

DEVICE AVAILABILITY UNDER MDR

Date: 1 May 2021

Formlabs, Inc. hereby certifies that the medical devices listed in the following table manufactured before May 25th, 2021 and expiring no later than May 25th, 2023 can be used and sold in accordance with the EU MDR¹.

According to the EU MDR Article 120, Paragraph 4, devices lawfully placed on the market pursuant to Directive 93/42/EEC (MDD) prior to 26 May 2021 may continue to be made available on the market or put into service until 27 May 2025.

Product Name	Catalog Code	SKU	Manufacturer
Dental SG Resin	FLDGOR01	RS-F2-DGOR-01	Vertex Dental BV
Surgical Guide Resin	FLSGAM01	RS-F2-SGAM-01	Formlabs Ohio Inc.
Custom Tray Resin	FLCTBL01	RS-F2-CTBL-01	Formlabs Ohio Inc.
IBT Resin	FLIBCL01	RS-F2-IBCL-01	Formlabs Ohio Inc.



Sam Murray
Director, Regulatory Affairs and Quality Assurance

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Device (most current version)