



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: ComDel Innovation LLC

2100 15th Street North Wahpeton North Dakota 58075 USA

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

FM 583929

The contract manufacturing of plastic and metal components, along with the assembly of components into semi-finished or finished medical device products.

For and on behalf of BSI:

Holds Certificate Number:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2012-03-20 Latest Revision Date: 2024-02-26 Effective Date: 2024-04-25 Expiry Date: 2027-04-24

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...making excellence a habit."





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 <u>online</u>.

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