

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 Number:

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-02-11

Latest Revision Date: 2023-12-06

Effective Date: 2024-01-05

Expiry Date: 2027-01-04

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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.



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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](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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