



DEVICE DETAILS

NAME OF DEVICE	HEADLOOP SURGICAL FACE MASK
ESTABLISHMENT NAME	ROCKY SCIENTIFIC INSTRUMENTATION
REGISTRATION NO	GA6265621-80554
BRAND NAME	FRONTIFIE
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	This surgical face mask offers a moderate barrier protection against fluid exposure and meets the requirements of ASTM Level 2. This Type IIR surgical mask is a surgical grade face mask that includes an outer splash-resistant layer to protect against blood and other bodily fluids. BFE measures the filtration efficiency of a mask using viable (live) particles (bacteria) that vary in size from 5 microns to 1 micron. PFE measures the filtration efficiency of a mask using nonviable (nonliving) particles that are fixed in size from 1 micron to 0.1 microns
DEVICE INTENDED PURPOSE	The Frontifie Surgical Face Mask is used inside the operating room to protect the patient environment from contamination. It is also intended to protect the wearer against splashes of potentially contaminated liquids
VALIDITY DATE OF REGISTRATION	06/12/2021 - 05/12/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	HEADLOOP SURGICAL FACE MASK	FTF008
2	HEADLOOP SURGICAL FACE MASK	FTF007