

# STATEMENT OF QUALITY

**Date:** 18 September 2020

Formlabs Inc. is committed to providing 3D printers and 3D printing photopolymer resins that comply with all relevant regulations and consistently meet and exceed our customers' expectations. Our company is committed to the continuous improvement of our processes by performing appropriate quality control on our hardware and SLA resins to ensure each product meets the specifications and expectations for quality established by Formlabs.

Formlabs selectivity chooses suppliers and subcontractors that maintain ISO certified Quality Management Systems and produces some medical products in our ISO 13485:2016 certified facility. For details on which products fall under the scope of this certification (Attachment 1), please contact your sales representative.



---

Sam Murray  
Director, Regulatory Affairs and Quality Assurance

ATTACHMENT 1



# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Formlabs Ohio dba Spectra Photopolymers

Main Site: 27800 Lemoyne Rd, Suite J, K, L, M, N & O,  
Millbury, Ohio, 43447, United States

has been registered by Intertek as conforming to the requirements of:

## ISO 13485:2016

The management system is applicable to:

Design and manufacture of 3D Printing Photopolymer resins for dental,  
audiology and surgical planning tools.

**Certificate Number:**

0089023-01

**Initial Certification Date:**

29 March 2019

**Date of Certification Decision:**

26 March 2020

**Issuing Date:**

26 March 2020

**Valid Until:**

28 March 2022



Intertek

**Calin Moldovean**  
President

Intertek Testing Services NA Ltd.,  
1829, 32nd avenue, Lachine, QC, H8T 3J1,  
Canada



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-ISO 13485\_2016-SCC-EN-LT-P-12.dec.17

