

# Accreditation Certificate

## SteriPack Laboratory Ltd.,

Kilbeggan Road, Clara, Co. Offaly

Testing Laboratory

Registration number: 263T

is accredited by the Irish National Accreditation Board (INAB) to undertake testing as detailed in the Schedule bearing the Registration Number detailed above, in compliance with the International Standard ISO/IEC 17025:2005 2<sup>nd</sup> Edition "General Requirements for the Competence of Testing and Calibration Laboratories"

*(This Certificate must be read in conjunction with the Annexed Schedule of Accreditation)*

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Date of award of accreditation: 01:06:2010

Date of last renewal of accreditation: 01:06:2010

Expiry date of this certificate of accreditation: 01:06:2015

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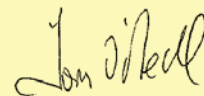
This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 17025 and any further requirements specified by the Irish National Accreditation Board.

Manager:



Dr Adrienne Duff

Chairperson:



Mr Tom O'Neill

Issued on 01 June 2010

Organisations are subject to annual surveillance and are re-assessed every five years. The renewal date on this Certificate confirms the latest date of renewal of accreditation. To confirm the validity of this Certificate, please contact the Irish National Accreditation Board.

The INAB is a signatory of the European co-operation for Accreditation (EA) Testing Multilateral Agreement (MLA) and the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

# Schedule of Accreditation



(Annex to Accreditation Certificate)

Permanent Laboratory:  
Category A

## STERIPACK LABORATORY LTD.

### Mechanical Testing Laboratory

### Chemical Testing Laboratory

**Initial Registration Date :** 1-June-2010  
**Postal Address:** Kilbeggan Road, Clara, Co. Offaly.  
*(Address of other locations as they apply)*  
**Telephone:** +353 (57) 9331888  
**Fax:** +353 (57) 9331887  
**E-mail:** thayden@steripackgroup.com  
**Contact Name:** Gary Leonard / Thomas Hayden  
**Facilities:** Public testing service

13 - September - 2011

# Schedule of Accreditation



Permanent Laboratory:  
 Category A

THE IRISH NATIONAL ACCREDITATION BOARD (INAB) is the Irish body for the accreditation of organisations including laboratories.

Laboratory accreditation is available to testing and calibration facilities operated by manufacturing organisations, government departments, educational institutions and commercial testing/calibration services. Indeed, any organisation involved in testing, measurement or calibration in any area of technology can seek accreditation for the work it is undertaking.

Each accredited laboratory has been assessed by skilled specialist assessors and found to meet criteria which are in compliance with ISO/IEC 17025 or ISO/IEC 15189 (medical laboratories). Frequent audits, together with periodic inter-laboratory test programmes, ensure that these standards of operation are maintained.

## Testing and Calibration Categories:

- Category A:** Permanent laboratory calibration and testing where the laboratory is erected on a fixed location for a period expected to be greater than three years.
- Category B:** Site calibration and testing that is performed by staff sent out on site by a permanent laboratory that is accredited by the Irish National Accreditation Board.
- Category C:** Site calibration and testing that is performed in a site/mobile laboratory or by staff sent out by such a laboratory, the operation of which is the responsibility of a permanent laboratory accredited by the Irish National Accreditation Board.
- Category D:** Site calibration and testing that is performed on site by individuals and organisations that do not have a permanent calibration/testing laboratory. Testing may be performed using
- (a) portable test equipment
  - (b) a site laboratory
  - (c) a mobile laboratory or
  - (d) equipment from a mobile or site laboratory

## Standard Specification or Test Procedure Used:

The standard specification or test procedure that is accredited is the issue that is current on the date of the most recent visit, unless otherwise stated.

## Glossary of Terms

### Facilities:

- Public calibration/testing service:** Commercial operations which actively seek work from others.
- Conditionally available for public calibration/testing:** Established for another primary purpose but, more commonly than not, is available for outside work.
- Normally not available for public calibration/testing:** Unavailable for public calibration/testing more often than not.

Laboratory users wishing to obtain assurance that calibration or test results are reliable and carried out to the Irish National Accreditation Board criteria should insist on receiving an accredited calibration certificate or test report. Users should contact the laboratory directly to ensure that this scope of accreditation is current. INAB will, on request, verify the status and scope.

# Scope of Accreditation



**SteriPack Laboratory Ltd.**

Permanent Laboratory:

Category A

**Mechanical Testing Laboratory**

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1146 Packages and containers	Vibration testing of Shipping containers  Max Load 45kg Peak-peak displacement 1" Frequency range 2-5 Hz	In house method SOPTL009 based on ASTM D 999 method A2. ISTA 1A(2001) and ISTA 2A(2008) fixed frequency vibration method only
	Drop testing of loaded containers by free fall Max capacity 79kg Max drop height 1.8m	In house method SOPTL016 based on ASTM D5276 ISTA 1A(2001) and ISTA 2A(2008) fixed frequency vibration method only
	Compression resistance of a container under a constant load  Max load 2.27kg	In house method SOPTL017 based on ASTM 642 and ASTM D4577 ISTA 1A(2001) and ISTA 2A(2008) fixed frequency vibration method only
	Detection of gross leaks in Medical packaging by internal pressurization (Bubble Test)	In house method SOPTL008 based on ASTM F2096
	Internal pressurisation Failure resistance of unrestrained packages (Burst Test)  Pressure range 5-50psi	In house method SOPTL 015 based on ASTM F1140

# Scope of Accreditation



## SteriPack Laboratory Ltd.

Permanent Laboratory:  
Category A

### Mechanical Testing Laboratory

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1129 <b>Plastics and related products</b> .71    Plastic films	Package Yield of Plastic Film Measured as m <sup>2</sup> /kg, max sample weight of 0.21kgs  Flex Durability of Flexible Barrier Materials (Gelbo) Measured as number of pinholes/300cm <sup>2</sup> at a specified cycle number as per the ASTM method.  Static and Kinetic Co-efficient of Friction of plastic film and sheeting, max load 2kN.	In house method SOPTL001 based on ASTM D 4321  In house method SOPTL011 based on ASTM F 392  In house method SOPTL007 based on ASTM D 1894
1127 <b>Pulpwood, pulp, paper, paperboard and products</b> .15    Hardness tests	Determination of air permeance and air resistance of packaging materials, 0.6 - 33µm/Pa s.	In house method SOPTL005 based on ISO 5636
1129 <b>Plastics and related products</b> .23    Ageing and environmental tests	Conditioning containers, Packages, or Packaging Componentents for testing -40°C to 180°C 15% RH to 90% RH Max chamber size 0.9m X 1.5m X 0.7m	In house method SOPTL002 based on ASTM D 4332

# Scope of Accreditation



## SteriPack Laboratory Ltd.

Permanent Laboratory:  
Category A

### Mechanical Testing Laboratory

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1129    Plastics and related products .23    Ageing and environmental tests	Conditioning containers, Packages, or Packaging Componentents for testing 20°C to 65°C 15% RH to 90% RH Max chamber size 2m X 2m X 2m  Accelerated aging of Sterile Barrier systems. 20°C to 60°C, 15% to 90% RH. Max chamber size 0.9m x 1.5m x 0.7m	In house method SOPTL002 based on ASTM F 1980       In house method SOPTL002 based on ASTM F 1980
1129    Plastics and related products .49    Other tests	Determination of the effects of High Altitude on Packaging systems by Vacuum method. Max chamber size 0.24m x0.3m x 0.25m 100mbar to 1000 mbar  Seal strength of flexible barrier materials, up to 2 kN.  Detection of seal leaks in porous medical Packaging by Dye penetration	In house method SOPTL010 based on ASTM D 6653       In house method SOPTL003 based on ASTM F 88   In house method SOPTL004 based on ASTM F 1929

# Scope of Accreditation



**SteriPack Laboratory Ltd.**

Permanent Laboratory:

Category A

**Chemical Testing Laboratory**

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
<p>737     Plastics .11     Chemical Analysis</p>	<p>FTIR Machine; Perkin Elmer Spectrum 65  Range; Spectral resolution of 0.5cm-1 (cm-1 = wave number)</p>	<p>In house method SOPTL013 based on ASTM E1252-98 Sections 7.9 and 11.4 ASTM E573-01</p>
<p>.24     Thermal Properties</p>	<p>DSC Machine; Perkin Elmer DSC4000  Range; Dynamic range ±175Mw Accuracy ±2% Precision ±0.1% Temperature range - 100°C to 450°C</p>	<p>In house method SOPTL014 based on ISO 11357-1 and ISO 11357-3</p>