

## SURGICAL N95 MASK

Device Classification Name	: Respirator, Surgical
Submission Type	: 510(k) exempt
Regulation Number	: 878.4040
Regulation Description	: Surgical Apparel
Regulation Medical Speciality	: General & Plastic Surgery
Definition	: A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labelled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures subject to 21 CFR 878.9 and the conditions for exemption identified in 21 CFR 878.4040(b)(1).
Device Classification	: Class II
Classification Product Code	: FXX
GMP Exempt?	: NO
Intended Use	: Intended for single use by operating room personnel or general health care workers for protection against microscopic organisms, body fluids and particulates.
Recognized Consensus Standards	: <ul style="list-style-type: none"><li>• 3-129 AAMI ANSI EC53:2013 <u>ECG trunk cables and patient lead-wires</u></li><li>• 6-254 ASTM F2100-11 (Reapproved 2018) <u>Standard Specification for Performance of Materials Used in Medical Face Masks</u></li><li>• 6-335 ASTM F2101-14 <u>Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus</u></li><li>• 6-406 ASTM F1862/F1862M-17 <u>Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)</u></li><li>• 6-425 ASTM F2100-19 <u>Standard Specification for Performance of Materials Used in Medical Face Masks</u></li><li>• 6-427 ASTM F2101-19 <u>Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus</u></li></ul>