



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ComDel Innovation Inc. 2100 15th Street N Wahpeton North Dakota 58075 USA

Holds Certificate No:

FM 583929

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

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2012-03-20 Latest Revision Date: 2021-04-14 Effective Date: 2021-04-25 Expiry Date: 2021-10-24

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...making excellence a habit."