

# Schedule of Accreditation



|   |  |
|---|--|
| Organisation Name                             | Synergy Health Ireland Ltd                                     |
| Trading As                                    |  |
| INAB Reg No                                   | 164T   |
| Contact Name                                  | Brenda Molloy  |
| Address                                       | IDA Business & Technology Park, Tullamore,<br>Offaly, R35 X865 |
| Contact Phone No                              | 057 9349910  |
| Email   | Brenda_Molloy@steris.com                                       |
| Website                                       |  |
| Accreditation Standard                        | ISO 17025 T  |
| Date Initially Awarded                        | 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 Culture of bacteria | Microbial counts | WI-LAB-015<br>Bioburden (Pour plate and membrane filtration)   | Medical devices | WI-LAB-15<br>Bioburden   | WI-LAB-015<br>based on ISO 11737-1:2006   |  |
|  | Sterility Tests  | I-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>I-LAB-041<br>Bacteriostatis and Fungistatsis Test | Medical devices | I-LAB-042 Sterility, I-LAB-041<br>Bacteriostatis and Fungistatsis Test | I-LAB-042 based on US and European Pharmacopeia (Current Revision)<br>I-LAB-042 based on EN ISO 11137-2:2013 and ISO 11737-2:2009<br>I-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 Culture of fungi    | Microbial counts | WI-LAB-015<br>Bioburden (Pour plate and membrane filtration)   | Medical devices | WI-LAB-15<br>Bioburden   | WI-LAB-015<br>based on ISO 11737-1:2006   |  |
|  | Sterility Tests  | I-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>I-LAB-041<br>Bacteriostatis and Fungistatsis Test | Medical devices | I-LAB-042 Sterility, I-LAB-041<br>Bacteriostatis and Fungistatsis Test | I-LAB-042 based on US and European Pharmacopeia (Current Revision)<br>I-LAB-042 based on EN ISO 11137-2:2015 and ISO 11737-2:2009<br>I-LAB-041 based on US and European Pharmacopeia (Current Revision). Plus based on EN ID ISO 11137- |  |

|   |                 |  |                 |                |   |  |
|---|-----------------|--|-----------------|----------------|---|--|
|   |                 |  |                 |                | 2:2015 and ISO 11737-2:2009                                     |  |
| 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) |  |