

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

Holds Certificate Number: FM 574120

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

Design, manufacture, technical support and servicing of optical systems used for diagnosis and treatment related to the blood circulatory system and other medical applications. Manufacture and distribution of sterile coronary and peripheral catheters (and catheter components) for minimally invasive medical procedures.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2011-09-06

Latest Revision Date: 2022-09-15

Effective Date: 2021-06-07

Expiry Date: 2024-06-06

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