

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

Formlabs Ohio, Inc.

Main Site: 27800 Lemoyne Rd,

Millbury, Ohio, 43447, United States (FIN F000964)

Additional Site: Formlabs Inc.

35 Medford St, Somerville, Massachusetts, 02143, United States (FIN F006110)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

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

Main site: Manufacture and distribution

Additional site: Design

Certificate Number:

0123343

Initial Certification Date:

2022-04-26

Date of Certification Decision:

2022-04-26

Certification Effective Date:

2022-04-26

Certification Expiry Date:

2025-04-25



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc. 900 Chelmsford Street Lowell, MA, USA 01851



