

Accreditation Certificate

Synergy Health Ireland Limited t/a STERIS AST

15-16E Mervue Business Park, Mervue, Galway, H91 D3T0

Testing Laboratory

Registration number: 383T


is accredited by the Irish National Accreditation Board (INAB) to undertake testing as detailed in the scope bearing the registration number detailed above, in conformity with ISO/IEC 17025:2017

"General requirements for the competence of testing and calibration laboratories"
(This certificate must be read in conjunction with the publicly available scope of accreditation)

Date of award of accreditation: 13/01/2020
Date of last renewal of accreditation: 11/05/2021
Expiry date of this certificate of accreditation: 11/05/2026

This accreditation shall remain in force until further notice subject to continuing conformity with the above standard, applicable EA/ILAC requirements and any further requirements specified by the Irish National Accreditation Board.

Manager: 
Dr Adrienne Duff

Chairperson: : 
Ms Ita Kinahan

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.

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

Schedule of Accreditation



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| Organisation Name | Synergy Health Ireland Limited |
| Trading As | STERIS AST |
| INAB Reg No | 383T |
| Contact Name | Laura Fahy |
| Address | 15-16E Mervue Business Park, Mervue, Galway, H91 D3T0 |
| Contact Phone No | 91 740 350 |
| Email | laura_fahy@steris.com |
| Website | https://www.steris-ast.com |
| Accreditation Standard | EN ISO/IEC 17025 T |
| Standard Version | 2017 |
| Date of award of accreditation | 13/01/2020 |
| Scope Classification | Mechanical testing |
| Services available to the public ¹ | No |

¹ Refer to document on interpreting INAB Scopes of Accreditation

| Sites from which accredited services are delivered | | |
|--|-------------|---------|
| (the detail of the accredited services delivered at each site are on the Scope of Accreditation) | | |
| | | |
| | Name | Address |
| 1 | Head Office | Galway |

Scope of Accreditation

Head Office

Mechanical Testing

Category: A

| Product categories - Tests | Test detail | Product detail | Range of Measurement | Equipment/Technique | Std. Ref & SOP | |
|---|---|---|--|---------------------|---|--|
| 1101 Metals and metal products - .99 Other tests | Corrosion resistance | Sterile and Single Use Catheters | Sterile, single-use intravascular catheters Part 1: General Requirements | | EN ISO 10555-1:2014 Annex A – Test method for corrosion resistance EN ISO 10555-1:2013/AMD 1:2017 Annex A – Test method for corrosion resistance | |
| 1129 Plastic and related products - .99 Other tests | Luer Test - Falling drop positive-positive pressure liquid leakage test | Small-bore connectors for liquids and gases - connectors for intravascular or hypodermic applications | | | ISO 80369-7:2016 ISO 80369-7:2021 ISO 80369-20:2015 Annex C | |
| | Luer Test - Leakage by pressure decay test | | | | ISO 80369-7:2016 ISO 80369-7:2021 ISO 80369-20:2015 Annex B | |

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| | Luer Test - Resistance to overriding test | | | | ISO 80369-7:2016 ISO 80369-7:2021 ISO 80369-20:2015 Annex H | |
| | Luer Test - Resistance to separation from axial load test | | | | ISO 80369-7:2016 ISO 80369-7:2021 ISO 80369-20:2015 Annex F | |
| | Luer Test - Resistance to separation from unscrewing test | | | | ISO 80369-7:2016 ISO 80369-7:2021 ISO 80369-20:2015 Annex G | |
| | Luer Test - Stress cracking test | | | | ISO 80369-7:2016 ISO 80369-7:2021 ISO 80369-20:2015 Annex E | |
| | Luer Test - Sub atmospheric pressure air leakage test | | | | ISO 80369-7:2016 ISO 80369-7:2021 ISO 80369-20:2015 Annex D | |
| | Peak Tensile Force | Sterile and Single Use Catheters | Sterile, single-use intravascular catheters -- Part 1: General Requirements | | IS EN ISO 10555-1:2014 Annex B - Test method for determining force at break EN ISO 10555-1:2013/AMD 1:2017 Annex B - Test method for determining force at break | |
| 1146 Packages and containers - .01 Physical tests | Accelerated and Real Time Ageing | Plastics and related products | Accelerated and Real Time Ageing | Accelerated and Real Time Ageing of Sterile barrier systems | ASTM F1980-21 | |
| | | | Accelerated and Real Time Ageing | Accelerated and Real Time Ageing of Sterile barrier systems | ASTM F1980-16 ASTM F1980-07(2011) | |

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| Altitude Test | General Equipment | Determining effects of altitude on packaging by vacuum method | | ASTM D6653/D6653M-13(2021) | |
| Bubble Leak Testing | Plastics and related products | Bubble Leak | Detection of gross leak in Medical packaging by internal pressurisation | ASTMF2096-11 ASTM F2096-11(2019) | |
| Concentrated Impact Test | Packages and Containers | | Concentrated impacts to transport packages | ASTM D6344 - 04(2017) | |
| Conditioning containers, packages or packaging components of testing | Packages and Containers | | Standard Practice for Conditioning containers, packages or packaging components of testing | ASTM D4332-13 ASTM D4332-14 | |
| Degree of protection provided by enclosures | General Non-explosive stores and equipment | IP1X, 1P2X, IP3X, IP4X | Degree of protection provided by enclosures (IP-Codes) | IEC 60529:2013-08 ISO 20653:2013 | |
| | | Platform size: 60cm diameter | IPX1 | IEC 60529:2001-02 IEC 60529:2013 Ed2.2 | |
| Drop Test of Loaded Containers | Packages and Containers | | Drop test of loaded containers by freefall | ASTM D5276-19(2023) | |
| Dye Penetration | Plastics and related products | Dye Penetration | Non Porous Packaging | ASTM F3039-2015 ASTM F3039-2023 | |
| | | Dye Penetration | Porous Packaging | ASTM F1929-2012 ASTM F1929-2015 ASTM F1929-2023 | |
| Dynamic Shock & Bump | General Non-explosive stores and equipment | Max Severity: 100g Pulse Duration: 0.6 to 60mS Max Load: 90Kg Table Diameter: 0.8m | Dynamic Shock & Bump | IEC 60068-2-27:2008 EN 60068-2-27:2009 | |
| Heat Seal Peel Testing Seal Strength of Flexible barrier materials | Plastics and related products | Heat Seal Peel Testing | Seal Strength of Flexible barrier materials | ASTM F88/F88M-23 ASTM F88 / F88M-2021 ASTM F88/ F88M-2015 ASTM F88-09 | |

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| Incline Impact | Packages and Containers | Max Load: 200kg Max Impact Velocity: 3.0m/s | Standard Test for Impact Testing for Shipping Containers and Systems | ASTM D880-92(2021) | |
| | | Max Load: 750 kg Max Impact Velocity: 3.0 m/s | Impact testing for shipping containers and systems | ASTM D880-92(2015) | |
| Peel Test Determination of a strength of the seal joint for pouches and reel material | | | | EN 868-5:2009 Annex D EN 868-5:2018 Annex D | |
| Peel Test Determination of peel characteristics of paper/plastic laminate products | | | | EN 868-5:2009 Annex E EN 868-5:2018 Annex E | |
| Transportation testing | | Transportation testing | Standard Practice for performance testing of packages for single parcel delivery systems | ASTM D7386-2016 ASTM D7386-2012 Standard (TS4) Packs Small (TS1) Packs | |
| Transportation testing Conditioning Compression Vibration Shock | | Conditioning, Compression, Vibration, Shock | Sequential Tests (Conditioning, Compression, Vibration, Shock) based on above equipment | ASTM D4169-2022 ASTM D4169-2005, 2008, 2009, 2014, 2016 ASTM D642-20 ISTA Series 1A, B, C, D, E, G, H ISTA Series 2A, B, C, ISTA 3A, E, F ISTA Series 7D | |
| Vibration Testing of Shipping Containers | General Non-explosive stores and equipment | | Standard Test Methods for Vibration Testing of Shipping Containers | ASTM D4728-17 ASTM D999-08 (2015) Method A1 | |
| Vibration, broad-band random | | | 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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| | | | | | ISEN 60068-2-64:2008&A1:2019 | |
| 1146 Packages and containers - .99 Other tests | Climatic Stressing of Packaging System for Single Parcel Delivery | Packaging System | | Standard Practice for Conditioning containers, packages or packaging components of testing | ASTM F2825-18 | |
| | Conditioning containers, packages or packaging components of testing | Packages and Containers | | Standard Practice for Conditioning Containers, Packages or Packaging Components of Testing | ASTM D4332-22 | |
| | Visual Inspection Determining Integrity of Seals for Medical Packaging by Visual Inspection | | Visual Inspection | ASTM F1886 / F1886M-2009(2013) | ASTM F1886 / F1886M-2009(2013) ASTM F1886 / F1886M-16 | |
| 1150 General Non Explosive Stores and Equipment - .01 Environmental Tests | Cold | General equipment | To -60°C | | IEC 60068-2-1:2007 EN 60068-2-1:2007 | |
| | Dry Heat | | To +125°C | | IEC 60068-2-2:2007 EN 60068-2-2:2007 | |
| | Dynamic Shock & Bump | General Non-explosive stores and equipment | Max Severity: 100gPulse Duration: 3 to 30mSMax Load: 150kgTable Diameter: 0.8m | Dynamic Shock & Bump | IEC 60068-2-27:2008 EN 60068-2-27:2009 | |
| | Thermal Shock Automated Transfer | | Max Temperature +150°C Min Temperature - 75°C Max Chamber Size:.45m x .63m x .4m Thermal Shock | Thermal Shock | IS EN 60068-2-14:2009 IEC EN 60068-2-14:2009 | |
| | Vibration - Sinusoidal & Random | | Vibration - Sinusoidal & RandomFrequency range: 1 to | Vibration - Sinusoidal & Random | IEC 60068-2-6:2007 EN 60068-2-6:2008 IEC 60068-2-64:2008 | |

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| | | | 2000HzMax load: 150KgPk-Pk Displacement: 50mmMax Acceleration: 17gTable Size: 0.8m diameterSpectral Frequency range: 1 to 2000Hz, 51mm pk- pk, Max Acceleration 100g, Table Diameter 50cm x 50 cm | | EN 60068-2-64:2008 ISEN 60068-2-64: 2008&A1:2019 | |
| | | | Vibration - Sinusoidal & RandomFrequency range: 1 to 2000HzMax load: 150KgPk-Pk Displacement: 50mmMax Acceleration: 17gTable Size: 0.8m diameterSpectral Frequency range: 1 to 2000Hz, 51mm pk- pk, Max Acceleration 100g, Table Diameter 80cm x 80 cm | Vibration - Sinusoidal & Random | IEC 60068-2-6:2007 EN 60068-2-6:2008 IEC 60068-2-64:2008 EN 60068-2-64:2008 ISEN 60068-2-64: 2008&A1:2019 | |