

Formlabs Inc
35 Medford Street,
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MA, 02143 USA

DECLARATION OF NON-MEDICAL DEVICES

Date: 27 November 2019

Formlabs, Inc. hereby declares that it deems its 3D Printer, FormCure, FormWash and the resins listed on pages 2 and 3 not to be classified as Medical Devices as defined in Article I of the Medical Device Directive (93/42/EEC) in the EU at the present time.

If you have further questions, don't hesitate to contact:
Sam Murray at sam.murray@formlabs.com



Sam Murray
Director, Regulatory Affairs and Quality Assurance



Overview of non-medical devices:

SKU	Description	HTS Codes/Schedule B	HS Code	Country of Origin
F2-PRINTER	Form 2 3D Printer	8443.32.1090	844332	HU
F3-PRINTER	Form 3 3D Printer	8443.32.1090	844332	CN
F3B-PRINTER	Form 3B 3D Printer	8443.32.1090	844332	CN
F3L-PRINTER	Form 3L 3D Printer	8443.32.1090	844332	CN
FK-F2-01	Finish Kit (Form 2)	8443.32.1090	844332	CN
FK-F3-01	Form 3 Finish Kit	8443.32.1090	844332	CN
RT-F2-01	Resin Tank (Form 2)	8443.99.2050	844332	TW
RT-F3-01	Form 3 Resin Tank	8443.99.2050	844399	CN
RT-F2-02	Resin Tank LT (Form 2)	8443.99.2050	844332	TW
BP-F2-01	Build Platform (Form 2)	8443.99.2050	844332	CN
BP-F3-01	Form 3 Build Platform	8443.99.2050	844399	CN
RS-F2-GPCL-04	Clear Resin Cartridge v4 (Form 2)	2916.14.2050	291614	US
RS-F2-GPGR-04	Grey Resin Cartridge v4 (Form 2)	2916.14.2050	291614	US
RS-F2-TOTL-05	Tough Resin Cartridge v5 (Form 2)	2916.14.2050	291614	US
RS-F2-FLGR-03	Flexible Resin Cartridge v3 (Form 2)	2916.12.5050	291612	US
RS-F2-GPBK-04	Black Resin Cartridge v4 (Form 2)	2916.14.2050	291614	US
RS-F2-CABL-02	Castable Resin Cartridge v2 (Form 2)	2916.14.2050	291614	US
RS-F2-GPWH-04	White Resin Cartridge v4 (Form 2)	2916.14.2050	291614	US
RS-F2-HTAM-01	High Temp Resin Cartridge (Form 2)	2916.12.5050	291612	US
RS-F2-DUCL-02	Durable Resin Cartridge v2 (Form 2)	2916.14.2050	291614	US
RS-F2-DMBE-02	Dental Model Resin Cartridge v2 (Form 2)	2916.14.2050	291614	US
RS-F2-GPCB-01	Color Base Resin Cartridge (GPCB01)	2916.14.2050	291614	US
RS-F2-CRCY-01	Cyan Pigment Bottle (CRCY01)	2916.14.2050	291614	US
RS-F2-CRMA-01	Magenta Pigment Bottle (CRMA01)	2916.14.2050	291614	US
RS-F2-CRYL-01	Yellow Pigment Bottle (CRYL01)	2916.14.2050	291614	US

RS-F2-CRBK-01	Black Pigment Bottle (CRBK01)	2916.14.2050	291614	US
RS-F2-CRWH-01	White Pigment Bottle (CRWH01)	2916.14.2050	291614	US
RS-F2-CRRB-01	Color Resin Recipe Book	2916.14.2050	291614	US
RS-F2-PRGR-01	Grey Pro Resin Cartridge	2916.14.2050	291614	US
RS-F2-RGWH-01	Rigid Resin Cartridge	2916.14.2050	291614	US
RS-F2-CWPU-01	Castable Wax Resin Cartridge	2916.14.2050	291614	US
RS-F2-ELCL-01	Elastic Resin Cartridge	2916.14.2050	291614	US
RS-F2-DRBL-01	Draft Resin Cartridge	2916.14.2050	291614	US
FH-CU-01	Form Cure	8443.99.2050	844399	CN
FH-WA-01	Form Wash	8443.99.2050	844399	CN