

Certificate of Registration

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

This is to certify that:

Systagenix Wound Management
Manufacturing Limited
Gargrave
North Yorkshire
BD23 3RX
United Kingdom

Holds Certificate Number:

MD 550349

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, manufacture, distribution and provision of customer care services in relation to medicated, non medicated, sterile and non sterile wound care products. Design control for surgical and wound care products. Manufacture and distribution of biocide based disinfectants. Distribution of in-vitro diagnostic medical devices.

The provision of a contract irradiation service for medical devices in accordance with ISO 11137-1:2006.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-06-23

Latest Revision Date: 2020-03-29

Effective Date: 2020-03-30

Expiry Date: 2022-03-29

Page: 1 of 2



003

...making excellence a habit.™

Certificate No: **MD 550349**

Location	Registered Activities
Systagenix Wound Management Manufacturing Limited Gargave, North Yorkshire BD23 3RX United Kingdom	The design, development, manufacture, distribution and provision of customer care services in relation to medicated, non medicated, sterile and non sterile wound care products. Design control for surgical and wound care products. Manufacture and distribution of biocide based disinfectants. Distribution of in-vitro diagnostic medical devices. The provision of a contract irradiation service for medical devices in accordance with ISO 11137-1:2015.
Systagenix Wound Management Limited Gargrave, North Yorkshire BD23 3RX United Kingdom	The design, development, manufacture, distribution and provision of medicated, non medicated, sterile and non sterile wound care products. Design control for surgical and wound care products.



Original Registration Date: 2009-06-23

Latest Revision Date: 2020-03-29

Effective Date: 2020-03-30

Expiry Date: 2022-03-29

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.