

Pull out your current policy and check the box next to any coverage you can confirm is already in place — anything unchecked is worth a quick conversation with your advisor. Coverage checklist for medical device manufacturers, contract manufacturers, and component suppliers. Priorities reflect typical exposure for this class; confirm against your actual devices, customers, and contracts.

CORE

PREVALENT

SITUATIONAL

— Core: almost always needed · Prevalent: commonly carried by businesses in this class · Situational: depends on specific exposure

COVERAGE	WHY THIS BUSINESS NEEDS IT	PRIORITY
☐ Products Liability (Life Sciences)	Covers patient injury claims from devices or components — check for implant, material, and claims-made retro-date limits.	CORE
☐ Product Recall	Pays to notify, retrieve, and replace recalled devices — products liability does not.	CORE
☐ Commercial General Liability	Covers premises and operations claims at plants and customer sites.	CORE
☐ Umbrella / Excess Liability	Adds limits for mass-tort claims; OEM contracts often require high limits.	CORE
☐ Clinical Trials Liability	Covers injury to study participants; usually excluded elsewhere.	PREVALENT
☐ Errors & Omissions (Contract Manufacturing / Design)	Covers financial loss to OEMs from out-of-spec parts or design work.	PREVALENT
☐ Cyber / Privacy Liability	Covers connected-device data, patient information, and ransomware on production systems.	PREVALENT
☐ Commercial Property & Business Income	Covers clean rooms, equipment, and income lost while production is down.	PREVALENT
☐ Contingent Business Income	Covers income lost when a critical supplier or sterilizer shuts down.	SITUATIONAL
☐ Directors & Officers / Regulatory	Covers investor suits and FDA-related defense costs.	SITUATIONAL
☐ Foreign Liability	Needed for devices sold or trials run outside the U.S.	SITUATIONAL
☐ Workers' Compensation	Required by law; machining, chemical, and repetitive-motion injuries.	SITUATIONAL

COMMON COVERAGE GAP FOR THIS CLASS

The gap most often missed by medical device makers is long-tail exposure on a claims-made policy. Device injuries can surface years after sale — the Philips CPAP recall covered machines sold over 13 years — and many life sciences policies are claims-made, so a lapse, a new retro date, or an implant exclusion can leave older products uncovered. Component suppliers face the same risk through OEM contracts that push recall costs down the chain. Confirm your retro date reaches back to your first sale, and add recall coverage that matches your OEM contracts.

IMPORTANT — PLEASE READ

This checklist is a free educational tool from Cory Washington & Co. to help you review your own coverage and have a more informed conversation with a licensed insurance professional. It is general information only — not insurance, legal, or financial advice, and not a recommendation to buy, change, or cancel any policy. The Core / Prevalent / Situational labels describe general patterns observed for this class of business — what is commonly carried, not a personalized recommendation or needs analysis for your specific operations. Coverage terms, availability, limits, and requirements vary by policy, carrier, and state, and only the language in your actual policy governs what is and isn't covered. Checking or leaving blank any item above does not indicate that you are adequately insured or under-insured. Using this checklist does not create a client, agency, or fiduciary relationship. Always consult a licensed professional about your specific situation.