Guidance for Industry and Food and Drug Administration Staff, March 2020, "Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency".

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from threats including emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic. FDA issued this guidance to provide a policy to help expand the availability and capability of sterilizers, disinfectant devices, and air purifiers during this public health emergency.

For the purposes of this guidance, FDA recommended that manufacturers of air purifiers evaluate or perform the following:	
• Demonstration of a 4 log reduction (through a combination of capture or destruction) of claimed particulates.	[IVP Fulfills]
• If intended for use against bacteria, effectiveness against representative gram positive and gram negative species.	[IVP Fulfills]
• If intended for use related to SARS-CoV-2, effectiveness against a representative virus	[IVP Fulfills]
• If the device generates ozone, the maximum acceptable level of ozone per 21 CFR 801.415.	[IVP Fulfills]
• If intended for use in areas that have a sterile field or controlled air flow, a risk assessment to address turbulent air flow and/or potential site contamination.	[IVP Fulfills]

IVP's proprietary biodefense technology fulfills the criteria, as listed above, and thus is FDA Compliant to Enforcement Policy for Sterilizers, Disinfectant Devices and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: 21 CFR 880.5045, Medical Recirculation Air Cleaner (Product Code: FRF, Device Classification: II) and 21 CFR 880.6500 Medical UV Air Purifier (Product Code: FRA, Device Classification: II) that is intended for use related to SARS-CoV-2 and is proven to not to generate ozone per 21 CFR 801.415. The Biodefense Indoor Air Protection System is permitted to be sold under the FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency published in March 2020. FDA 510(k) is in process (45-60 days).

Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 880.5045	Medical recirculation air cleaner	FRF	II
21 CFR 880.6500	Medical UV air purifier	FRA	II