Irish National Accreditation Board

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.

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Schedule of Accreditation

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
	Luer Test - Resistance to overriding test				ISO 80369-7:2016 ISO 80369-7:2021 ISO 80369-20:2015 Annex

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	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)
	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 and Containers		Standard Practice for Conditioning containers, packages or packaging	ASTM D4332-13 ASTM D4332-14

packages or packaging components of testing			components of testing	
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
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				EN 868-5:2009 Annex E EN 868-5:2018 Annex E

	laminate products				
	Transportation testing		Transportation testing	Standard Practice for performance testing of packages for single parcel delivery systems	ASTM D7386-2016ASTM D7386-2012Standard (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 D4169-23 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, D
	Vibration Testing of Shipping Containers			Standard Test Methods for Vibration Testing of Shipping Containers	ASTM D4728-17 ASTM D999-08 (2015) Method A1
	Vibration, broad-band random	General non-explosive stores and equipment		Vibration, broad-band random (digital control) and guidance	IEC 60068-2-64:1993-05 IEC 60068-2-64:2008 ISEN 60068-2-64:2008 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	Cold	General equipment	To -60°C		IEC 60068-2-1:2007 EN 60068-2-1:2007

and Equipment - .01 Environmental Tests					
	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 +150ºC Min Temperature - 75ºC 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 & Random Frequency range: 1 to 2000HzMax load: 150KgPk-Pk Displacement: 50mmMax Acceleration: 17gTable Size: 0.8m diameter Spectral Frequency range: 1 to 2000Hz, 51mm pk-pk, Max Acceleration 100g Table Diameter 50cm x 50 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
			Vibration - Sinusoidal & Random Frequency range: 1 to 2000HzMax load: 150KgPk-Pk Displacement: 50mmMax Acceleration: 17gTable Size: 0.8m diameter Spectral 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