

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:

Original Registration Date: 2009-06-23
Latest Revision Date: 2020-03-29



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Effective Date: 2020-03-30
Expiry Date: 2022-03-29

Gary E Slack, Senior Vice President - Medical Devices

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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](http://www.bsigroup.com/ClientDirectory).
Printed copies can be validated at www.bsigroup.com/ClientDirectory.
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