MontRidge Insurance Services

MEDICAL DEVICE MANUFACTURERS CHECKLIST

Commercial Risk Education Series

A practical self-assessment to help identify insurance and operational risk topics for further discussion. Select Yes, No or Not Sure for each item. Leave items that do not apply blank. There is no score or passing grade.

PRODUCTS

	Yes	No	Not Sure
Are device types and intended uses accurately described?	○	○	○
Are component suppliers and contract manufacturers documented?	○	○	○
Are product changes and design reviews recorded?	○	○	○
Are distribution territories reviewed?	○	○	○

QUALITY

	Yes	No	Not Sure
Are complaint handling and traceability procedures documented?	○	○	○
Are recall responsibilities and decision authority defined?	○	○	○
Are applicable quality system obligations reviewed by qualified staff?	○	○	○
Are connected-device cybersecurity risks evaluated?	○	○	○

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Continue your review. Select one response per item; leave non-applicable items blank.

INSURANCE

	Yes	No	Not Sure
Are products liability and recall coverage distinguished?	○	○	○
Are technology E&O and cyber exposures reviewed?	○	○	○
Are contamination and equipment breakdown provisions evaluated?	○	○	○
Are exclusions for particular devices or territories reviewed?	○	○	○

CONTRACTS

	Yes	No	Not Sure
Are manufacturing and quality agreements coordinated?	○	○	○
Are supplier indemnities and insurance requirements reviewed?	○	○	○
Are product launch changes communicated to the insurance advisor?	○	○	○
Are incident and claim reporting procedures established?	○	○	○

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NEXT STEPS

Use your responses to identify questions for your insurance advisor. A No or Not Sure response may warrant further review; a Yes response does not establish adequate insurance or compliance. Keep the completed checklist for your own records.

OPTIONAL CONSULTATION REQUEST

- [ ] I would like to discuss this checklist with Montridge.
- [ ] I would like to review my current insurance program.
- [ ] I would like to receive future educational resources.

OPTIONAL CONTACT INFORMATION

Name

Company

Title

Phone

Email

Preferred contact method

Questions or topics to discuss (avoid confidential or sensitive information)

To arrange a discussion, visit www.montridgeinsurance.com. This PDF does not transmit your responses automatically.

Educational use only. This checklist is not an insurance application, policy, coverage determination, compliance audit, or legal, tax, engineering, medical or financial advice. Coverage depends on actual policy terms, endorsements, exclusions and facts. Consult qualified advisers for your circumstances.