

To: Alpha Omega Engineering Ltd.
P.O.B 810
Nof Ha'Galil 1710801

Package Integrity Test

Receiving site: Milouda
Operating Site: Milouda
Date of report: 31.12.24
Laboratory Number: SO24167908
Order Number: 138040 Production: 27.12.24
Sample description: Neuroprobe STR-009080-00 Lot: 93274,93279,93281
2
Date sample received: 30.12.24
Beginning of Test: 31.12.24
End of Test: 31.12.24

Introduction:

The methods described in this document constitute as a standardized test methods and procedures that may be used to demonstrate compliance with the requirements of ISO 11607-1:2019/Amd.1:2023.

1. Package Integrity- Seal Strength Test (Peel Test) ¹

- 1.1. 2 packages tested according method MIM- 47 and to ASTM F88/F88M-24
– 15mm of the seal of the device pouch was tested for Tensile Strength
using LF-Plus, LLOYD INSTRUMENTS testing machine (No.1/121).

Explanations: ¹ - Under accreditation of the Israel Laboratory Accreditation Authority.

2. Test Results:

Test		Peel Test
Specification		Minimum 1.5/1.2 N/15mm (EN868-5 – Annex D)
Result 1	-	3.87500
Result 2	-	4.68840

3. Conclusions:

According to the results above, all the units passed the tests for Package Integrity.

*****End of Test Results*****

Ronit Ben Avraham PhD
Professional Manager
Microbial Laboratory

Authorized Signature

פרח הינו
אביזרים רפואיים
pearah hino
medical devices

Reviewed by

Remarks:

- The laboratory operates under established working procedures which correlate to the international standard ISO/IEC17025 in those Disciplines where accreditation has been granted, as detailed for each site in the schedule of Accreditation.
- The microbiological tests are within the recognized framework of the Ministry of Health as published in the registrations for each site.
- The results relate only to the tested sample.
- This document should be referred to in its entirety, and no part may be quoted or copied to other documents.
- Sampling was carried out by the customer and under his sole responsibility, unless otherwise noted.
- The Israel Laboratory Accreditation Authority is not responsible for the test results.
- The valid results are those of the most updated report.
- Interpretations (of results) are not accredited by the Israel Laboratory Accreditation Authority.