

What makes an ISO 13485 certified company different than an ISO 9001/9002 company?

ISO 13485 Certification is specific to the repair of medical devices.

For each medical device, master device records containing device specifications and process requirements must be established and maintained.

★ CALIFORNIA ENDOSCOPY



A documented feedback system to provide early warning of quality problems and for input into corrective/preventive action systems must be established and maintained.

Document and maintain procedures for the issue of advisory notices for medical devices. These procedures must be capable of being implemented at any time.

Rework must be documented in a work instruction. This work instruction must undergo the same authorizations & approvals as the original work instruction. A determination of any adverse effects of the rework on the product shall be made & documented.

Records from customer complaint investigations shall be recorded. If any customer complaint is not followed by corrective/preventive action, the reason must be recorded.

★ CALIFORNIA ENDOSCOPY



Batch records that provide traceability & identify quantities must be maintained. These batch records must be verified & authorized.

Establish, document, & maintain procedures for traceability. Extent of traceability must be defined & should facilitate corrective & preventive action.

★ CALIFORNIA ENDOSCOPY



Obsolete controlled documents must be retained for historical purposes. They should be retained for at least the expected lifetime of the medical device.

Quality records must be maintained for the expected lifetime of the device or 2 years, whichever is greater.

Environmental conditions must be controlled and monitored if they could affect product quality.

As you can see, a company's ISO 13485 certification has a direct and very positive impact on you, the customer. So why settle for anything less? Yes, a company with a 9001/9002 certification may have some or even all of the above attributes. But it may not. Is it really worth the risk? You know for certain that an ISO 13485 certified company has all of the above. If you decide to use a company that is not ISO 13485 certified, your scopes may be in danger of substandard repairs and your suite may be vulnerable to long delays in getting your scope back.

California Endoscopy is the only scope repair facility in the nation that is ISO 13485 certified. Only California Endoscopy has taken the initiative to adopt, implement and earn the ISO 13485 certification. And we undergo semi-annual audits by an outside certifying organization to ensure that our quality systems are properly maintained and continual improvements occur.

The choice is yours. Don't settle. Demand ISO 13485 certification from your scope repairer.