

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:

Contract design and development services, contract manufacture activities, distribution and provision of customer care services in relation to contract manufactured medicated, non medicated, sterile and non sterile wound care products and components. Contract manufacture activities and distribution of biocide based disinfectants.

The provision of contract gamma irradiation sterilization services in accordance with EN ISO 11137-1:2015 and the provision of contract microbiological laboratory testing services.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2009-06-23

Latest Revision Date: 2025-03-03

Effective Date: 2025-03-30

Expiry Date: 2028-03-29



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