

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Cirtec Medical, Corporation

9200 Xylon Avenue North
Brooklyn Park
Minnesota
55445
USA

Holds Certificate Number:

FM 662611

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

Contract design, development, manufacturing and cleanroom packaging of medical devices and components. The provision of contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2015-01-12

Latest Revision Date: 2023-11-15

Effective Date: 2024-01-12

Expiry Date: 2027-01-11

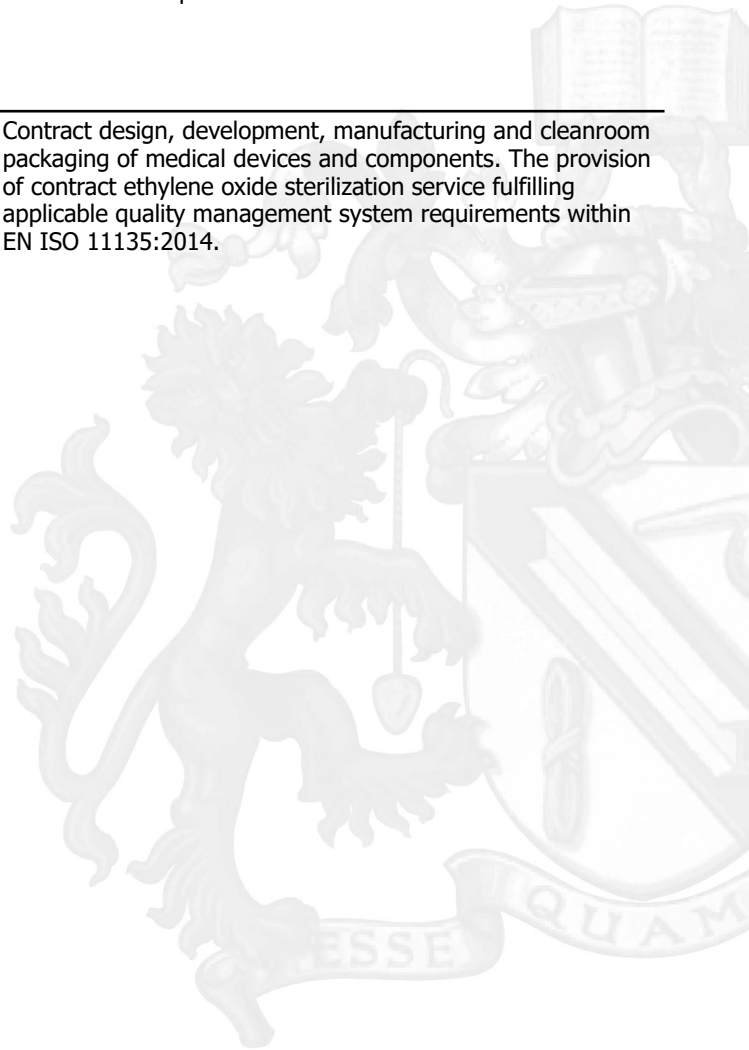
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...making excellence a habit.™

Certificate No: FM 662611

Location	Registered Activities
Cirtec Medical, Corporation 9200 Xylon Avenue North Brooklyn Park Minnesota 55445 USA	Contract design, development, manufacturing and cleanroom packaging of medical devices and components.
Cirtec Medical Corporation Edificio B11 Zona Franca Coyol Coyol Costa Rica	Contract manufacturing and cleanroom packaging of medical devices and components.
Cirtec Medical, Corporation 9315 Winnetka Ave N Brooklyn Park Minnesota 55445 USA	Contract design, development, manufacturing and cleanroom packaging of medical devices and components. The provision of contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.



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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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