

April 11, 2019

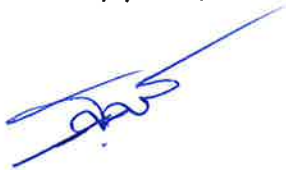
Subject: ISO 13485:2016 Certification

Valued Customer,

Optinova (Thailand) Co.,Ltd has successfully completed the re-certification audit January 18, 2019 without any issues and currently waiting to receive the updated certification. Unfortunately, there has been a significant backlog with the notified body's documentation process, which has resulted in a delay in receiving the new certification. In the meantime, please see the attached memo from the notified body indicating approval to the current ISO13485:2016 standard. The updated certification will be uploaded to the website upon receipt.

Thank you for your understanding.

Sincerely yours,

A handwritten signature in blue ink, appearing to be 'Sukhon Kotedee', written over a horizontal line.

Mr.Sukhon Kotedee
Quality Manager

Optinova (Thailand) Co., Ltd.143 Moo 1, Tambon Bokwangthong,
Amphur Bothong, Cholburi,
20270, Thailand**ATTN: Whom It May Concern****Date: 2019-03-01****Project: PRJC-589748****STATUS LETTER FOR MANAGEMENT SYSTEM OF OPTINOVA (Thailand) Co. Ltd.**

Dear Sir/Madam,

This letter serves to confirm that the Optinova (Thailand) Co. Ltd. has signed an agreement with DNV GL International Sdn Bhd, and audit will be performing at the following location and scope:

Company	Address	Scope
OPTINOVA (Thailand) Co. Ltd.	143 Moo 1, Tambon Bokwangthong, Amphur Bothong, Cholburi, 20270, Thailand	Manufacturing of Fluoropolymer tubing and profiles for use as a component in Medical Devices.

Certificate will be issued subject to successful completion of DI/IA (Initial Audit), Technical Review and approval by our Accredited Office Certification Manager.

Yours faithfully
or DNV GL BUSINESS ASSURANCE SINGAPORE PTE. LTD.



Wee Kiah Boon
Technical Manager, South East Asia
DNV GL – Business Assurance

BUREAU VERITAS
Certification



Certification

Awarded to

THAI SCANTUBE CO., LTD.

*143 Moo 1, Tambon Bokwangthong, Amphur Bo Thong,
Cholburi 20270, Thailand*

Bureau Veritas Certification Holding SAS – UK Branch certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below.

STANDARD

DS/EN ISO 13485:2012

SCOPE OF SUPPLY

**Manufacture of Fluoropolymer tubing and profiles for use
as a component in Medical Devices.**

Original approval date: 09-08-2016

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: 28-02-2019

To check the validity of this certificate, please call: (+45) 77 311 000.

Further clarification regarding the scope of this certificate and the applicability of the system requirements may be obtained by consulting the organisation

Certificate Number: DNKIFRC100625A

Date: 09-08-2016

Certification office: Bureau Veritas Certification Denmark A/S
Oldenborgsgade 1B, 7000 Fredericia, Denmark
E-mail: medicdk@mail@dk.bureauveritas.com
Managing office: 16TH Floor, Bangkok Tower, 2170 New Petchburi Road,
Bangkapi, Huaykwng, Bangkok 10310, Thailand

 **DANAK**
SYSTEM Reg nr 5005

