

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Opsens Inc.  
750 Boulevard du Parc Technologique  
Québec  
Québec  
G1P 4S3  
Canada

Facility ID Number: F000349

Holds Certificate No:

**MDSAP 692129**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, manufacture, technical support and servicing of optical systems used for diagnosis and treatment related to the blood circulatory system and other medical applications.

For and on behalf of BSI:

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Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-12-04

Effective Date: 2021-06-07

Expiry Date: 2022-06-06



BSI Group America Inc. is an MDSAP authorized auditing organization

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