

Certificate of Registration

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

This is to certify that:

ConvaTec Inc.
7815 National Service Road
Suite 600
Greensboro
North Carolina
27409
USA

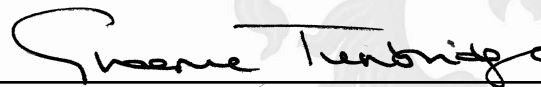
Holds Certificate Number:

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 catheters, sterile and non-sterile ostomy system and their accessories, fecal diversion and containment systems, urinary incontinence systems, peristomal skincare wipes, sprays and foams, sterile and non-sterile wound care products including wound dressings and negative pressure wound therapy system and their accessories.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-03-07

Latest Revision Date: 2025-12-16

Effective Date: 2026-01-04

Expiry Date: 2029-01-03

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...making excellence a habit.™

Certificate No: MD 670405

Location	Registered Activities
Convatec Limited First Avenue Deeside Industrial Park Deeside Flintshire CH5 2NU United Kingdom	The design, development and manufacture of sterile and non-sterile catheters, sterile and non-sterile ostomy system and their accessories, fecal diversion and containment systems, urinary incontinence systems, peristomal skincare wipes, sprays and foams, sterile and non-sterile wound care products including wound dressings and negative pressure wound therapy system and their 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.
Unomedical s.r.o. Priemyselny Park 3 07101 Michalovce Slovakia	Manufacture of sterile and non-sterile catheters; and non-sterile ostomy products.
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).

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.

A Member of the BSI Group of Companies.

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Registered Activities

Global Quality Compliance, Corporate Complaint Handling and MDR/AE Reporting, North American Regulatory Affairs, Purchasing Controls, Post Market Quality, Sourcing, Planning and Supplier Quality Change.



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