

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ComDel Innovation LLC.
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: 2021-09-15

Effective Date: 2021-04-25

Expiry Date: 2024-04-24

