SAINT-GOBAIN MEDICAL

Regulatory Checklist: Filtration

Every application is different, but the right questions remain consistent. Use this checklist to guide your team through key regulatory considerations and support more confident material decisions early in development.

GENERAL INFORMATION

Name & Title: _____ Timeline: _____

INTENDED USE

☐ Direct patient contact ☐ Indirect patient contact ☐ No patient exposure

EXPECTED FILTER USE LIFE

FILTERED FLUID TYPE & FUNCTION

BIOLOGICAL COMPATIBILITY REQUIREMENTS

☐ Cytotoxicity (ISO 10993 5) ☐ Blood contact → Hemolysis (ASTM F756) ☐ Endotoxin control (USP <85>)

FUNCTIONAL SAFETY REQUIREMENTS

☐ Bacteria retention (ASTM F838) ☐ Particulates (USP <788>)

MATERIALS OF CONSTRUCTION REQUIREMENTS

☐ Animal Derived Component Free / EMA 410 ☐ PFAS-alternative

STERILIZATION REQUIREMENTS

☐ EtO ☐ Gamma Irradiation ☐ Autoclave ☐ Other _____

PROCESSING REQUIREMENTS

☐ ISO 13485 ☐ FDA Registered Facility ☐ ISO 9001

ADDITIONAL INFORMATION

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