



LEGAL DISCLAIMER

Disclaimer of Liability for Personal Protection Equipment (PPE) Manufacturing and Plan Distribution

During the COVID-19 pandemic of 2020, Talent Maker City (“TMC”) and other makers collaborated with regional healthcare professionals and engineers to prototype, manufacture, and distribute certain Personal Protection Equipment (PPE) devices, accessories, components, and/or parts in urgent demand.

TMC, and its staff and volunteers, claim no specialized medical knowledge, education, or experience, and are merely utilizing TMC’s production equipment, space and staff time to assist with the response to this unprecedented global pandemic.

In providing its volunteer manufacturing support assistance, TMC has completely relied on the designs and specifications that have been provided by its engineering and healthcare partners. Further, TMC is operating under the informed understanding that all such designs are being vetted, tested (expressly fluid barrier protection tested) and approved by the Asante Rogue Regional Medical Center (“Asante”) prior to any direct use with patients in a medical capacity and that Asante is conducting post-manufacturing safety surveillance to monitor any material defects.

While TMC has reviewed the Federal Food and Drug Administration guidelines on additive manufacturing during the COVID-19 health crisis,* TMC has neither sought nor received any federal or state regulatory or industry approval for such 3D printed or other TMC manufactured or supported medical or protective devices. TMC has not tested or approved the medical safety or efficacy of any of the devices it prints, or any of the plans it distributes to other printers or manufacturers. (*[3D Printing of Medical Devices](#))

TMC therefore expressly disclaims any warranties of merchantability, any defects in design or production, and any liability for any injuries or other claims for its supportive manufacturing or plan/pattern distributing role in any Personal Protection Equipment (PPE) devices, accessories, components, and/or parts. TMC disclaims that it is a “medical device manufacturer” as defined by Section 820.3 of the Code of Federal Regulations (“CFR”) or equivalent state law. TMC has no ability or intention of conducting any post-manufacturing or market surveillance of any of the PPE or other medical support equipment.

FDA Contact Information

If you have questions about 3D printing to meet product demand during the COVID-19 emergency, please email COVIDManufacturing@fda.hhs.gov. For general questions, contact the Division of Industry and Consumer Education (DICE) or email DICE@fda.hhs.gov.