PHARMACEUTICAL | SURGICAL DEVICES | DRUG DELIVERY | MEDICAL EQUIPMENT
OCULAR | IMPLANTS | DENTAL | DIAGNOSTIC DEVICES | ENT | VETERINARY | VASCULAR

ISO 13485:2016 & ISO 9001:2015 Certified | ISO 17025:2005 Accredited for Several Test Methods
ISTA Certified Testing Laboratory Member

December 2019

The European Medical Device Regulation

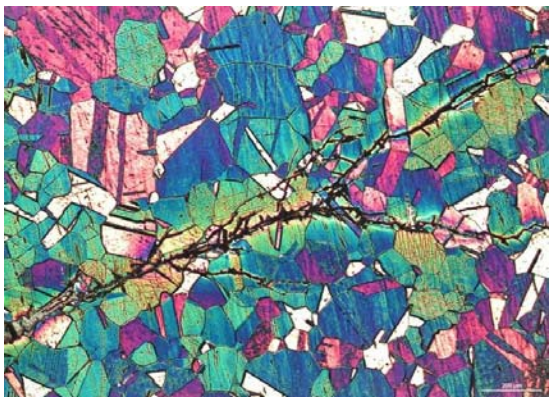
The European Union Medical Device Regulation (EU MDR) deadline is fast approaching. This new regulation (EU) 2017/745 (MDR) replaces the EU Medical Device Directive (93/42/EEC) (MDD). As the 26 May 2020 deadline approaches, even the most well-prepared medical device company may be facing numerous questions and challenges:

- Will my Notified Body receive its designation?
- Will my current products require reclassification?
- Are my devices eligible for the grace period?
- Do I have sufficient clinical evidence for MDR compliance on current products?
- Is my technical documentation adequate?
- What impacts will MDR have on my current supply chain and distribution chain?
- How will the EUDAMED delay affect my data management?
- Do I need to change my Post Market Surveillance process?
- How does MDR affect my new product launches?

European Commission - Brussels, Belgium

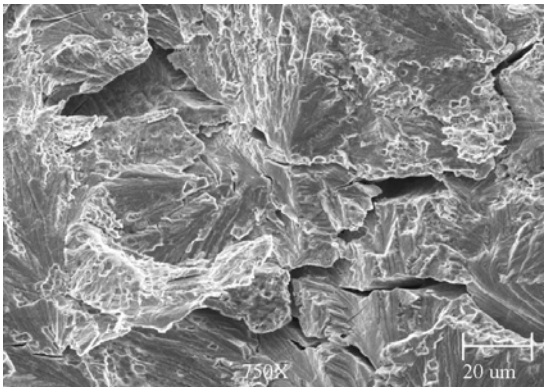
SES resources have a long history of supporting our clients throughout the medical device life-cycle and are ready to support or supplement your team as needed during the MDR transition. Let SES help your team by participating in an MDR gap analysis, providing an interface between regulatory and technical resources, generating technical documentation, researching state of the art for your device, updating your Quality Management System processes and policies, and more.

Lab Feature - Metallurgical Capabilities



Optical microscope view of cross section of chloride stress corrosion cracking in austenitic stainless steel

SES operates a full service metallurgical lab in Mason, OH providing metallurgical analysis and consultation services to a variety of industries including oil and gas, consumer products, and medical devices. One of the key offerings of the metallurgical lab is comprehensive metallurgical failure analysis of components. Irrespective of the industry, component failures very rarely have a single "root" cause. The physical failure of a component is often the culmination of a multilevel failure process involving a combination of design deficiencies, material defects, material degradation, manufacturing defects, service anomalies, and/or human errors. Failures of components in service have significant costs associated with them in the form of lost production time,



Fracture surface of cross section of chloride corrosion cracking in austenitic stainless steel under a scanning electron microscope

collateral damage, and in extreme cases, personnel injuries. Metallurgical failure analysis is a crucial first step in implementing remedial steps to avoid repeat failures as it helps in identifying the damage made and cause(s) of failure. SES has a fully equipped metallurgical lab with a variety of instruments to perform non-destructive examination, metallography, fractography, and mechanical testing of materials on small and large scale components.

While a metallurgical failure analysis is one of the most important steps in avoiding repeat failures, a comprehensive root cause analysis often requires a diverse team of engineers from various disciplines. SES metallurgical engineers work closely with mechanical design and testing engineers to provide value to its clients in delivering the critical services that are needed to avoid repeat failures, all under one organizational roof.


Fracture surface of a shaft that failed due to rotational bending fatigue

Upcoming Events

Please join us at **MD&M West in Anaheim, CA February 11-13** and learn more about how Stress Engineering Services can help you with your engineering needs.

Missed our latest newsletter?

Click **here** to learn more about our Materials Expertise and Capabilities for Enhanced Failure Analysis and our Storage Stability Testing Services.

Stress Engineering Services, Inc. provides expert engineering consulting services for:

- New Product Development
- Material Science & Engineering (Full Polymer & Metallurgical Labs)
- Systems Engineering
- Risk Assessment
- Human Factors
- Sustaining Engineering
- Failure Analysis
- Package Development
- Verification Testing
- Equipment Validation & Development

Our services help clients achieve not only technical success in problem avoidance or remediation of failures, but also commercial success in reducing or removing costs, risk and time from their development process and product designs.

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To learn more about Stress Engineering Services Inc., visit our website
or contact us at 513-336-6701.

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