



DEVICE DETAILS

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| NAME OF DEVICE | SURGICAL FACE MASK |
| ESTABLISHMENT NAME | ROCKY SCIENTIFIC INSTRUMENTATION |
| REGISTRATION NO | GA9474121-80502 |
| 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 like an impenetrable wall that protects you against germs, bacteria and viruses. It is effective against droplets and other contaminants, allowing you to breathe freely while feeling safe and secure to do great things |
| VALIDITY DATE OF REGISTRATION | 06/12/2021 - 05/12/2026 |



LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|----|--------------------|------------|
| 1 | SURGICAL FACE MASK | FTF003 |
| 2 | SURGICAL FACE MASK | FTF002 |
| 3 | SURGICAL FACE MASK | FTF004 |