



# Management System Certificate

Certificate No.:  
**245250-2017-AQ-USA-NA-PS Rev. 2.0**

Project No.:  
**PRJC-409818-2012-MS-C-USA**

Initial Certification Date:  
**10 April 2019**

Valid Until:  
**28 October 2020**

This is to certify that the management system of:

**Optinova-MLE, Inc./Optinova Production, LLC**  
9900 13th Avenue North, Suite 150, Plymouth, MN 55441 USA

With sites as listed overleaf.

Complies with the requirements of:

**ISO 13485:2016/NS-EN ISO 13485:2016**

The Certificate is valid for the following scope:

**Manufacture and Sales of Medical Grade Tubing Using Thermoplastic Polymers, Fluoropolymers and Braid Reinforcement to OEM and Finished Medical Device Manufacturers.**

Place and Date:  
**Høvik, 11 April 2019**



For:  
**DNV GL PRESAFE AS**

**Björg Synnøve Nesgård**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



A DNV GL COMPANY

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The certification covers the following locations:

| <b>Site Name</b>               | <b>Address</b>  | <b>Site Scope</b>   |
|--------------------------------|---|---|
| Optinova-<br>MLE, Inc.         | 9900 13th Avenue North,<br>Suite 150, Plymouth, MN<br>55441 USA | Manufacture and Sales of Medical<br>Grade Tubing Using Thermoplastic<br>Polymers, and Braid Reinforcement<br>to OEM and Finished Medical Device<br>Manufacturers. |
| Optinova<br>Production,<br>LLC | 5565 Pioneer Creek Drive,<br>Maple Plain, MN 55359 USA          | Manufacture of Medical Grade Tubing<br>Using Thermoplastic Fluoropolymers<br>to OEM and finished Device Medical<br>Manufactures.                                  |

End of Certificate