By Royal Charter

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** **CE 550336**

Issued To: **Systagenix Wound Management Ltd**
**Gargrave**
**North Yorkshire**
**BD23 3RX**
**United Kingdom**

In respect of:

**The design, development and manufacture of medicated and non-medicated sterile wound dressings (non-adherent, hydrogel, film, bovine collagen, hydrocolloid, cellulose and foam, with activated charcoal, petroleum-based or alginate components), and non-sterile hydrogels.**
**Those aspects of Annex II concerned with securing and maintaining sterile conditions of non-medicated wound care products (non-adherent, bandage, gauze, absorbent pad and swab).**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-06-24** Date: **2021-05-25** Expiry Date: **2024-05-26**

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**Supplementary Information to CE 550336**

Issued To:

**Systagenix Wound Management Ltd**
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| Number | Device Name | Intended purpose per IFU |
|---|---|---|
| **Class III** | | |
| - | Actisorb (Silver) | As per CE 552030 |
| - | Fibracol | As per CE 552031 |
| - | Inadine | As per CE 552032 |
| - | Promogran | As per CE 552033 |
| - | Promogran Prisma | As per CE 552034 |
| **Class IIb** | | |
| **MD 0301** | Tielle Foam Dressings | Management of non/low to heavily exuding or bleeding wounds or surgical incisions |
| **MD 0301** | Solugel Gel | Management of minor burns, scalds, sunburn, chronic ulcerative wounds, cuts, grazes |
| **MD 0301** | NU-GEL Hydrogel | Debridement and desloughing of wounds and management of chronic wounds |
| **MD 0301** | Nu-Derm Hydrocolloid Dressings | For use on dry/light to moderately exuding wounds |
| **MD 0301** | N-A Knitted Viscose Dressings | For use on leg ulcers, pressure sores, burns and other granulating wounds |
| **MD 0301** | Biosorb Gelling Fibre Dressing | For use on moderate to heavily exuding wounds |

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| Number | Device Name | Intended purpose per IFU |
|---|---|---|
| **Class IIb** | | |
| **MD 0301** | Bioclusive Film Dressing | Management of non to lightly exuding wounds and catheter securement |
| **MD 0301** | Adaptic Non-Adhering Dressings | For use in dry to heavily exuding wounds |
| **MD 0301** | Actisorb (Charcoal) | Management of odorous wounds |
| **Class Is** | | |
| **MD 0301** | Adaptic Digit | Not applicable for Class Is |

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# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

# List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

| | |
|---|---|
| Certificate No: | **CE 550336** |
| Date: | **2021-05-25** |
| Issued To: | **Systagenix Wound Management Ltd**<br>**Gargrave**<br>**North Yorkshire**<br>**BD23 3RX**<br>**United Kingdom** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Aspen Surgical Products Inc.<br>6945 Southbelt Drive, SE<br>Caledonia<br>Michigan<br>49316<br>USA | **Finished Device Supplier** |
| BASF SE<br>BASF Corporation<br>8404 River Road<br>70734-0457 Geismar<br>Louisiana<br>USA | **Crucial Supplier** |
| Chemviron Carbon Cloth Division<br>Rainton Bridge Industrial Estate<br>Houghton - le - Spring<br>Tyne and Wear<br>DH4 5PP<br>UK | **Crucial Supplier** |

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Devro Pty Ltd<br>139 Sydney Road<br>Bathurst<br>New South Wales<br>2795<br>Australia | **Crucial Supplier** |
| Ensign Laboratories Pty Ltd<br>490 Wellington Road<br>Mulgrave<br>Victoria<br>3170<br>Australia | **Manufacture**<br>**Packaging** |
| EUROMED, Inc.<br>25 Corporate Drive<br>Orangeburg<br>New York<br>10962<br>USA | **Finished Device Supplier** |

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Fisher Scientific UK Ltd.<br>Bishop Meadow Road<br>Loughborough<br>LE11 5RG<br>United Kingdom | **Crucial Supplier** |
| Holopack Verpackungstechnik GmbH<br>Plant 2<br>Bahnhofstrasse<br>73453 Untergröningen<br>Germany | **Manufacture**<br>**Moist Heat Sterilization** |
| Isomedix Operations Inc.<br>2 Nucifora Boulevard<br>Chester<br>New York<br>10918<br>USA | **Radiation (E Beam Sterilization)** |

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| KCI Manufacturing<br>IDA Business & Technology Park<br>Dublin Road, Athlone,<br>Co. Westmeath,<br>Ireland | **EU Representative** |
| Palmhive Technical Textiles Limited<br>NTG House, Willow Road<br>Nottingham<br>NG7 2TA<br>United Kingdom | **Crucial Supplier** |
| Sterigenics UK Ltd<br>Cotes Park Lane<br>Somercotes<br>Alfreton<br>DE55 4NJ<br>United Kingdom | **ETO Sterilization** |

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Systagenix Wound Management Manufacturing Ltd<br>Gargrave<br>North Yorkshire<br>BD23 3RX<br>United Kingdom | **Finished Device Supplier Manufacture** |

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# EC Certificate - Full Quality Assurance System Certificate History

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| Date | Reference Number | Action |
|---|---|---|
| 24 June 2009 | 7372237 | First Issue. |
| 08 December 2009 | 7462564 | Certificate Renewal. Updated s/c details – various (minor changes only); change of address for s/c Euromed Inc. |
| 30 September 2011 | 7753720 | Certificate scope amendment (Addition of Class I sterile devices on Annex II, Section 3.2) and removal of subcontractors Ethicon Sårl, Leoni Studer Hard AG, ethicon LLC and Steris Isomedix Services. |
| 20 July 2012 | 7866022 | Change of significant subcontractor names: Isotron Limited to Synergy Health Sterilisation UK Ltd; and BeamOne LLC to Synergy Health AST, LLC. |
| 03 December 2014 | 8195509 | Certificate renewal. Removal of subcontractors Kendall (Covidien), MA; Synergy Health Sterilisation UK Ltd., Reading; Synergy Health Sterilisation UK Ltd., Daventry; Synergy Health AST LLC, Denver; Synergy Health AST LLC, Lima. Scope clarification. |
| 11 April 2016 | 8430686 | Extension to scope to include non-sterile hydrogels. Addition of subcontractor Ensign, Laboratories Pty Ltd, Mulgrave, Victoria. |

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| Date | Reference Number | Action |
|---|---|---|
| 21 July 2016 | 8467635 | Extension of scope to include cellulose based wound dressings and related subcontractors: SFM Limited, Chester Medical Solutions, and Synergy Health, Bradford.<br>Update to certificate to include crucial suppliers Recipharm, Devro, Chemviron Carbon Cloth, BASF and Fisher Scientific. |
| 09 March 2017 | 8689119 | Transfer of sterile film wound dressing from OBL certificate CE 617261 to Full Quality Assurance certificate CE 550336, including addition of Finished Device Supplier Aspen Surgical Products Inc.<br>Addition of 'Manufacture' activity for significant sub-contractor Speciality Fibres and Materials. |
| 19 October 2018 | 9646722 | Addition of significant subcontractors: Synergy Health AST, LLC (Lima and Denver) and Isomedix Operations Inc. (Chester, New York). |

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| Date | Reference Number | Action |
|---|---|---|
| 06 February 2019 | 7779589 | Traceable to NB 0086. |
| 26 November 2019 | 3067436 | Certificate renewal.<br>Inclusion of product tables.<br>Removal of the following Subcontractors :-<br>Chester Medical, Synergy Health (Bradford, Ohio and Denver) and Speciality Fibres and Material.<br>Removal of "an affiliate of Systagenix Wound Management Manufacturing Limited" from the certificate address<br>Addition of Systagenix Wound Management Manufacturing Ltd as a subcontractor. |
| 07 April 2020 | 3159667 | Addition of Palmhive Technical Textiles Limited as a Crucial Supplier. |
| 31 August 2020 | 3270650 | Addition of EU Authorised Representative, KCI Manufacturing, Ireland. |

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| Date | Reference Number | Action |
|---|---|---|
| Current | 3447148 | Addition of "Manufacture" to the services provided by Systagenix Wound Management Manufacturing Ltd, Gargrave.<br>Administrative correction to name and address details of BASF SE.<br>Removal of Recipharm Ltd as a Crucial Supplier. |