

# Accreditation Certificate

## Synergy Health Ireland Ltd

IDA Business & Technology Park, Tullamore, Offaly, R35 X865

### Testing Laboratory

Registration number: 164T

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)*

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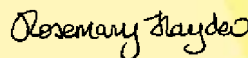
Date of award of accreditation: 23/05/2005

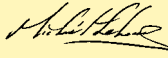
Date of last renewal of accreditation: 04/07/2024

Expiry date of this certificate of accreditation: 04/07/2029

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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:   
Ms Rosemary Hayden

Chairperson:   
Dr Micheal Lehan

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



|   |  |
|---|--|
| Organisation Name                             | Synergy Health Ireland Ltd   |
| Trading As                                    |  |
| INAB Reg No                                   | 164T   |
| Contact Name                                  | Stephanie Parsons  |
| Address                                       | IDA Business & Technology Park, Tullamore,<br>Offaly, R35 X865                 |
| Contact Phone No                              | 057 9349910  |
| Email   | <a href="mailto:stephanie_parsons@steris.com">stephanie_parsons@steris.com</a> |
| Website                                       |  |
| Accreditation Standard                        | ISO 17025 T  |
| Date of award of accreditation                | 23/05/2005   |
| Scope Classification                          | Biological and veterinary testing  |
| Services available to the public <sup>1</sup> | Yes  |

<sup>1</sup> 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  | Business Office | IDA Business & Technology Park, Tullamore, Offaly, R35 X865 |

# Scope of Accreditation

## Business Office

### Biological and Veterinary Testing

Category: A

| Biology/veterinary field - Tests  | Test name        | Technique   | Matrix          | Equipment   | Std. reference   |
|---|------------------|---|-----------------|---|--|
| 803 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01<br>Culture of bacteria | Microbial counts | WI-LAB-015 Bioburden (Pour plate and membrane filtration)   | Medical devices | WI-LAB-15 Bioburden   | WI-LAB-015 based on ISO 11737-1:2018   |
|   | Sterility Tests  | WI-LAB-042- Sterility test using TSB incubated at 20°C - 25°C or FTM incubated at 30°C - 35°C<br>Sterility Test using TSB incubated at 28°C - 32°C<br>WI-LAB-041 Bacteriostatis and Fungistatsis Test | Medical Devices | WI-LAB-042 Sterility, WI-LAB-041 Bacteriostatis and Fungistatsis Test | WI-LAB-042 based on US and European Pharmacopeia (Current Revision)<br>WI-LAB-042 based on EN ISO 11137-2:2013 and ISO 11737-2:2019<br>WI-LAB-041 based on US and European Pharmacopeia (Current Revision) |
| 803 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02<br>Culture of fungi    | Microbial counts | WI-LAB-015 Bioburden (Pour plate and membrane filtration)   | Medical devices | WI-LAB-15 Bioburden   | WI-LAB-015 based on ISO 11737-1:2018   |
|   | Sterility Tests  | WI-LAB-042- Sterility test using TSB incubated at 20°C - 25°C or FTM incubated at 30°C - 35°C   | Medical Devices | WI-LAB-042 Sterility, WI-LAB-041 Bacteriostatis and Fungistatsis Test | WI-LAB-042 based on US and European Pharmacopeia (Current Revision)  |

|   |                 |   |                 |                |  |
|---|-----------------|---|-----------------|----------------|--|
|   |                 | Sterility Test using TSB incubated at 28°C - 32°C<br>WI-LAB-041 Bacteriostatis and Fungistatis Test |                 |                | WI-LAB-042 based on EN ISO 11137-2:2015 and ISO 11737-2:2019<br>WI-LAB-041 based on US and European Pharmacopeia (Current Revision). Plus based on EN ID ISO 11137-2:2015 and ISO 11737-2:2019 |
| 822 Detection of Bacterial Endotoxins - .01 Kinetic Turbidimetric, CE marked commercial systems | Endotoxin tests | Turbidimetric method: 0.01 to 10 EU/mL  | Medical devices | WI-LAB-027-LAL | Method based on US and European Pharmacopeia (Current revision)  |
| 822 Detection of Bacterial Endotoxins - .03 Gel-clot test, CE marked commercial systems         |                 | Gel Clot method: 0.007 to 0.25 EU/mL  | Medical devices | WI-LAB-027-LAL | Method based on US and European Pharmacopeia (Current revision)  |