

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Swiss American CDMO  
2055 Luna Road, #126  
Carrollton  
Texas  
75006  
USA

Holds Certificate No:

**FM 543685**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture and distribution of sterile and non-sterile wound care products, dressings, medicated wound dressings and other topically applied medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-02-11

Latest Revision Date: 2021-01-01

Effective Date: 2021-01-05

Expiry Date: 2024-01-04



Certificate No: **FM 543685**

Location

Swiss American CDMO  
2055 Luna Road, #126  
Carrollton  
Texas  
75006  
USA

Registered Activities

The design, manufacture and distribution of sterile and non-sterile wound care products, dressings, medicated wound dressings and other topically applied medical devices.

Swiss American CDMO  
1540 Luna Road  
Carrollton  
Texas  
75006  
USA

The warehousing and distribution of finished goods.



Original Registration Date: 2009-02-11

Latest Revision Date: 2021-01-01

Effective Date: 2021-01-05

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.