

Certificate of Registration

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

This is to certify that:

ConvaTec Inc.
7900 Triad Centre Drive
Suite 400
Greensboro
North Carolina
27409
USA

Holds Certificate Number:

MD 670405

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

The design, development and manufacture of sterile and non-sterile ostomy, wound care, continence, securement devices, critical care hospital and skincare products.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-03-07

Latest Revision Date: 2019-02-25

Effective Date: 2018-03-07

Expiry Date: 2020-01-03

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Certificate No: **MD 670405**

Location	Registered Activities
ConvaTec Limited Unit 37 First Avenue Deeside Industrial Park Deeside CH5 2NU United Kingdom	The manufacture and assembly of sterile and non-sterile ostomy and wound care devices. The control of manufacture of sterile and non-sterile catheters, cannulae and accessories; sterile tubes; sterile suction sets; sterile and non-sterile urinary drainage systems and accessories; sterile and non-sterile collection devices and accessories; sterile wound drainage systems, bags and accessories; sterile surgical disposables; sterile and non-sterile airways management accessories; sterile and non-sterile umbilical cord cutters; sterile and non-sterile collection devices and accessories for urinary and pleura applications, sterile and non-sterile clamps, sterile intra-abdominal pressure monitoring devices, sterile and non-sterile securement devices; sterile and non-sterile ostomy accessories.
ConvaTec Limited Units 1&2 Heads Of The Valley Industrial Estate Rhymney, Tredegar NP22 5RL United Kingdom	The processing of materials for wound management products using chemical conversion, spinning and textiling.
Convatec Limited Global Development Centre First Avenue Deeside Industrial Park Deeside Flintshire CH5 2NU United Kingdom	The design and development of wound care, skincare, ostomy, continence and critical care products.
FE Unomedical Ltd Zavodskaya Str. 50 Fanipol 222750 Dzerzhinsk District Minsk Region Belarus	The manufacture of sterile and non-sterile catheters, cannulae and accessories; sterile tubes; sterile suction sets; sterile and non-sterile urinary drainage systems and accessories; sterile and non-sterile collection devices and accessories for urinary, ostomy and pleura applications; sterile wound drainage systems, bags and accessories; sterile surgical disposables; sterile and non-sterile airways management accessories; sterile and non-sterile umbilical cord cutters; and sterile securement devices.

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Location	Registered Activities
Unomedical s.r.o. Priemyselny Park 3 07101 Michalovce Slovakia	The manufacture of sterile and non-sterile catheters; sterile tubes; sterile suction sets; sterile surgical disposables; sterile and non-sterile airways management accessories; sterile and non-sterile collection devices and accessories for urinary and pleura applications; sterile and non-sterile clamps; sterile wound drainage systems, bags and accessories; non-sterile ostomy products; and sterile and non-sterile securement devices.
ConvaTec Inc. 7900 Triad Centre Drive Suite 400 Greensboro North Carolina 27409 USA	Global Quality Compliance, Corporate Complaint Handling and MDR/AE Reporting, North American Regulatory Affairs, Purchasing Controls and Post Market Quality.
ConvaTec Dominican Republic, Inc. Carretera Sánchez, Km. 18.5 Parque Industrial Itabo, S.A. Buildings 23, 29, 30 Haina, San Cristobal 91000 Dominican Republic	The manufacture of non-sterile ostomy products.
ConvaTec Dominican Republic, Inc. Carretera Sánchez, Km. 18.5 Parque Industrial Itabo, S.A. Building 8A Haina, San Cristobal 91000 Dominican Republic	The manufacture of non-sterile and sterile ostomy products and sterile wound management dressings (incorporating porcine gelatin based hydrocolloid and silver fibrous hydrocolloid technologies).
ConvaTec Inc. 7815 National Service Road Suite 600 Greensboro North Carolina 27409 USA	Sourcing, Planning and Supplier Quality Change Control.

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