



List of Significant Subcontractors

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

Certificate No. **CE 01965**
 Date: **5 Jun 2013**
 Issued to: **Mölnlycke Health Care AB**
Göteborg
Sweden

Subcontractor	Service(s) supplied
Synergy Health AST, Ede Morsestraat 3 6716 AH Ede Netherlands	Sterilization
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Swindon) Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	Gamma Sterilization
Sterigenics 7695 Formula Place San Diego CA 92121 USA	E beam Sterilization
Dakota Pack, Inc. 2421 9th Avenue South Estherville Iowa 51334 USA	Animal substances Supply

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Subcontractor	Service(s) supplied
Pine Ridge Farms 1800 SE Maury St. Des Moines Iowa 50317 USA	Animal substances Supply
Stellen Medical, LLC 1290 Hammond Road St. Paul Minnesota 55110 USA	Control of Sterilization Manufacture
Winner Industries (Shenzhen) Co., Ltd. Winner Industrial Park Bulong Road, Longhua 518109 Shenzhen China	Manufacture Control of Sterilization
Molnlycke Health care Oy Saimaankatu 6 P.O.Box 76 FI-50101 Mikkeli Finland	ETO Sterilization Manufacture



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Mölnlycke Health Care Ltd 2 Omega Drive Irlam Manchester M44 5BJ United Kingdom	Complaints Handling Vigilance
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	Gamma Sterilization
Statens Serum Institut (SSI) Artillerivej 5 2300 Copenhagen Denmark	Manufacture Aseptic Processing
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue du Parc, 29 B-4800 Verviers Belgium	ETO Sterilization

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Biora AB Medeon Science Park SE-205 12 Malmö Sweden	Aseptic Processing Manufacture
Orifice Medicals AB Aktergatan 2 SE-271 53 Ystad Sweden	Packaging
Mölnlycke Health Care Klinipro, s.r.o. Na Novém Poli 382/1 733 01 Karviná – Staré Mesto Czech Republic	Manufacture
Mölnlycke Health Care AB T/A Mölnlycke Health Care SA Parc Industriel B-4300 Waremmé Belgium	E beam Sterilization Manufacture Moist Heat Sterilization
Synergy Health AST, Etten-Leur Soevereinstraat 2 4879 NN Etten-Leur Netherlands	Gamma Sterilization

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Advanced Medical Solutions Ltd Premier Park 33 Road One Winsford Industrial Estate Winsford, Cheshire CW7 3RT United Kingdom	Control of Sterilization Manufacture Moist Heat Sterilization
Ebster s.r.o. Průmyslová Zóna Košikov 59501 Velká Bíteš Czech Republic	ETO Sterilization
Unither Z.I. Longpre 10, rue Andre Duouchez 80052 Amiens Cedex 2 France	Manufacture
Mölnlycke Health Care (Oldham) Ltd Tubiton House Medlock Street Oldham OL1 3HS United Kingdom	Manufacture



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SSL International PLC Whitehouse Business Park Traynor Way Peterlee County Durham SR8 2RU United Kingdom	Manufacture
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Bradford) Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	Gamma Sterilization
Pharmaset SAS 3 Avenue de Luan 31130 Balma France	ETO Sterilization Manufacture
Copious International Inc Wei 11 Road, Huada Street New City, Heyuan Guangdong China	Manufacture

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History of Quality Assurance Certificate

Certificate No: CE 01965
Issue Date: 5 Jun 2013
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Date	Reference Number	Action
29 June 1998		First issue
13 November 1998		Addition of cavity dressings to scope
11 June 1999		Re-structure of certificate
01 October 1999		Addition of new subcontractor
26 October 1999		Addition of Advanced Medical Solutions as a subcontractor
11 December 2000		Removal of Swedish manufacturing site
30 March 2001		Addition of new subcontractor
19 June 2001		Addition of new subcontractor
15 November 2002		Addition of Mölnlycke Health Care Klinipro S.R.O and Mölnlycke Health Care Inc, El Paso. Change of subcontractor name from Gammaster to Isotron
26 February 2004		Reissue in new format and addition of Waremmes Isotron NL and IBA Belgium as subcontractors
04 June 2004		Addition of Sterigenics Holland BV as a subcontractor
21 January 2005		Correction of subcontractor address and activities
23 June 2005		Change to scope to state surgical swabs, addition of Bioster SPA (Italy) as a subcontractor
18 July 2005		Addition of Sterigenics in Germany as a new sterilisation facility.

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Date	Reference Number	Action
18 November 2009	7446394	Removal of sterile saline solutions for topical irrigation (moved to CE 01966). Medicated statement repositioned.
14 September 2010	7574343	Addition of significant subcontractor IDT Biologika GmbH
24 February 2011	7649524	Addition of significant subcontractor Statens Serum Institut, Denmark
29 March 2012	7790680	Extension of scope to include self-warming blankets; addition of subcontractor Copious International Inc for the manufacture of self-warming blankets; addition of subcontractor PHARMASET for the manufacture and sterilisation of procedure packs. Subcontractor name update for Synergy Group sites (formerly Isotron).
23 August 2012	7802614	Scope extension to include emollient creams; updates to subcontractor addresses (Mölnlycke Health Care Klinipro s.r.o., Czech Republic, Mölnlycke Health Care Oy, Finland, Pharmaset SAS, France and Advanced Medical Solutions Limited, UK)
26 April 2013	7961702	Scope extension to include abdominal wound dressings
03 Jun 2013	7956998	Extension to scope to include beta-glucan based devices and the addition of related subcontractors: Stellen Medical, LLC, Dakota Pack, Pine Ridge Farms, LLC and Sterigenics, San Diego CA



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Date	Reference Number	Action
5 June 2013	7997983	Certificate renewal. Registered changes for significant subcontractors Winner Industries (Shenzhen) Co Ltd, Synergy Health - AST – Daventry, Mölnlycke Healthcare (Mikkeli) and Stellen Medical LLC. Addition of significant subcontractor Mölnlycke Healthcare (Oldham). Removal of significant subcontractors Bioster SPA, Sterigenics Germany GmbH (Kalle-Albert), Sterigenics Holland BV (Storkstraat), Simco/SSL, Theo Manufacturing and IDT Biologika GmbH. Scope clarification.