISO17665 Manufacturer/customer specifications SOP-CAL-05	PRT, TC, Data logger
17	A	P;T		(60 °C to 150 °C)	0.8 °C		
18	A	P;T		(150 °C to 260 °C)	1.0 °C		
19	A	P;T	Temperature controlled bath Including uniformity אמבט מבוקר טמפרטורה כולל בדיקת אחידות.	[-196 °C to 150 °C]	0.1 °C	Manufacturer/customer specifications SOP-CAL-05	PRT, TC, Data logger
20	A	P;T		(150 °C to 260 °C)	0.25 °C		
21	A	P;T	Temperature indicators, controllers and recorders in controlled temperature chambers, incubators & ovens. מדי, בקרי ורשמי טמפרטורה, בתאים מבוקרי טמפרטורה, אינקובטורים ותנורים.	[-80 °C to -20 °C]	0.35 °C	Manufacturer/customer specifications Customer requirements נוהל משרד הבריאות מס' 126 SOP-CAL-16	RRT, TC, Data logger comparison calibration in customer chamber conditions
22	A	P;T		[-20 °C to 150 °C]	0.3 °C		
23	A	P;T		(150 °C to 400 °C)	0.4 °C		
24	A	P;T	Temperature Sensor at LN רגש טמפרטורה בחנקן נוזלי	-196 °C	0.1 °C	Manufacturer/customer specifications Customer requirements SOP-CAL-15	RRT, TC, Data logger



Item	Scope Type	Site	Measurand Instrument, Gauge	Range [Including margins] (Does not include margins)	Uncertainty of Measurement <sup>1</sup>	Reference Documents	Remarks
<b>Calibration - Physical quantities - Humidity</b>							<b>כיוול - גדלים פיזיקליים – לחות</b>
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, כיוול 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	Humidity controlled chambers	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



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



Item	Scope Type	Site	Measurand Instrument, Gauge	Range [Including margins] (Does not include margins)	Uncertainty of Measurement <sup>1</sup>	Reference Documents	Remarks
<b>Calibration - Physical quantities - Mass</b>							<b>כיוול - גדלים פיזיקליים - מסה</b>
37	A	P;T	Nom automatic weighting machines מאזניים לא אוטומטיים	Up to 200 kg	$2 \times \sqrt{\left(\frac{res}{\sqrt{12}}\right)^2 + \left(\frac{mpe}{1.7}\right)^2}$	OIML-R76-1	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).





Item	Scope Type	Site	Measurand Instrument, Gauge	Range [Including margins] (Does not include margins)	CMC Expressed as an Expanded Uncertainty (95%)	Reference Documents	Remarks
<b>Calibration - Physical quantities – Torque</b>							<b>כיוול - גדלים פיזיקליים – מומנט</b>
38	A	P	Torque Torque Wrenches and Drivers	מומנט ידיות ומברגי מומנט	[0.04 Nm to 0.1 Nm]	ISO 6789	Torque measuring system
39	A	P	Electric screwdrivers	מברגות חשמליות	(0.1 Nm to 0.2 Nm)	Manufacturer/customer specifications	Torque transducers
40	A	P			(0.2 Nm to 0.4 Nm)	SOP-CAL-17	
41	A	P			(0.4 Nm to 0.8 Nm)		
42	A	P			(0.8 Nm to 1.2 Nm)		
43	A	P			1.2 Nm to 2 Nm]		
44	A	P			(2 Nm to 5 Nm)		
45	A	P			(5 Nm to 10 Nm)		
46	A	P			(10 Nm to 25 Nm)		
47	A	P			(25 Nm to 50 Nm)		
48	A	P			(50 Nm to 100 Nm)		
49	A	P			(100 Nm to 200 Nm)		
50	A	P			(200 Nm to 400 Nm)		
51	A	P	Electric screwdrivers	מברגות חשמליות	[0.1 Nm to 1 Nm)	ISO 6789	Torque measuring system
52	A	P			(1 to 10 Nm)	Manufacturer/customer specifications SOP-CAL-18	Torque transducers



Item	Scope Type	Site	Measurand Instrument, Gauge	Range [Including margins] (Does not include margins)	CMC Expressed as an Expanded Uncertainty (95%)	Reference Documents	Remarks
<b>Calibration - Physical quantities - Length</b>							<b>כיול - גדלים פיזיקליים - אורך</b>
53	A	P, T	Vernier Caliper	Up to 200 mm]	0.015 mm	ISO 13385-1	Gauge blocks, caliper checker
			Digital Caliper			DIN 862	
54	A	P, T	Dial Caliper	(200 mm to 600 mm]	0.03 mm	Manufacturer/customer specifications SOP-CAL-19	
55	A	P, T	Micrometer	Up to 25 mm]	0.0012 mm	ISO 3611	Gauge blocks
						DIN 863	
56	A	P, T		(25 mm to 125mm]	0.0017 mm	Manufacturer/customer specifications	
57	A	P, T		(125 mm to 225 mm]	0.0024 mm	Manufacturer/customer specifications SOP-CAL-20	
58	A	P	Length Rod	[25 mm to 100 mm]	0.0032 mm	ASME B89.1.13	Gauge blocks, Dial indicator
						Manufacturer/customer specifications	
59	A	P		(100 mm to 200 mm]	0.0048 mm	SOP-CAL-21	
60	A	P; T	Height Gauge	Up to 600 mm]	0.0055 mm	Based on JIS B 7517	Caliper checker
						Manufacturer/customer specifications	
						SOP-CAL-22	
61	A	T	Measuring Microscope	Up to 50 mm]	0.0015 mm	Based on JIS B 7184	Standard scales
			Profile Projector			Based on JIS B 7153	Profile projector calibration does not include parts 5.7 & 5.11 at reference document JIS B 7184
62	A	T		[50 mm to 300 mm]	0.0035 mm	Manufacturer/customer specifications	
						SOP-CAL-23	

<sup>1)</sup> 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 %.