



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

**STERIS Applied Sterilization Technologies**

5960 Heisley Road  
Mentor  
Ohio  
44060  
USA

Holds Certificate Number:

MD 741352

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-12-21

Latest Revision Date: 2024-10-14

Effective Date: 2024-07-18

Expiry Date: 2027-07-17



Certificate No: MD 741352

## Registered Scope:

The provision of contract gamma, electron beam and X-ray irradiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.

The provision of contract vaporised hydrogen peroxide sterilization services.

The provision of distribution services for the purpose of medical device storage.

The provision of laboratory testing services.

The provision of cross-linking modification of polymers and experimental irradiation processes.

The provision of irradiation for testing gamma to customer requirements fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

The provision of validation studies of cleanrooms, associated controlled environments and related tests and analyses.



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#### Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780  
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Certificate No: MD 741352

| Location  | Registered Activities  |
|---|--|
| Synergy Health Sterilisation UK Ltd<br>Moray Road<br>Elgin Industrial Estate<br>Swindon<br>SN2 8XS<br>United Kingdom              | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.   |
| Synergy Health Sterilisation UK Ltd<br>Roydsdale Way<br>Euroway Industrial Estate<br>Bradford<br>BD4 6SE<br>United Kingdom        | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.<br>The provision of irradiation for testing gamma to customer requirements fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. |
| Synergy Health Sterilisation UK Ltd<br>Marcus Close<br>Tilehurst<br>Reading<br>Berkshire<br>RG30 4EA<br>United Kingdom            | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.   |
| Synergy Health Sterilisation UK Ltd<br>Brunel Close<br>Drayton Fields Industrial Estate<br>Daventry<br>NN11 8RB<br>United Kingdom | The provision of contract gamma and electron beam irradiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.  |
| Synergy Sterilisation (M) Sdn Bhd.<br>Plot 203<br>Kuala Ketil Industrial Estate<br>Kuala Ketil<br>Kedah<br>09300<br>Malaysia      | The provision of contract ethylene oxide, gamma and x-ray sterilization services with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014 and EN ISO 11137-1:2015.  |
| Synergy Health Westport Ltd<br>Lodge Road<br>Westport<br>County Mayo<br>Ireland   | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.   |

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| Location   | Registered Activities   |
|--|---|
| Synergy Health Ireland Ltd<br>IDA Business & Technology Park<br>Tullamore<br>Co. Offaly<br>R35 X865<br>Ireland                           | The provision of contract ethylene oxide and electron beam sterilization services with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014 and EN ISO 11137-1:2015.<br>The provision of contract vaporised hydrogen peroxide sterilization services. |
| Synergy Health Ede BV<br>Morsestraat 3<br>Ede<br>6716 AH<br>The Netherlands  | The provision of a contract gamma irradiation sterilization service with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.  |
| Synergy Health Ede BV<br>Soevereinstraat 2<br>Etten-Leur<br>4879 NN<br>The Netherlands   | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.  |
| Synergy Health Marseille - SAS<br>Site de Marseille<br>MIN 712 - LES Arnavaux<br>MARSEILLE CEDEX 14<br>13323<br>France                   | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.  |
| Synergy Health Allershausen GmbH<br>Kesselbodenstrasse 7<br>Allershausen<br>D-85391<br>Germany   | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.  |
| Synergy Sterilisation South Africa<br>Proprietary Ltd<br>5 Waterpas Street<br>Isando Extension 3<br>Kempton Park<br>1620<br>South Africa | The provision of a contract gamma irradiation sterilization service with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.  |

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| Location   | Registered Activities   |
|--|---|
| Synergy Health (Thailand) Ltd<br>700/465 Amata Nakorn Industrial<br>Moo 7 Tambon Donhuaroh<br>Amphur Muang Chonburi<br>Chonburi<br>20000<br>Thailand | The provision of contract gamma and x-ray irradiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.   |
| Synergy Health Sterilisation UK Ltd<br>1 Alpha Court<br>Capitol Park<br>Thorne<br>Doncaster<br>DN8 5TZ<br>United Kingdom                             | The provision of a contract ethylene oxide sterilization service with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014.                       |
| Synergy Health Ede BV<br>Faunalaan 38<br>Venlo<br>5928 RZ<br>The Netherlands   | The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.   |
| Synergy Health Sterilization UK Ltd<br>Thornhill Road<br>South Marston<br>Swindon, Wiltshire<br>SN3 4TA<br>United Kingdom                            | The provision of laboratory testing services.   |
| Synergy Health Radeberg GmbH<br>Juri-Gagarin-Strasse 15<br>Radeberg<br>01454<br>Germany  | The provision of contract gamma and electron beam irradiation sterilization services with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. |
| Synergy Sterilisation Kulim (M) Sdn. Bhd<br>Lot 71, Kulim Industrial Estate<br>Kulim<br>Kedah<br>09000<br>Malaysia                                   | The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.   |

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| Location   | Registered Activities  |
|--|--|
| Synergy Sterilisation Rawang (M) Sdn. Bhd.<br>Lot 42, Jalan Industri 2/1<br>Rawang Integrated Industrial Park<br>Rawang<br>Selangor<br>48000<br>Malaysia | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.   |
| Synergy Health Marseille - SAS<br>Site de Marcoule<br>Lieu dit Combe Bertrand<br>RD 138<br>CHUSCLAN<br>30200<br>France                                   | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.<br>The provision of irradiation for testing gamma to customer requirements fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.   |
| Synergy Health Däniken AG<br>Hogenweidstrasse 6<br>Däniken<br>CH-4658<br>Switzerland   | The provision of contract gamma and X-ray irradiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015 and cross-linking modification of polymers.   |
| STERIS S.p.A.<br>Via Cà Bertoncina, 29<br>Seriate (BG)<br>24068<br>Italy   | The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.<br>The provision of laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015 and EN ISO 11135:2014.<br>The provision of validation studies of cleanrooms, associated controlled environments and related tests and analyses. |
| STERIS AST CZ s.r.o.<br>Prumyslová Zona Kosikov 80<br>Velka Bites<br>59501<br>Czech Republic   | The provision of a contract ethylene oxide sterilization service with associated testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014.   |
| STERIS S.p.A.<br>Via Einaudi, 3, 5, 7, 9<br>Calcinato (BG)<br>24050<br>Italy   | The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.  |

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| Location   | Registered Activities   |
|--|---|
| STERIS Sterilization Technologies<br>(Suzhou) Ltd<br>No. 26 Xinchang Road<br>Suzhou Industrial Park<br>Jiangsu<br>215125<br>China                                | The provision of a contract ethylene oxide sterilization service with associated laboratory testing services fulfilling applicable quality management system requirements within EN ISO 11135:2014.   |
| STERIS AST d.o.o<br>Pod gabri 18, PC Zeje pri Komendi<br>1218 Komenda<br>Slovenia  | The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.<br>The provision of distribution services for the purposes of medical device storage.              |
| Herotron E-Beam Service GmbH<br>Guardianstr. 6-10<br>06766 Bitterfeld-Wolfen<br>Germany  | The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.<br>The provision of cross-linking modification of polymers and experimental irradiation processes. |
| STERIS Applied Sterilization Technologies<br>5960 Heisley Road<br>Mentor<br>Ohio<br>44060<br>USA   | Group Level Headquarters.   |
| STERIS TOMOE (Thailand) Ltd.<br>700/644 Moo 3<br>Tambon Bankao<br>Amphur Panthong<br>Chonburi<br>20160<br>Thailand   | The provision of a contract gamma irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.  |
| Electron Beam Sdn. Bhd.<br>Lot 7, Jalan Sungai Pinang 4/3<br>Taman Perindustrian Pulau Indah (Fasa 2)<br>Port Klang<br>Selangor Darul Ehsan<br>42920<br>Malaysia | The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.  |

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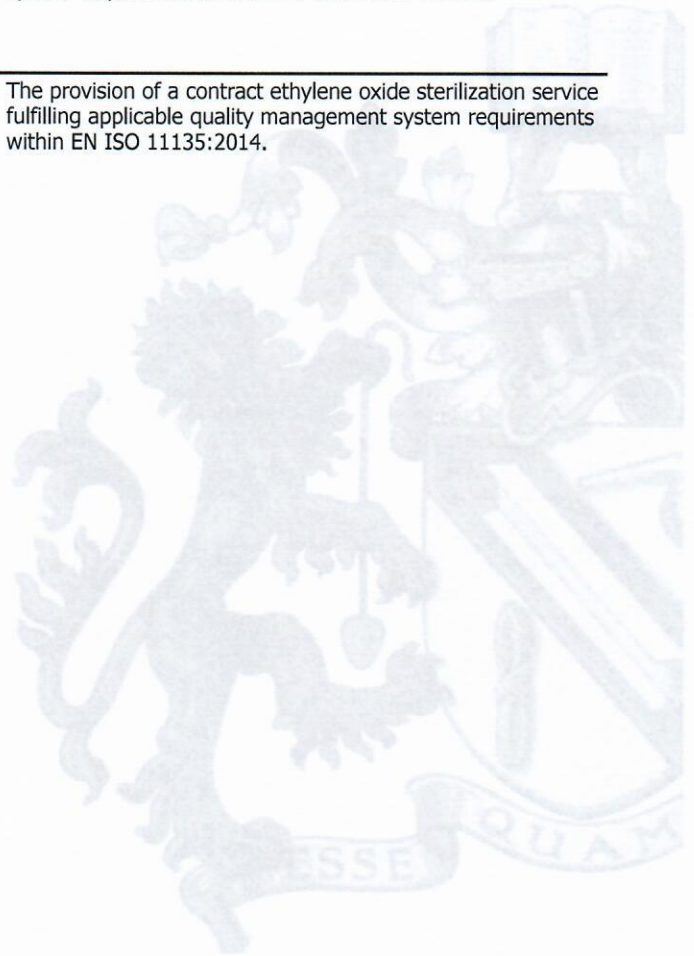
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| Location  | Registered Activities  |
|---|--|
| Synergy Health Ede BV<br>Faunalaan 46<br>Venlo<br>5928 RZ<br>The Netherlands  | The provision of a contract x-ray irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.         |
| STERIS S.p.A.<br>Biassono (Monza) Via Parco, 47<br>Biassono (MB)<br>20853<br>Italy  | The provision of a contract electron beam irradiation sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015. |
| Synergy Sterilisation Kulim (M) Sdn.Bhd<br>Plot 329F, Jalan Cassia Selatan 6/4<br>Kawasan Perindustrian Batu Kawan<br>Seberang Perai Selatan<br>Pulau Pinang<br>14110<br>Malaysia | The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.              |



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## Supplementary Information

Certificate Number: MD 741352  
Date: 14 October 2024  
Issued to: STERIS Applied Sterilization Technologies  
5960 Heisley Road  
Mentor  
Ohio  
44060  
USA

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The holder of the ISO13485 certificate referenced above provides sterilisation services at some or all of the certified locations.

Assessments to achieve and maintain certification at the certified locations are conducted by qualified BSI microbiologists. These assessments include verification that the quality system complies with the full requirements of applicable harmonised sterilisation standards relevant to health care products.

The information provided in this document summarises the harmonised sterilisation standards implemented within the quality system at each certified location. All certified locations have been assessed and found to comply with the full requirements of the harmonised standards specified in the table below.

BSI Assurance UK Limited, BSI The Netherlands B.V. and BSI Americas Inc. apply identical processes for the audit and ISO13485 certification of sterilisation service providers, including certification scheme and competency requirements. Audits are conducted by technical specialists qualified in the field of microbiology.

Should you have any questions regarding the information included in this document, please contact me or BSI's dedicated certificate verification team at [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com).

**Lynette Hilton**  
Digitally signed by Lynette  
Hilton  
Date: 2024.10.29 15:39:31 Z

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Lynette Hilton  
Senior Certification Specialist, Medical Devices  
[lynette.hilton@bsigroup.com](mailto:lynette.hilton@bsigroup.com)

## Certified Locations

| BSI Location Reference | Location Name and Full Address   | Sterilisation Standards |
|------------------------|--|-------------------------|
| ISOTRO-0008903820-051  | STERIS Applied Sterilization Technologies<br>5960 Heisley Road<br>Mentor<br>Ohio<br>44060<br>USA                           | None                    |
| ISOTRO-0008903820-000  | Synergy Health Sterilisation UK Ltd<br>Moray Road<br>Elgin Industrial Estate<br>Swindon<br>SN2 8XS<br>United Kingdom       | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-001  | Synergy Health Sterilisation UK Ltd<br>Roydsdale Way<br>Euroway Industrial Estate<br>Bradford<br>BD4 6SE<br>United Kingdom | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-002  | Synergy Health Sterilisation UK Ltd<br>Marcus Close<br>Tilehurst<br>Reading<br>Berkshire<br>RG30 4EA<br>United Kingdom     | EN ISO 11137-1:2015     |

## Certified Locations

| <b>BSI Location Reference</b> | <b>Location Name and Full Address</b>   | <b>Sterilisation Standards</b>           |
|-------------------------------|---|--|
| ISOTRO-0008903820-003         | Synergy Health Sterilisation UK Ltd<br>Brunel Close<br>Drayton Fields Industrial Estate<br>Daventry<br>NN11 8RB<br>United Kingdom | EN ISO 11137-1:2015                      |
| ISOTRO-0008903820-005         | Synergy Sterilisation (M) Sdn Bhd.<br>Plot 203<br>Kuala Ketil Industrial Estate<br>Kuala Ketil<br>Kedah<br>09300<br>Malaysia      | EN ISO 11135:2014<br>EN ISO 11137-1:2015 |
| ISOTRO-0008903820-006         | Synergy Health Westport Ltd<br>Lodge Road<br>Westport<br>County Mayo<br>Ireland   | EN ISO 11137-1:2015                      |
| ISOTRO-0008903820-007         | Synergy Health Ireland Ltd<br>IDA Business & Technology Park<br>Tullamore<br>Co. Offaly<br>R35 X865<br>Ireland                    | EN ISO 11135:2014<br>EN ISO 11137-1:2015 |

## Certified Locations

| <b>BSI Location Reference</b> | <b>Location Name and Full Address</b>  | <b>Sterilisation Standards</b> |
|-------------------------------|--|--------------------------------|
| ISOTRO-0008903820-009         | Synergy Health Ede BV<br>Morsestraat 3<br>Ede 6716 AH<br>The Netherlands   | EN ISO 11137-1:2015            |
| ISOTRO-0008903820-010         | Synergy Health Ede BV<br>Soeverinstraat 2<br>Etten-Leur<br>4879 NN<br>The Netherlands                                  | EN ISO 11137-1:2015            |
| ISOTRO-0008903820-011         | Synergy Health Marseille - SAS<br>Site de Marseille<br>MIN 712 - LES Arnavaux<br>MARSEILLE CEDEX 14<br>13323<br>France | EN ISO 11137-1:2015            |
| ISOTRO-0008903820-012         | Synergy Health Allershausen GmbH<br>Kesselbodenstrasse 7<br>Allershausen<br>D-85391<br>Germany                         | EN ISO 11137-1:2015            |

## Certified Locations

| BSI Location Reference | Location Name and Full Address   | Sterilisation Standards |
|------------------------|--|-------------------------|
| ISOTRO-0008903820-013  | Synergy Sterilisation South Africa Proprietary Ltd<br>5 Waterpas Street<br>Isando Extension 3<br>Kempton Park<br>1620<br>South Africa                | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-014  | Synergy Health (Thailand) Ltd<br>700/465 Amata Nakorn Industrial<br>Moo 7 Tambon Donhuaroh<br>Amphur Muang Chonburi<br>Chonburi<br>20000<br>Thailand | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-016  | Synergy Health Sterilisation UK Ltd<br>1 Alpha Court<br>Capitol Park<br>Thorne<br>Doncaster<br>DN8 5TZ<br>United Kingdom                             | EN ISO 11135:2014       |
| ISOTRO-0008903820-017  | Synergy Health Ede BV<br>Faunalaan 38<br>Venlo<br>5928 RZ<br>The Netherlands   | EN ISO 11135:2014       |

## Certified Locations

| BSI Location Reference | Location Name and Full Address   | Sterilisation Standards |
|------------------------|--|-------------------------|
| ISOTRO-0008903820-021  | Synergy Health Sterilization UK Ltd<br>Thornhill Road<br>South Marston<br>Swindon, Wiltshire<br>SN3 4TA<br>United Kingdom                                | None                    |
| ISOTRO-0008903820-022  | Synergy Health Radeberg GmbH<br>Juri-Gagarin-Strasse 15<br>Radeberg<br>01454<br>Germany  | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-032  | Synergy Sterilisation Kulim (M) Sdn. Bhd<br>Lot 71, Kulim Industrial Estate<br>Kulim<br>Kedah<br>09000<br>Malaysia                                       | EN ISO 11135:2014       |
| ISOTRO-0008903820-033  | Synergy Sterilisation Rawang (M) Sdn. Bhd.<br>Lot 42, Jalan Industri 2/1<br>Rawang Integrated Industrial Park<br>Rawang<br>Selangor<br>48000<br>Malaysia | EN ISO 11137-1:2015     |

## Certified Locations

| <b>BSI Location Reference</b> | <b>Location Name and Full Address</b>  | <b>Sterilisation Standards</b>           |
|-------------------------------|--|--|
| ISOTRO-0008903820-034         | Synergy Health Marseille - SAS<br>Site de Marcoule<br>Lieu dit Combe Bertrand<br>RD 138<br>CHUSCLAN<br>30200<br>France | EN ISO 11137-1:2015                      |
| ISOTRO-0008903820-035         | Synergy Health Däniken AG<br>Hogenweidstrasse 6<br>Däniken<br>CH-4658<br>Switzerland                                   | EN ISO 11137-1:2015                      |
| ISOTRO-0008903820-039         | STERIS S.p.A.<br>Via Cà Bertoncina, 29<br>Seriate (BG)<br>24068<br>Italy   | EN ISO 11137-1:2015<br>EN ISO 11135:2014 |
| ISOTRO-0008903820-040         | STERIS AST CZ s.r.o.<br>Prumyslová Zona Kosikov 80<br>Velka Bites<br>59501<br>Czech Republic                           | EN ISO 11135:2014                        |

## Certified Locations

| <b>BSI Location Reference</b> | <b>Location Name and Full Address</b>   | <b>Sterilisation Standards</b> |
|-------------------------------|---|--------------------------------|
| ISOTRO-0008903820-044         | STERIS S.p.A.<br>Via Einaudi, 3, 5, 7, 9<br>Calcinate (BG)<br>24050<br>Italy  | EN ISO 11135:2014              |
| ISOTRO-0008903820-046         | STERIS Sterilization<br>Technologies (Suzhou) Ltd<br>No. 26 Xinchang Road<br>Suzhou Industrial Park<br>Jiangsu<br>215125<br>China | EN ISO 11135:2014              |
| ISOTRO-0008903820-047         | STERIS AST d.o.o<br>Pod gabri 18, PC Zeje pri<br>Komendi<br>1218 Komenda<br>Slovenia  | EN ISO 11137-1:2015            |

## Certified Locations



| BSI Location Reference | Location Name and Full Address   | Sterilisation Standards |
|------------------------|--|-------------------------|
| ISOTRO-0008903820-050  | Herotron E-Beam Service GmbH<br>Guardianstr. 6-10<br>06766 Bitterfeld-Wolfen<br>Germany  | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-052  | STERIS TOMOE (Thailand) Ltd.<br>700/644 Moo 3<br>Tambon Bankao<br>Amphur Panthong<br>Chonburi<br>20160<br>Thailand   | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-053  | Electron Beam Sdn. Bhd.<br>Lot 7, Jalan Sungai Pinang 4/3<br>Taman Perindustrian Pulau Indah (Fasa 2)<br>Port Klang<br>Selangor Darul Ehsan<br>42920<br>Malaysia | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-054  | Synergy Health Ede BV<br>Faunalaan 46<br>Venlo<br>5928 RZ<br>The Netherlands   | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-055  | STERIS S.p.A.<br>Biassono (Monza) Via Parco, 47<br>Biassono (MB)<br>20853<br>Italy   | EN ISO 11137-1:2015     |
| ISOTRO-0008903820-056  | Synergy Sterilisation Kulim (M) Sdn.Bhd<br>Plot 329F, Jalan Cassia Selatan<br>6/4  | EN ISO 11135:2014       |

|  |  |  |
|--|--|--|
|  | Kawasan Perindustrian Batu<br>Kawan<br>Seberang Perai Selatan<br>Pulau Pinang<br>14110<br>Malaysia |  |
|--|--|--|