

Accreditation Certificate

Anecto Ltd.

Ballybrit Business Park, Galway

Testing Laboratory

Registration number: 175T

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 2nd Edition** “*General Requirements for the Competence of Testing and Calibration Laboratories*”
(This Certificate must be read in conjunction with the Annexed Schedule of Accreditation)

Date of award of accreditation: **12:12:2006**

Date of last renewal of accreditation: **22:07:2016**

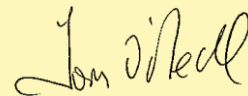
Expiry date of this certificate of accreditation: **22:07:2021**

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:



Chairperson:



Dr Adrienne Duff

Mr Tom O'Neill

Issued on 26 September 2011

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

ANECTO LTD

Mechanical/Environmental Testing Laboratory

| | |
|---|-------------------------|
| <i>Initial Registration Date :</i> | 12-December-2006 |
| <i>Postal Address:</i> | Ballybrit Business Park |
| <i>(Address of other locations as they apply)</i> | Ballybrit Galway |
| <i>Telephone:</i> | +353 (91) 757404 |
| <i>Fax:</i> | +353 (91) 757387 |
| <i>E-mail:</i> | njordan@anecto.com |
| <i>Contact Name:</i> | Mr Noel Jordan |
| <i>Facilities:</i> | Public testing service |

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 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



Anecto Ltd Ballybrit Business Park Galway Mechanical/Environmental Testing Laboratory

Permanent Laboratory:
Category A

| INAB Classification number (P9) Materials/products tested | Type of test/properties measured Range of measurement | Standard specifications Equipment/techniques used |
|--|---|---|
| 1146 Packages and Containers | Visual Inspection | ASTM F1886/ F1886M-2009(2016) |
| 1129 Plastics and related products | Dye Penetration Porous Packaging | ASTM F1929-98(2004) ASTM F1929-2015 |
| | Dye Penetration Non Porous Packaging | ASTM F3039-2015 |
| | Heat Seal Peel Testing Standard Test Method for Seal Strength of Flexible barrier materials | ASTM F88/ F88M-2015 ASTM F88-09 |
| | Detection of gross leaks in Medical packaging by internal pressurisation (Bubble Leak) | ASTM F2096-04 ASTM F2096-11 |
| | Accelerated and Real Time Ageing of Sterile barrier systems | ASTM F1980-02 ASTM F1980-07 ASTM F1980-07(2016) |

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|--|---|---|
| 1127 Pulpwood, Pulp, Paper, Paperboard and Products Corrugated and Paper Packaging | Edge Crush Test Waxed edge method | TAPPI T 811-2007 TAPPI T 811 om-2011 |
| | Edge Crush Test Unwaxed edge method | ISO 3037:2013 |
| | Edge Crush Test Clamp Method (Short Column Test) | TAPPI T839-2008 Clamp Method (Short Column Test) TAPPI T839 om-2012 Clamp Method (Short Column Test) |
| | Grammage Corrugated Fibreboard- Determination of the grammage of the component Papers after separation | ISO 3039-2010 |
| | Paper and Board-Determination of grammage | IS EN ISO536:1997 IS EN ISO536: 2012 IS EN ISO536: 2014 |
| | Cobb test Paper and Board-Determination of water absorptiveness-Cobb Method | ISO 535:2014 |

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Anecto Ltd Ballybrit Business Park Galway Mechanical/Environmental Testing Laboratory

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|--|--|---|
| 1146 Packages and Containers | Transportation testing | ASTM D4169-2005, 2008, 2009, 2016 |
| | Sequential Tests (Conditioning, Compression, Vibration, Shock) Based on above equipment | ASTM D642-15 ISTA Series 1A, B, C, D, E, G, H ISTA Series 2A, B, C, D, E ISTA Series 3A, E, F ISTA Series 7B, D |
| | Transportation testing. Standard Practice for performance testing of packages for single parcel delivery systems | ASTM D7386-2008 ASTM D7386-2016 Standard (TS4) Packs Small (TS1) Packs |
| | Incline Impact Max Load: 750Kg Max Impact Velocity: 3.0m/s Standard Test for Impact Testing for Shipping Containers and Systems Max Load: 200Kg Max Impact Velocity: 3.0m/s | ASTM D880-92 (2002) ASTM D880-92 (2015) |

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|--|--|--|
| 1146 Packages and Containers | Standard Practice for Conditioning containers, packages or packaging components of testing | ASTM D4332-13 ASTM D4332-14 |
| | Standard Test Method for Thermal Insulation Performance of distribution Packages | ASTM D3103-14 e1 |
| | Standard Test Methods for Vibration Testing of Shipping Containers | ASTM D4728-01 ASTM D4728-06 ASTM D4728-06(2012) ASTM D999-08 (Method A1)-2015 |
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Permanent Laboratory:
Category A

| INAB Classification number (P9) Materials/products tested | Type of test/properties measured Range of measurement | Standard specifications Equipment/techniques used |
|--|---|---|
| General Non-explosive stores and equipment | Ingress Protection IPX1 Platform Size: 60cm Diameter | IEC 60529:2001-02 IEC 60529: 2013 Ed 2.2 |
| | IPX5 NozzelSize: 6.3mm | |
| | Ingress Protection IPX6 | ISO 20653:2013 |
| | IPX6K | DIN 40050:1993 Part 9 |
| | Corrosion Resistance Testing Salt Spray Standard practice for operating Salt Spray (Fog) apparatus | ISEN 60068-2-11:1999 ASTM B117-03 ASTM B117-07 ASTM B117-07a ASTM B117-09 ASTM B117-11 ASTM B117-16 |
| | Water Immersion | SAE J2030 JUN2015 Section 6.19 |
| | Salt Fog | SAE J2030 JUN2015 Section 6.12 |
| | Pressure Washing | SAE J2030 JUN2015 Section 6.5 |

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Category A

| INAB Classification number (P9) Materials/products tested | Type of test/properties measured Range of measurement | Standard specifications Equipment/techniques used |
|--|--|--|
| General Non-explosive stores and equipment | Cleaning process with high pressure / steam jet cleaning | DIN 40050 Part 9, 1993 IPX9K |
| | Cleaning process with high pressure / steam jet cleaning | ISO 20653:2013 IPX9K |
| | Dynamic Shock & Bump Max Severity: 20g Pulse Duration: 3 to 30mS Max Load: 150Kg Table Diameter 0.8m | IEC 68-2-27:1987 IEC 68-2-29:1987 IEC60068-2-27:2008 |
| | Max Severity: 100g Pulse Duration: 3 to 30mS Max Load: 22.7Kg Table Diameter 30cm x 30cm | |
| | Max Severity: 1500g Pulse Duration: 0.6 to 60m S Max Load: 90Kg Table Diameter 0.8 m | |
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Category A

| INAB Classification number (P9) Materials/products tested | Type of test/properties measured Range of measurement | Standard specifications Equipment/techniques used |
|--|---|--|
| General Non-explosive stores and equipment | DEGREES OF PROTECTION PROVIDED BY ENCLOSURES (IP CODE) - IP1X, IP2X, IP3X, IP4X, IP5X, IP6X, IP5kX & IP6kX | IEC 60529 Edition 2.1 2001-02 |
| | Road vehicles - Degrees of protection (IP code) - Protection of electrical equipment against foreign objects, water and access: IP1X, IP2X, IP3X, IP4X, IP5X, IP6X, IP5kX & IP6kX | ISO 20653-2013 |
| | ROAD VEHICLES; DEGREES OF PROTECTION (IP-CODE); PROTECTION AGAINST FOREIGN OBJECTS; WATER AND CONTACT; ELECTRICAL EQUIPMENT IP1X, IP2X, IP3X, IP4X, IP5X, IP6X, IP5kX & IP6kX | DIN 40050-1993 Part 9 |
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| INAB Classification number (P9) Materials/products tested | Type of test/properties measured Range of measurement | Standard specifications Equipment/techniques used |
|--|--|---|
| General Non-explosive stores and equipment | Rough Handling Tests Rough Handling shocks, primarily for equipment - type specimens | IS EN 60068-2-31 (2008) |
| General Non-explosive stores and equipment | DYNAMIC Environmental testing. Test methods. Test Fc. Vibration (sinusoidal) Vibration - Sinusoidal & Random Frequency range: 3 to 2000Hz Max load: 150Kg Pk-Pk Displacement: 25mm Max Acceleration: 17g Table Size: 0.8m diameter Spectral Frequency range: 5 to 2000Hz, 51mm pk-pk, Max Acceleration 100g, Table Diameter 30cm x 30 cm | IEC 60068-2-6:1995-03 IS EN 60068-2-6 / IEC 60068-2-6 (ISEN)2008 / (IEC)2007 |

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Permanent Laboratory:
Category A

| INAB Classification number (P9) Materials/products tested | Type of test/properties measured Range of measurement | Standard specifications Equipment/techniques used |
|--|--|--|
| General Non-explosive stores and equipment | Vibration - Sinusoidal & Random Frequency range: 3 to 2000Hz Max load: 1000Kg Pk-Pk Displacement: 64mm Max Acceleration: 7g Table Size: 1.2m x 1.2m | IEC 60068-2-6:1995-03 IS EN 60068-2-6 / IEC 60068-2-6 (ISEN)2008 / (IEC)2007 IEC 60068-2-27:2008 |
| General Non-explosive stores and equipment | Test methods. Test Fh. Vibration, broad-band random (digital control) and guidance | IEC 60068-2-64:1993-05 IEC 60068-2-64:2008 ISEN 60068-2-64:2008 |
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| INAB Classification number (P9) Materials/products tested | Type of test/properties measured Range of measurement | Standard specifications Equipment/techniques used |
|--|---|--|
| General Non-explosive stores and equipment | <p>ENVIRONMENTAL TESTS</p> <p>CLIMATIC</p> <p>Temperature</p> <p>Steady State & Cyclic</p> <p>Temperature range -60°C to +100°C</p> <p>Max Chamber Size 2.4m x 1.5m x 1.5m</p> <p>Temperature range -40°C to +125°C</p> <p>Max Chamber Size .96m x .96m x .96m</p> <p>Environmental Testing</p> <p>Temperature/humidity cyclic test</p> <p>Temperature range -40°C to +100°C</p> <p>Humidity range 10 - 98%</p> <p>Max Chamber Size 0.96m x 0.96m x 0.96m</p> <p>Temperature range -60°C to +100°C</p> <p>Humidity range: 40 - 95%</p> <p>Max Chamber Size 2.4m x 1.5m x 1.5m</p> <p>Temperature Life</p> | <p>IEC 60068-2-1:2007</p> <p>ISEN 60068-2-1:2007</p> <p>IEC 60068-2-2:2007</p> <p>ISEN 60068-2-2:2007</p> <p>IS EN 60068-2-14 - 2009(IEC)</p> <p>IEC 60068-2-3:1969</p> <p>IEC 60068-2-56:1988</p> <p>IEC 60068-2-78:2012</p> <p>IEC 60068-2-30:2005</p> <p>IS EN 60068-2-14 - 2009(IEC)</p> <p>IS EN60068-230:2005</p> <p>IEC 60068-2-38:1999</p> <p>IS EN 60068-2-38 2009 (IEC)</p> <p>SAE J2030 JUN2015 Section 6.7</p> |
| | <p>Thermal Shock</p> <p>Automated Transfer</p> <p>Max Temperature +150°C</p> <p>Min Temperature - 75°C</p> <p>Max Chamber Size:.45m x .63m x .4m</p> <p>Thermal Shock</p> | <p>IEC 60068-2-14:1986-04</p> <p>IS EN 60068-2-14 - 2009(IEC)</p> <p>SAE J2030 JUN2015 Section 6.13</p> |

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|--|---|--|
| General Non-explosive stores and equipment | Drop Test | SAE J2030 JUN2015 Section 6.17 |
| | Current Test | SAE J2030 JUN2015 Section 6.22 |
| | Current Cycling | SAE J2030 JUN2015 Section 6.25 |
| | Examination of Product | SAE J2030 JUN2015 Section 6.1 |
| | Low Voltage Resistance | SAE J2030 JUN2015 Section 6.2 |
| | Insulation Resistance | SAE J2030 JUN2015 Section 6.3 |
| | Connection Resistance | SAE J2030 JUN2015 Section 6.4 |
| | Visual Examination | SAE J2030 JUN2015 Section 6.27 |
| | Heavy-Duty Electrical Connector Performance Standard-Sections 6.6, 6.15, 6.16, 6.23, 6.24 | SAE J2030 JUN2015 |

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| INAB Classification number (P9) Materials/products tested | Type of test/properties measured Range of measurement | Standard specifications Equipment/techniques used |
|---|--|--|
| 1146 Packages and Containers Packaging for the transportation of dangerous goods Drums: Metals Fibreboard Plastics Jerricans: Metal Plastics Boxes: Fibreboard Plastics Bags: Plastics Textiles Paper Composite packaging Plastics receptacle Glass, porcelain or stone receptacle | Environmental tests Performance tests Drop tests Max Height 1.8m Preconditioning at -18°C (plastics) Stack tests Max Weight 1000Kg (ambient temperature & 40°C as required) Leakproofness tests Max Pressure 30KPa Internal pressure (hydraulic) tests Max Pressure 300 kPa Conditioning at 23°C/50% RH (Fibreboard) as required Preconditioning at -18°C (plastics) | UN Chapter 6.1 Packagings (Ed 16) ISO 16104:2003 UN Modal Regulations Chapter 6.1 Packagings (Orange Book) Ed 17 ISO 16495:2013 |

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| INAB Classification number (P9) Materials/products tested | Type of test/properties measured Range of measurement | Standard specifications Equipment/techniques used |
|--|---|--|
| <p>General Non-explosive stores and equipment including:</p> <p>1129 Plastics and related products</p> | Determining effects of altitude on packaging by vacuum method | <p>ASTM D6653-01(06)</p> <p>ASTM D6653/D6653M-01(2013)</p> |
| <p>Material Testing</p> | <p>Stainless steel needle tubing for the manufacture of medical devices</p> <p>Saline solution - temperature maintained at 23oC ± 2°C</p> | <p>ISO 9626: 1991 (2001) Annex E</p> |
| | <p>Sterile, single-use intravascular catheters -- Part 1: General Requirements</p> | <p>IS EN ISO 10555-1:1997 Annex A</p> <p>IS EN ISO 10555-1:2009 Annex A -</p> <p>IS EN ISO 10555-1:2013 Annex A - Test method for corrosion resistance</p> |
| | <p>Sterile, single-use intravascular catheters -- Part 1: General Requirements</p> | <p>IS EN ISO 10555-1:2015 Annex B - Test method for determining force at break</p> |
| | <p>Luer Testing</p> <p>Gauging</p> <p>Test Method for Liquid Leakage</p> | <p>ISO 594/1-1986 Sec 5.1</p> <p>ISO 594/1-1986 Sec 5.2</p> |

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|---|---|---|
| 1129 Plastics and related products | Standard Practice for Abrasion Resistance of Printed Materials | SUTHERLAND® 2000™ Rub Tester D5264-98 (2001) |
| General Non-explosive stores and equipment including: 1129 Plastics and related products Material Testing | Testing of small-bore connectors for liquids and gases in healthcare applications Luer Testing Leakage by pressure decay test method Falling drop positive-pressure liquid leakage test method Subatmospheric-pressure air leakage test method Stress cracking test method Resistance to separation from axial load test method Resistance to separation from unscrewing Resistance to overriding test method | ISO 80369-7:2016 Part 7 Connectors for intravascular or hypodermic applications Section 6 Performance requirements ISO 80369-20:2015 Common Test Methods Annex B Annex C Annex D Annex E Annex F Annex G Annex H |

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Anecto Ltd Ballybrit Business Park Galway Mechanical/Environmental Testing Laboratory

Permanent Laboratory:
Category A

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|--|--|---|
| 590 Environmental Tests .02 | High Temperature | General Thermotron Chambers - ±125°C MIL-STD 810G Method 501.0, Procedure 1 - Storage |
| .02 | High Temperature | General Thermotron Chambers - ±125°C MIL-STD 810G Method 501.0, Procedure 11 - Operation |
| .01 | Low Temperature | General Thermotron Chambers - ±125°C MIL-STD 810G Method 502.5, Procedure 1 - Storage |
| 590 Environmental Tests | Low Temperature | General Thermotron Chambers - ±125°C MIL-STD 810G Method 502.5, Procedure 11 - Operation |
| .03 | Humidity | General Thermotron Chambers - ±125°C MIL-STD 810G Method 507.5, (Induced Humidity Only) |