

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Facility ID Number: F000437

Holds Certificate No:

**MDSAP 697343**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The contract design and development services, contract manufacture activities, distribution of medicated, non-medicated, sterile and non-sterile wound care products.  
Contract manufacture activities and distribution of biocide disinfectants.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-08-21

Effective Date: 2025-03-30

Expiry Date: 2028-03-29



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